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April 26, 2018

Ramy A. Arnaout, MD, DPhil  
Chair, Clinical Laboratory Improvement Advisory Committee  
Centers for Disease Control and Prevention  
Division of Laboratory Systems  
1600 Clifton Road, Mailstop F-11,  
Atlanta, GA 30329-4018, USA

Dear Dr. Arnaout:

On behalf of the American Society for Clinical Pathology (ASCP), I am writing to provide additional details to comments provided by Danny A. Milner, Jr., MD, MSc(Epi) before the Clinical Laboratory Improvement Advisory Committee on April 10, 2018. This letter provides additional background on ASCP's comments on the recent Centers for Medicare and Medicaid Services (CMS) Request for Information (RFI) on possible changes to regulations implementing the Clinical Laboratory Improvement Amendments (CLIA) of 1988.

The ASCP is a 501(c)(3) nonprofit medical specialty society representing over 100,000 members. Our members are board certified pathologists, other physicians, clinical scientists (PhDs), certified medical laboratory scientists/technologists and technicians, and educators. ASCP is one of the nation's largest medical specialty societies and is the world's largest organization representing the field of laboratory medicine and pathology. As the leading provider of continuing education for pathologists and medical laboratory personnel, ASCP enhances the quality of the profession through comprehensive educational programs, publications, and self-assessment materials. The ASCP also supports our membership and customers as we strive to stay on the leading edge of the profession.

The ASCP submitted two separate comments on the CMS CLIA RFI, one focused on the personnel regulations and the second on the CLIA proficiency testing requirements. Our comments on personnel regulations, submitted by the ASCP Board of Certification (BOC) Board of Governors (BOG), address CMS's flawed proposal to allow individuals with a nursing to degree to perform high complexity laboratory testing and supervise moderate complexity testing. Instead, we proposed a more appropriate change to the CLIA regulations to expand the labor pool of potential laboratory testing personnel. Our comments of the CLIA proficiency testing rules urge CMS to secure for itself more flexibility in dealing with proficiency testing referral, particularly with regard to referrals that are accidental or unintended in nature. The following is a summary of the concerns expressed in our two comment letters.

## **I. CLIA Personnel Issues**

In our comments on the CMS's CLIA personnel regulation and policies, ASCP rejected the Agency's interpretation that a nursing degree is equivalent to a biological sciences degree. In our comments, the ASCP BOC BOG observed that the academic coursework requirements are profoundly different. Nursing degrees, while providing training appropriate for nursing, do not provide the amount and depth of instruction required for a biological sciences degree. Generally, at the baccalaureate

degree level, nursing degree provides about 1/3 of the amount of instruction in the biological and chemical sciences as would be required for a biological sciences degree. Moreover, nursing degrees do not provide similar “hands-on” training in a laboratory setting. We believe that this, in part, explains why the National Association for Credentials Evaluation, an organization dedicated to professionalism in determining degree equivalency, rejects the notion that these two degrees are equivalent. Because of these differences, ASCP does not believe that the nursing degree should allow its holders to perform high complexity testing or supervise moderate complexity testing.

Instead, ASCP believes that the CLIA rules for high complexity testing should be expanded to recognize an earned baccalaureate degree and 30 semester hours (or the equivalent) in the biological and chemical sciences. In addition, ASCP notes that the CLIA rules do not currently identify what sort of training, if any, is required for an individual with a baccalaureate degree in a biological, chemical, or physical science. We believe that this is an oversight and that the CLIA regulations need to specify that individuals with a baccalaureate degree in an area other than laboratory science or medical technology need some form of training to perform high complexity testing. ASCP also urged that the CLIA regulations adopt a requirement that individuals that either supervising or perform high complexity testing must be appropriately certified. In addition, ASCP argued that histology should be classified as high complexity, requiring that sites providing histology services must have the requisite CLIA certificate, be under the direction of a board certified pathologist, follow application proficiency testing requirements, and utilize laboratory personnel that meet appropriate personnel qualifications, such as certified histotechnologists and histotechnicians.

## **2. PT Referral and Cytology PT Referral**

In our comments to CMS, we stated that ASCP supports the use of strong sanctions against those providers or laboratories whose conduct shows a malicious or willful and purposeful intent to evade CLIA regulatory requirements or a general disregard for the CLIA PT requirements. That said, under the current regulatory framework developed by CMS to handle PT referral, the Agency lacks sufficient discretion to differentiate appropriately between those cases that are truly egregious and those that are not. ASCP is concerned that the rules currently have the potential to deal more harshly than necessary with certain cases of PT referral, such as those that are accidental or unintentional in nature. ASCP believes that CMS must provide itself with more discretionary authority for all categories of PT referral.

With regard to Cytology PT programs, we noted a disconcerting development that the Agency has recently decided its regulations prohibit. In the past, PT providers were allowed to replicate the workflow practice for those laboratories that separated the cytotechnologist from the pathology group, whether they were in different cities or even different states. In this scenario, the PT providers served as the middle-man for the transfer of testing materials from location to another. The testers never moved the testing materials to the other testers; the PT Provider did. Even though this had already been an approved process by CMS and mirrored the normal workflow for these locations, it was now considered PT Referral. CMS has taken the position that the pathologist and cytotechnologist must be located in the same location during the cytology proficiency testing event. If the pathologist does not complete his or her cytology proficiency testing exam at the same location that the cytotechnologist performs the preliminary screening at, the transmission of the PT sample between locations results in what is considered PT referral. This Agency position can

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effectively prevent cytology practices from being able to comply with the current PT regulations if the cytotechnologists and cytopathologists are not physically in the same location. Given practice and limited reimbursement realities today, this position may discourage pathologists from performing cytology services and could hit rural areas the hardest. Please see the attached comments for more information.

### **3. Personnel Vacancies and Labor Force Issues**

We note that ASCP representative Barbara Caldwell provided a presentation to the Committee regarding the results of recent ASCP Wage and Vacancy Surveys. Clearly, the data presented to the Committee reveals that there are serious reasons to be concern about the adequacy of the workforce supporting laboratory medicine. As noted above, ASCP proposed an alternative to CMS's nursing degree proposal. Allowing an earned baccalaureate degree and 30 semester hours (or the equivalent) of coursework in the biological and chemical sciences to satisfy the academic requirements necessary for high complexity testing along with an appropriate clinical training requirement should, we believe, improve the ability of clinical laboratories to fill testing personnel vacancies with individuals who have the capacity necessary to begin rewarding careers in laboratory medicine.

ASCP appreciates the opportunity to provide input to CLIAC on the CLIA regulations and workforce issues. If we can be of any assistance, please contact Matthew Schulze, Director of the ASCP Center for Public Policy at 202-408-1110 (x 2905) or [Matthew.Schulze@ASCP.org](mailto:Matthew.Schulze@ASCP.org).

Sincerely,

Matthew Schulze  
Director, ASCP Center for Public Policy

Attachments