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March 12, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue SW
Washington, DC 20201

RE: Revisions to Personnel Regulations, Proficiency Testing Referral, Histocompatibility Regulations and Fe Regulations Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA): *Request for Information [CMS-3326-NC]*

Dear Administrator Verma:

On behalf of America's Blood Centers (ABC), thank you for the opportunity to provide information requested by the Centers for Medicare and Medicaid Services in the Federal Register on 9 January 2018. Community blood centers, which make up ABC, are driven by a profound commitment to safety and quality while working in a highly regulated arena. Blood centers meet the current Good Manufacturing Practices (cGMP) spelled out in 21 CFR Parts 200 and 600 as well as the CLIA 88 requirements of 42 CFR Part 493. A key provision of both cGMP and CLIA 88 is the requirement that laboratories have adequate, trained staff performing testing.

Background of ABC

America's Blood Centers (ABC) represents North America's largest network of non-profit community blood centers. Our member blood centers provide over half of the blood supply in the US, producing more than 12 million units of whole blood and blood components annually to support over 3,500 hospitals and health care facilities. These blood centers operate more than 600 blood collection sites and conduct thousands of mobile blood drives each year.

Comments for Consideration

We applaud the Center for seeking public input as they begin the process of updating the personnel requirements, proficiency testing referral, and histocompatibility issues of CLIA 88. These issues impact our members and we provide the following comments for your consideration.

A. Personnel Requirements:

1. Nursing Degrees: *We are seeking public comments related to whether, for purposes of meeting the educational requirements for moderate complexity technical consultants and testing personnel and high complexity testing personnel, §§ 493.1411, 493.1423, and 493.1489 should be amended: (1) To expressly reflect that a nursing degree is equivalent to a biological science degree; or (2) to add nursing degrees as a separate qualifying degree (as opposed to the equivalent of a biological science degree) to the current list of qualifying degrees.*

The American Society of Clinical Pathology (ASCP) Board of Certification is the largest certifying agency for medical laboratory professionals. To qualify for the ASCP Medical Laboratory Scientists (MLS) board certification examination, a candidate must have "a baccalaureate degree from a regionally accredited college/university, including 16 semester hours (24 quarter hours) of biological science (with one semester in microbiology), 16 semester hours (24 quarter hours) of chemistry (with one semester in organic or biochemistry)" combined with either completion of an accredited MLS program or multiple years of defined work experience in a CLIA certified laboratory. These requirements do not specify the degree granted, but define the educational foundation necessary for individuals in medical laboratories. These long-standing requirements should serve as the benchmark for the academic education requirements for laboratory personnel.

Nursing is not the same as laboratory science. Nurses are governed in every state and the District of Columbia by a board of nursing that establish the basic education, continuing education and competency requirements in their jurisdiction. There is no single accrediting/licensure agency with a minimum requirement. A bachelor of science degree in nursing (BSN) requires basic introductory level science requirements including biology or microbiology, chemistry with or without organic chemistry, and anatomy and physiology as prerequisites. NursingSchool.org is a comprehensive online resource of references with links to the various state requirements and nursing degree programs. Another reference is allnursingschool.org. After review of these sites, a BSN does not have the same in-depth science background as required for a MLS.

Given the information provided above, we do not agree with CMS's proposal that a BSN should serve as a qualifying degree, nor is it equivalent to a biological sciences degree, for the purposes of meeting the educational requirements for high complexity testing personnel or technical consultants. With sufficient training and adequate oversight, a BSN should provide an adequate educational foundation for the performance of moderate complexity testing.

2. Physical Science Degrees: *We are seeking public comments on what is considered a physical science degree and whether any physical science degree(s) should be considered as educational background(s) appropriate for qualifying to meet the CLIA educational requirements.*

In paragraph I.A.4. of this Federal Register notice, it states "Generally, the type of training and experience required under the current CLIA personnel regulation at part 493, subpart M, is clinical in nature. This means examination and test performance on human specimens for purposes of obtaining or providing information for the diagnosis, treatment, and monitoring of patients." We fully endorse this interpretation of training and experience.

According to The College Board, "the physical sciences explore the concepts and processes of the nonliving physical world, as opposed to the life sciences. Students of the major study any combinations of its subjects: astronomy, chemistry, geology and geophysics, physics, math, statistics, and meteorology." Webster's New World College Dictionary, 5th edition, defines physical science as "any of the sciences that deal with inanimate matter or energy, as physics, chemistry, geology, astronomy, etc." Degrees of this nature do not prepare students for the world of clinical laboratories.

We do not believe that a physical science degree, not related to or combined with a biological science, should be considered appropriate for qualifying to meet the CLIA educational requirements for laboratory personnel. It would be more appropriate to specify minimum curriculum requirements as is done by ASCP to qualify for MLS certification (see A.1. above) rather than degree titles which CMS acknowledges in the RFI presents challenges.

3. Personnel Competencies: *We are seeking public comments regarding whether general supervisors, with associate's degrees, should be allowed to perform competency assessment for moderate complexity testing personnel in laboratories that perform both moderate and high complexity testing. A general supervisor with an associate's degree can, under current CLIA rules perform such competency assessments in high complexity laboratories but because there is no such position recognized for moderate complexity testing laboratories, technically they can't perform the same assessment in a lower complexity*.

   ABC agrees that this is obviously a technical oversight and we urge CLIA to rectify it in future updates to allow a general supervisor in a high complexity laboratory to perform the same functions in a moderate complexity laboratory.

4. Personnel Experience, Training and Skills: *We are seeking public comments on what should be considered appropriate laboratory training, experience and skills when determining the qualifications necessary for all personnel to meet CLIA requirements, and what comprises appropriate documentation to verify the training, experience and skills for all personnel positions in part 493, subpart M.*

   Current CLIA requirements specified in § 493.1407 state that the Laboratory Director is "responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures and record and report test results promptly, accurate and proficiently and for assuring compliance with the applicable regulations." We believe that the Laboratory Director should define appropriate training and experience necessary for the testing complexity of their labs as well as what is appropriate documentation of such. Attempting to define such details in regulations results in overly complex, inflexible regulations that do not enhance the safety or accuracy of laboratory results.

5. Non-traditional degrees: *We are seeking public comments (including information such as evidence, research, and trends) related to such non-traditional degrees, specifically whether these types of degrees should be considered to meet the requirements for a chemical, physical, biological or clinical.*

As states in A.5 above, we believe that validation of non-traditional degrees should be left to the designated Laboratory Director. Attempting to define details of degree titles and sources results in overly complex, inflexible regulations that do not enhance the safety or accuracy of laboratory results that is the goal of CLIA.

B. Proficiency Testing (PT) Referral: *We are seeking public comment related to applying discretion in situations where we determine that a laboratory has referred its PT samples to another laboratory and has reported the other laboratory's PT results as its own, and under what circumstances the discretion should be applied.*

PT programs are designed to challenge and assess a laboratory by comparing its results to those from different labs. Referring PT samples to other labs is not allowed to ensure the assessment is of the laboratory submitting the results. However, PT referral can inadvertently occur such as when there are multiple laboratories within an organization with different CLIA certificates or when organizations are undergoing merger/consolidation. If there is no malicious intent to defraud the system, the agency should have the flexibility to allow it without the need for extensive appeals. ABC fully endorses the maximum flexibility with regard to any testing activity that could inadvertently result in fines or the suspension or termination of certification.

C. Histocompatibility: *We are seeking public comments related to these two CLIAC recommendations; that is, whether virtual crossmatching should be an acceptable alternative to physical crossmatching, and under what criteria and decision-making algorithms virtual crossmatching would be an appropriate substitute for physical crossmatching*.

We applaud CMS for recognizing the advances in the field of histocompatibility and endorse integrating virtual crossmatches into the regulations, as is permitted by the *Standards for Blood Banking and Transfusion Services* of the AABB, the foremost accrediting organization for transfusion medicine. Additionally, CMS should continue to engage subject matter experts and industry representatives in developing regulatory criteria. Caution should be used so that the regulations will allow for the adoption of new technology as it becomes available in this rapidly evolving and growing area. Failing to do so, results in significant delays in capitalizing on new advances as they become the state-of-the-art, for example FDA cleared platforms for determination of predicted red blood cell phenotypes by molecular methods.

D. General feedback: *We are also soliciting general feedback from stakeholders on what other areas of CLIA that they would potentially have recommendations for changing.*

1. Technical Supervisor, Immunohematology: Currently, there is a disparity in § 493.1449, Standard; Technical supervisor qualifications for laboratories performing high complexity testing, between the various subspecialties and immunohematology. All subspecialties have provisions for non-physicians with varying degrees combined with general experience and in some cases specific experience in the subspecialty area except immunohematology. Immunohematology requires the technical supervisor be a doctor of medicine or osteopathy, certified in clinical pathology or possess qualifications that are equivalent to those required for such certification or be a doctor licensed in the state and have at least one year of laboratory training or experience in immunohematology. There is no recognition of the knowledge and experience of personnel with other degrees, certifications and/or experience as is allowed in the other subspecialty area outlined in § 493.1449.

The subspecialty of immunohematology is no more or less critical or complicated and the requirements of § 493.1449 (b) should apply.

ABC strongly recommends expanding § 493.1449 (q) to allow additional qualifications for technical supervisor to include master and bachelor degrees with full-time training or experience (e.g. 2 years and 3 years respectfully) in high complexity immunohematology laboratories within the last 6 years.

2. General supervisor responsibilities: Section § 493.1463(b)(4) is inconsistent with the requirements for testing personnel performance evaluation and documentation. All other references to evaluating and documenting testing personnel performance requires twice during the first year and annually thereafter. CLIA is aware of this issue and we include it simply for completeness of our input.

   We recommend § 493.1463(b)(4) be amended to include the requirement for semi-annual assessment in the first year of employment.

Again, we thank CMS for the opportunity to comment and stand ready to continue to support this initiative with additional information or support if needed. My point of contact for this is Ruth Sylvester and she can be contacted at rsylvester@americasblood.org.

Louis Katz, MD
Chief, Medical Officer
Americas Blood Centers