COLLEGE of AMERICAN PATHOLOGISTS

March 12, 2018

Seema Verma
Administrator
U.S. Centers for Medicare & Medicaid Services
7500 Security Boulevard,
Baltimore, MD 21244

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 Ms. Verma:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) request for information (RFI) about whether the agency should revise personnel regulations, proficiency testing referral, histocompatibility regulations and fee regulations under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide.

The objective of the CLIA is to ensure quality laboratory testing. Since the inception of CLIA, the quality of laboratory testing has improved even with the rapid changes in technology and integration of the healthcare delivery system. Clinical laboratories are no longer just stand-alone sites but are an integral part of the health systems, which includes at least one hospital and at least one group of physicians providing comprehensive care (including primary and specialty care) who are connected with each other and with the hospital through common ownership or joint management. Moreover, these healthcare systems are using advances in technology to perform clinical laboratory testing in a myriad of settings that are closer to the patients. **The CAP believes that CLIA provides an adequate baseline to ensure the accuracy and reliability of clinical laboratory results but recognizes that specific updates to CLIA are needed to address the changes in practice and technology to accommodate today's practice.** The CAP offers the following comments on the personnel regulations, histocompatibility regulations and PT referral provisions.

PERSONNEL REGULATIONS

Qualified and trained personnel are vital to clinical laboratories providing reliable and accurate test results. CLIA specifies the level of training and education in laboratory science necessary to fulfill this mandate. **The CAP believes the current CLIA requirements should be maintained to ensure the public's confidence in**

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laboratory testing; however, we offer the following recommendations for potential modifications on the personnel regulation proposals listed in the RFI.

- **Nursing degree**
  CMS considers a bachelor's degree in nursing to be equivalent to a bachelor's degree in biological science for purposes of the educational requirements for moderate and high complexity testing personnel under CLIA. The CAP believes a nursing degree is not equivalent to a bachelor's degree in the training necessary to perform high-complexity testing. While the nursing degree may include human biology courses, the nursing science course work is not equivalent to that of a bachelor's of biological science degree.

  The CAP recommends CMS consider the nursing degree as a separate qualifying degree. Nurses perform laboratory-related functions such as point-of-care testing (POCT), specimen collection, and test ordering, which are not their primary job functions, but rather secondary tasks performed outside of the central laboratory. Unlike laboratorians in the central laboratory, nurses often have minimal time to reflect on the total testing process. Nurses may have the understanding in terms of clinical knowledge but not in the laboratory medicine practice, which we believe a separate qualifying degree will better provide, of the skills, experience, and training necessary to perform these limited laboratory-related functions.

  Separate qualifying degree
  For the separate qualifying degree, we recommend CMS create testing personnel criteria that leverage POCT in settings of a hospital or healthcare facility where specialized or intensive treatment (eg, ICU) is provided. This testing mainly includes waived and moderate complexity testing, but can involve a limited number of modified FDA-cleared or approved POCT tests (eg, whole blood glucose). This category would allow nurses to fulfill their roles within the healthcare delivery team while ensuring the reliability and accuracy of laboratory testing. However to fulfill the role of technical consultant and technical supervisor, we believe nurses lack the specialized scientific and technical knowledge essential for understanding the preanalytic, analytic or postanalytic phases of the testing, which are critical to overseeing moderate- and high-complexity testing. Therefore, we also recommend CMS develop criteria for the technical consultant and general supervisor under this separate qualifying degree that would allow experienced and trained nurses to fulfill the role of technical consultant and general supervisor while remaining under the supervision of a pathologist.

  The CAP recommends CMS create nursing as a separate qualifying degree with criteria:

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- **Leveraging POCT in settings of a hospital or health care facility where specialized or intensive treatment (eg, ICU) is provided.**
- **Allowing trained and experienced nurses to fulfill the role of technical consultant and general supervisor under the supervision of pathologists.**
- **Expanding this designated nurse qualified category to include other allied health professionals (eg, respiratory therapists, interventional radiology technologists, and cardiac catheter technologists with bachelor degrees).**

- **Physical science degree**

  Physical science is a broad discipline often described as the study of non-living systems, such as astronomy, physics, and earth sciences. Generally, these types of degrees are not related to clinical laboratory testing but in some instances, individuals with these types of degrees have been able to qualify as high complexity testing personnel with requisite amount of training. The CAP Accreditation program has qualified individuals with physical science degrees that included human biology course work. We believe it necessary to broaden the list of degrees in order to increase the number of eligible clinical laboratory testing personnel particularly for small rural community hospitals. These institutions have difficulty finding qualified individuals.

  The CAP recommends CMS consider the physical science degree that includes human biology course work and strengthen the personnel experience and training requirements to ensure these individuals have a sufficient knowledge base to perform clinical laboratory testing.

- **Competency**

  Current CLIA regulations allow general supervisors with associate's degrees to perform competency assessment on high complexity testing personnel, but because the personnel requirements for moderate complexity testing do not include the general supervisor category, the same general supervisors cannot perform competency assessment on moderate complexity testing personnel unless they can meet the regulatory qualifications of a technical consultant (ie, high complexity testing). Technical consultants, at a minimum, are required to have a bachelor's degree in chemical, physical, or biological science or medical technology. The CAP believes that competency assessment qualifications should not be dependent on test complexity but rather allow a general supervisor with an associate's degree to perform these assessments for moderate- and high-complexity personnel.

  Furthermore, separating assessment of competency between tests of various test complexity within a laboratory section is burdensome and inefficient and does not improve patient safety, (eg: The elements of a CBC may include an automated

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hemogram and an abnormal manual differential, which are moderate and high complexity, respectively. A general supervisor with an associate's degree overseeing the CBC only qualifies to assess a portion of this testing).

The CAP recommends CMS allow general supervisors to perform competency assessments of moderate- and high-complexity personnel.

- **Personnel experience and training**
  When CMS currently refers to laboratory training, experience and/or skills, qualified individuals have clinical training and experience with non-waived clinical laboratory testing or in the specialties and subspecialties in which the individual is performing testing. **The CAP recommends CMS maintain the current level of experience and training required to determine potential personnel eligibility. In addition, the CAP believes CMS should provide the laboratory director with additional flexibility in order to identify and train potential personnel who meet the minimum educational coursework requirements.**

  Also, the CAP requests CMS change the requirement for performance of competency assessment for personnel working at more than one location within a hospital system or affiliated laboratory. Laboratories are required to perform competency assessment for personnel at every testing location for the same activity within a healthcare system while healthcare systems have become more integrated over time by using standardized procedures, instruments, equipment, etc. This allows for the test to be performed in the same manner across these integrated systems. The CMS should consider revisions to allow for a centralized competency assessment to be performed as long as the assessment addresses any variations in the testing in the different testing locations. This is especially important for POCT where it is common to hold skills fairs for nursing personnel that perform moderate and waived complexity testing. We believe this requirement is burdensome and unnecessary since the six elements of competency assessment assess the proficiency of testing staff for their core functions.

  The CAP recommends CMS allow for a centralized competency assessment to be performed as long as the assessment addresses any variations in the testing in the different testing locations.

- **Non-traditional degrees**
  Several current CLIA personnel requirements allow a position to be filled by an individual with a degree in a "chemical, physical, biological or clinical laboratory science, or medical technology." The CAP Accreditation program has qualified individuals with non-traditional degrees that included human biology course work. We believe it necessary to broaden the list of degrees in order to increase the

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number of eligible clinical laboratory testing personnel particularly for small rural community hospitals. These institutions have difficulty finding qualified individuals.

The CAP recommends CMS consider the non-traditional degrees that include human biology course work with robust personnel experience and training requirements to ensure these individuals have a sufficient knowledge base to perform clinical laboratory testing.

HISTOCOMPATIBILITY REGULATIONS

Histocompatibility testing has evolved from cell based assays to molecular typing and solid phase platforms for antibody detection, leading to improved accuracy, sensitivity, and specificity. Significant changes have occurred in the clinical practice of transplantation (immunosuppression, desensitization practices) and improvements in anti-rejection therapies have led to improved outcomes and mitigation of risk due to HLA antibodies. The virtual crossmatch involves a determination of the presence or absence of donor HLA specific antibodies (DSA) in a patient by comparing the patient's HLA antibody specificity profile to the HLA type of the proposed donor without carrying out a 'wet' crossmatch such as a Complement Dependent Cytotoxic or flow cytometric crossmatch. The CLIA histocompatibility regulations have not been updated since the virtual crossmatch has become reliable with the advent of molecular and solid phase testing.

The CAP supports CMS updated the histocompatibility regulations to include virtual crossmatch. In addition, the CAP believes CMS should define virtual crossmatch, develop performance criteria and establish personnel requirements. Moreover, CMS should use the recommendations developed by the Centers for Disease Control and Prevention (CDC) Virtual Crossmatch Workgroup Report from November 2014. Below is a summary of those recommendations:

- Virtual Cross-match definition
  An assessment of immunologic compatibility based on the patient's alloantibody profile compared to the donor's histocompatibility antigens.
- Performance Criteria
  - Virtual crossmatch on a patient's alloantibody status to meet the transplant program-specific criteria.
  - Virtual crossmatch by a serologic crossmatch
  - Acceptability of test results
- Personnel Requirements
  Personnel should meet the CLIA qualifications for a Clinical Consultant of histocompatibility testing as specified in 42 CFR 493.1457. Performing the analytic testing of donors and recipients is within responsibilities of a General Supervisor or Testing Personnel, but the interpretation of results, such as would

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occur with a virtual crossmatch, is covered in the Clinical Consultant responsibilities.

PT REFERRAL

The CAP has long advocated for a tiered approach to enforcement of PT referral sanctions and believes that the sanctions should increase in severity based on the extent and nature of the referrals. Moreover, the CAP believes CMS should use the statutorily mandated discretion when imposing the principal sanctions against any laboratory.

- **Egregious Sanctions**
  For the most egregious violations, laboratories are subjected to the revocation of the laboratory's CLIA certificate for at least one year, the owner and operator are banned from owning or operating a CLIA-certified laboratory for at least one year, and may include the imposition of a civil money penalty (CMP). The CAP supports CMS's use of discretion when implementing sanctions for PT referral cases. Distributive testing should be allowable for PT processes and not be considered as PT referral. For example, FISH testing where the probe is applied at a different location from the interpretation, NGS testing where the sequencing is done at one location and the analysis/interpretation is done at another location. This makes it difficult to assess the complete process. Imposing draconian sanctions discourages a good quality indicator.

  We believe draconian sanctions should not be applied for all egregious violations, and specifically not for those that involve distributive testing as described in the laboratories' protocols.

- **Waived laboratories**
  Waived laboratories are only exempt from quality standards and inspections of the CLIA statute. Therefore, waived laboratories that participate in PT are subject to principal PT referral sanctions such as revocation, suspension, or limitation. The CAP believes laboratories performing waived testing should perform proficiency testing. Imposing draconian sanctions against waived laboratories discourages a good quality indicator. We believe waived laboratories should not be subject to principal sanctions.

  The CAP supports the proposal to allow more discretion in issuing sanctions against waived laboratories.

The CAP supports the Agency's goals of assuring patient access to quality testing by affording the least burdensome approach to oversight. CLIA is a very important tool that can ensure the integrity of clinical laboratory testing. As clinical laboratory testing continues to evolve, CMS and interested stakeholders such as the CAP will need to

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work closely to ensure smarter regulations and policies. Please feel free to contact Helena Duncan, CAP Assistant Director, Economic and Regulatory Affairs at hduncan@cap.org if you have any questions on these comments.

Sincerely,

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President

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