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Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445–G
Washington, DC 20201

***RE: CMS–3326-NC, Request for Information: Revisions to Personnel Regulations, Proficiency Testing Referral, Histocompatibility Regulations and Fee Regulations under the Clinical Laboratory Improvement Amendments of 1988 (CLIA); Vol. 83, No. 6, January 9, 2018.***

Dear Ms. Verma:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to respond to the Centers for Medicare & Medicaid Services' (CMS) request for information (RFI) on revisions to personnel regulations, proficiency testing (PT) referral, histocompatibility regulations, and fee regulations under the Clinical Laboratory Improvement Amendments (CLIA) of 1988.

The objective of CLIA is to ensure high quality laboratory testing; indeed, since CLIA was enacted, the quality of laboratory testing has improved. In this RFI, CMS is seeking information, in advance of proposed rulemaking, regarding several components of the CLIA regulations, which the agency notes have not been substantially updated since 1992. In our comments below, the AHA offers feedback on the personnel requirements, PT referral requirements, histocompatibility regulations, and CLIA fees.

## PERSONNEL REQUIREMENTS

The nation's medical laboratory professionals play a critical role in health care. However, clinical laboratories are facing a critical and growing shortage of qualified laboratory personnel.

This shortage hampers the ability of clinical laboratories to meet patient testing demands, which may pose problems for patient access to appropriate care.

Rural areas and areas served by smaller hospitals, in particular, are finding it increasingly difficult to recruit and retain qualified laboratory personnel. **As such, we support efforts to expand the types of educational degrees that would be eligible under CLIA so as to increase the number of qualified laboratory testing personnel serving the nation's hospitals and health systems, especially small and rural hospitals.**

Nursing Degrees. In the RFI, CMS seeks public comment related to whether a bachelor's degree in nursing should be considered equivalent to a bachelor's degree in biological sciences or should be considered a separate qualifying degree to meet the CLIA requirements for moderate- and high-complexity testing personnel and technical consultants. In general, the AHA does not believe that a bachelor's degree in nursing is equivalent to a bachelor's degree in biological sciences. While many nursing programs include human biology courses, such as anatomy and physiology, the extent of the scientific course work covered in nursing programs is not as extensive as traditional biological science degree programs. Therefore, we do not believe that a bachelor's of nursing degree should qualify for non-waived testing in a hospital central laboratory.

However, advances in the technology of laboratory testing have allowed testing to be provided closer to where patients are located, through the expansion of point-of-care testing (POCT) in hospitals and health systems, such as bedside whole blood glucose testing and rapid coagulation testing. One of the main advantages of POCT is the rapid turn-around of results, so that this information can impact patient clinical management sooner. Nurses play an important laboratory-related role through performing such POCT, collecting laboratory specimens for hospital central laboratory testing and ordering tests requested by physicians. Nurses commonly perform waived and moderate complexity POCTs at the patient's bedside. In limited circumstances, nurses also perform modified Food and Drug Administration (FDA) approved or cleared POCT at the bedside, which, by definition, is considered to be high-complexity testing.

**Therefore, the AHA recommends that CMS approve a bachelor's degree in nursing as a separate qualifying degree to meet the CLIA requirements for POCT in hospitals and health systems, subject to the competency testing requirements of CLIA.** We recommend that CMS create a separate POCT category, which would allow nurses to carry out their essential role in health care delivery while ensuring the reliability and accuracy of laboratory testing. **We also support having the bachelor's degree in nursing be sufficient to fulfill the educational qualifications for a technical consultant in POCT, as long as they are under the supervision of a pathologist and meet other appropriate requirements as CMS may determine necessary.**

Physical Science Degrees. According to CMS, a "physical science degree" 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. However, in some instances, individuals with physical science degrees have been able to qualify as high-

complexity testing personnel. In the RFI, the agency seeks public comment on what is considered a physical science degree and if physical science degrees provide the educational background needed, such that all or some should be considered a qualifying degree to meet the intent of CLIA requirements.

As noted previously, in consideration of the challenging shortages of qualified laboratory personnel, particularly in small and rural hospitals, the AHA supports expanding the types of degrees eligible under CLIA. We understand that some national clinical laboratory accreditation programs, such as the College of American Pathologist (CAP) accreditation program, have permitted individuals with physical science degrees that include adequate human biology coursework to qualify. **Therefore, the AHA recommends that CMS allow physical science degrees that include adequate amounts of human biology coursework, along with enhanced requirements for personnel experience and training, to qualify. In this context, we urge the agency to describe in regulation the specific course requirements, experience, and training that would enable these types of physical science degrees to fulfill the educational requirements for CLIA testing.**

Non-traditional Degrees. The agency recognizes that non-traditional degrees that may be combined with job experience in lieu of coursework may be classified as general education degrees. CMS seeks public comment related to non-traditional type degrees (for example, Regents Bachelor of Arts); specifically, whether any of these types of degrees should be considered to meet the requirements for a chemical, physical, biological, or clinical laboratory science and/or medical laboratory technology degree.

**Similar to our comments above, the AHA recommends that CMS allow non-traditional degrees that include adequate amounts of human biology coursework, along with enhanced requirements for personnel experience and training, to qualify. In this context, we urge the agency to describe in regulation the specific course requirements, experience and training that would enable these types of degrees to fulfill the educational requirements of CLIA.**

Personnel Competencies. Current CLIA regulations allow general supervisors with associate's degrees to perform competency assessment on high-complexity testing personnel. However, general supervisors cannot perform competency assessments on moderate-complexity testing personnel unless they can meet the higher regulatory qualifications of a technical consultant. CMS is seeking public comment regarding whether general supervisors should be allowed to perform competency assessments for testing personnel performing moderate-complexity testing in laboratories that perform both moderate- and high-complexity testing.

**Given the fact that high-complexity testing is inherently more involved than moderate-complexity testing, the AHA recommends that CMS allow general supervisors to perform competency assessment for both moderate- and high-complexity testing personnel.**

## PROFICIENCY TESTING REFERRAL

CLIA requires laboratories that engage in moderate- or high-complexity testing to enroll in a PT program that covers all the specialties and subspecialties for which the laboratory is certified and all analyses listed in the CLIA regulations. Only those laboratories that hold Certificates of Waiver (CoW) are exempt from the requirement to perform and pass PT. PT is a tool to ensure the accuracy and reliability of laboratory test results. Laboratories are required to test PT samples in the same manner as patient specimens, except that they may not refer these samples to another laboratory for testing for any reason.

Discretion for Category 1 PT Referral. The Taking Essential Steps for Testing (TEST) Act (Pub. L. 112-202) gives the Secretary discretion as to which sanctions may be applied to cases of intentional PT referral. There are three categories of sanctions that apply under certain specified conditions depending on the extent of the violation. Category 1 PT referral is reserved for the most egregious violations, including repeat PT referrals and cases where a laboratory reports out another laboratory's PT result. Sanctions include loss of the laboratory's CLIA certificate for a minimum of a year and a ban on the owner or operator from running a CLIA-certified laboratory for a minimum of a year. It also may include a civil money penalty. Currently, the application of the owner exemption from the ban is determined on a case-by-case basis.

In the RFI, CMS seeks public comment related to applying discretion in situations where CMS determines that a laboratory has referred its PT samples to another laboratory and has reported those results from another laboratory as their own, and under what circumstances such discretion should be applied.

**The AHA supports CMS using discretion in determining the appropriate level of sanctions for violations of the PT referral requirements.** The agency should have flexibility to evaluate the various factors underlying irregularities in the handling of PT samples, as well as the ability to apply a range of sanctions appropriate for the level of violations. Such an approach is critical to ensuring quality, as well as access to laboratory testing.

**In particular, we have long advocated that clinical laboratories should not be punished for following their standard operating procedures (SOPs), which may result in the unintentional referral of a PT sample to another laboratory.** That is, if a laboratory handles a PT sample in the same way patient samples are handled, according to a written SOP or protocol, or as programmed into middleware, this should not be considered an impermissible PT referral. In fact, in order to ensure consistency and quality in laboratory testing, PT should incorporate the whole process the laboratory typically undertakes for patient samples, which may include referral to another laboratory for reflex, distributive or confirmatory testing.

Alternative Sanctions for PT Referral by CoW Laboratories. While PT is not required for CoW laboratories, CoW laboratories are not exempt from the ban against PT referral if they choose to participate in PT. However, CMS does not impose alternative sanctions on CoW laboratories because those laboratories are not inspected for compliance with condition-level requirements.

Therefore, CMS's only recourse in cases of PT referral is revocation, suspension, or limitation sanctions. In the RFI, the agency seeks public comment regarding the feasibility of applying alternative sanctions in case of PT referral that involves waived testing.

**The AHA supports CMS using discretion to apply alternative sanctions in these circumstances.** We believe that CoW laboratories should be encouraged to participate in PT in order to improve their quality of laboratory testing. Removing onerous sanctions would help achieve broader participation in PT.

## HISTOCOMPATIBILITY

The CLIA regulations related to histocompatibility have not been updated since 1992. As a result of changes in histocompatibility testing technology and practices, as well as advances in organ transplantation, CMS believes that some of its requirements have become outdated and may preclude the use of current transplantation practices. For example, in some cases, performing a "virtual crossmatch"[1] has replaced the use of a "physical crossmatch"[2] to determine compatibility between the donor and recipient.

CMS seeks public comments related to two CLIA Committee recommendations: whether virtual crossmatching should be an acceptable alternative to physical crossmatching; and, under what criteria and decision-making algorithms, would virtual crossmatching be an appropriate substitute for physical crossmatching.

**The AHA recommends that CMS consider virtual crossmatching to be an acceptable alternative to physical crossmatching under certain circumstances.** We are aware that the state of the art technologies in molecular typing and multiple solid phase platforms for antibody detection have significantly improved the accuracy, sensitivity, and specificity of donor human leukocyte antigen (HLA) typing and recipient HLA antibody results, making it possible and reliable to apply virtual crossmatching for pre-transplant histocompatibility assessment.

Improvement in the quality of an organ transplant requires timely evaluation of histocompatibility to reduce cold ischemia time during allograft allocation and to facilitate matching over a larger geographic area, which makes it necessary to apply virtual crossmatching in lieu of physical crossmatching in certain circumstances.

Virtual crossmatching can be an acceptable alternative to physical crossmatching under the following criteria and conditions:

[1] Virtual crossmatching means an assessment of immunologic compatibility based on the patient's alloantibody profile compared to the donor's histocompatibility antigens. In virtual crossmatching, laboratory test results already performed on donors and recipients are compared in order to predict compatibility and determine whether an organ is acceptable for a patient.
[2] Physical crossmatching means a mixing of specimens from donor and recipient to check for compatibility.

1. Virtual crossmatching can completely replace physical crossmatching for transplant candidates with Panel Reactive Antibodies (PRA) = 0 (not HLA-sensitized).
2. Virtual crossmatching can be prospectively performed to decide compatibility for transplant candidates with PRA > 0 (HLA-sensitized), but with a well-defined HLA antibody profile and intensity level. Donor and recipient compatibility should have perioperative or retrospective verification via a physical crossmatch.
3. Transplant candidate antibody testing and donor HLA typing should meet the following conditions:

    - HLA antibody specificity used for virtual crossmatching has to be confirmed by at least two different sample testing results.
    - The most current sample for antibody testing used for virtual crossmatching should be less than 30 days.
    - Antibody specificity should be reconfirmed by multiple solid-phase testing platforms when an ambiguity presents during antibody testing.
    - Donor HLA typing has to be performed to reach the resolution that is sufficient to define the allelic donor specific antibody for virtual crossmatch.

Virtual crossmatching cannot be an acceptable alternative to physical crossmatching if the HLA-antibody is not well-defined.

## CLIA FEES

In the RFI, CMS notes that it is exploring an appropriate methodology for determining a fair and reasonable fee to support requests for revised certificates, such as those due to a change in the laboratory's name, location, director, services offered, or certificate type.

**The AHA understands and supports the notion of CMS instituting a nominal fee that a clinical laboratory would be required to pay for obtaining a revised CLIA certificate if the request was initiated by the laboratory.** For instance, when a change is made in its laboratory director or its address, it is beneficial to the laboratory to have an updated CLIA certificate. Today, the laboratory notifies the state health department of the change but does not receive an updated CLIA certificate until the next CLIA certificate renewal date. A clinical laboratory should be permitted to choose whether or not it wants an updated CLIA certificate prior to its CLIA certificate renewal date and it is appropriate that a nominal fee be required in such circumstances.

**We also encourage the agency to institute the ability for laboratories to choose to receive its CLIA certificates via an electronic means, rather than only through the U.S. mail.** We understand that large health systems have experienced issues with lost CLIA certificates due to failures in delivery through the U.S. mail system.

## GENERAL SOLICITATION FOR FEEDBACK

CMS also is seeking general feedback from stakeholders on other areas of CLIA in which they would recommend changes.

In response to this general request, the AHA would like to raise an issue involving CLIA competency testing in large health systems that have multiple laboratory locations, each with a different CLIA number. Currently, CLIA regulations require that the same individual must undergo separate competency testing procedures at each of a health system's CLIA locations for an identical clinical laboratory test system. We believe that such redundant competency testing for identical test systems is burdensome and unnecessarily increases costs to the health system.

**The AHA recommends that an individual should have to undertake only one competency testing assessment, which should be acceptable across multiple CLIA locations within the same health system, as long as the competency assessment is for an identical test system. We further recommend that the laboratory director at each CLIA location be responsible for ensuring that the testing personnel comply with the competency testing requirements, either by completing competency testing at that specific CLIA location or by obtaining records from another of the health system's CLIA locations in order to verify the individual's competency on an identical test system.**

Again, we thank you for your consideration of our comments. Please contact me if you have questions or feel free to have a member of your team contact Roslyne Schulman, director of policy, at rschulman@aha.org or (202) 626-2273.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President
Government Relations and Public Policy