DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO 18-11-CLIA

DATE: **January 05, 2018**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety and Oversight Group *(formerly Survey and Certification Group)*

SUBJECT: Clinical Laboratory Improvement Amendments (CLIA) Release of Request for Information (RFI)

Memorandum Summary

- **The Centers for Medicare & Medicaid Services (CMS) published an RFI on January 5, 2018.**
- **The RFI is seeking public comment and information related to the following areas:**
  - Personnel requirements: nursing and physical science degrees, competency assessment, laboratory training and experience requirements and documentation;
  - Proficiency testing referral: Discretion for Category 1, alternative sanctions imposed for Certificate of Waiver (CoW);
  - Histocompatibility; and,
  - Compliance and additional fees.

Background

This RFI seeks public comment regarding several items related to CLIA personnel requirements and histocompatibility requirements, which, with minor exception, have not been updated since 1992. We are also seeking public comment regarding the flexibility to impose alternative sanctions for laboratories issued a CoW determined to have participated in proficiency testing (PT) referral. Finally, we are seeking public comment related to appropriate sanctions in situations where we determine that a laboratory has referred its proficiency testing PT samples to another laboratory and has reported the other laboratory's result as their own.

We are seeking information related to any histocompatibility regulations that have become outdated, and suggestions for updating the histocompatibility regulations to align with current laboratory practice. This RFI also seeks public comment regarding the updating of fees for determination of program compliance and additional fees for laboratories established under the CLIA regulations. We are also seeking public comment regarding the collection of other fees we are authorized to collect such as fees for revised certificates, post survey follow-up visits, complaint investigations, and activities related to imposition of sanctions.

Discussion

Specifically we are seeking information (for example, evidence, research, trends) related to the following topics:

1. Nursing Degrees: For purposes of meeting the educational requirements for technical consultants and moderate and high complexity testing personnel, should the regulations 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?
2. Physical Science Degrees: What is considered a physical science degree, and should any physical science degree(s) be considered as educational background(s) appropriate for qualifying to meet the applicable CLIA educational requirements?
3. Competency Assessment: Should the CLIA regulations be amended to allow general supervisors, with associate's degrees, to perform competency assessment for moderate complexity testing personnel in laboratories that perform both moderate and high complexity testing.
4. Laboratory Training and Experience: 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?
5. Non-Traditional Degrees: What types of degrees should be considered to meet the requirements for a chemical, physical, biological or clinical laboratory science, and/or medical technology degrees?
6. PT Referral Discretion: Under what circumstances should discretion be applied in situations where CMS determines that a laboratory has referred its PT samples to another laboratory and has reported the other laboratory's PT results as its own (Category 1)?
7. PT Referral, CoW: Should alternative sanctions instead of principal sanctions be an option in these cases in order to create parity for all certificate types for laboratories determined to have participated in PT referral?
8. Histocompatibility: Should virtual crossmatching 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? Suggestions for updating the histocompatibility regulations to align with current laboratory practice.
9. CLIA Fees: Updating of fees for determination of program compliance and additional fees for laboratories established under the CLIA regulations as well as the collection of other fees we are authorized to collect such as fees for revised certificates, post survey follow-up visits, complaint investigations, and activities related to imposition of sanctions.

How to Submit Public Comments: We intend to consider public comments and information received in response to this RFI in the event that we draft proposals to update the existing CLIA regulations through future rulemaking. CMS encourages comments, questions, or thoughts on this RFI and will accept comments until March 12, 2018. The RFI can be downloaded from the *Federal Register* at: https://www.federalregister.gov/public-inspection.

Effective Date: Immediately. This memorandum should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/
David R. Wright

cc: Survey and Certification Regional Office Management