



COLLEGE of AMERICAN PATHOLOGISTS

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Chiquita Brooks-LaSure, MPP
Administrator
U.S. Centers for Medicare & Medicaid Services
7500 Security Boulevard,
Baltimore, MD 21244

Rochelle Paula Walensky, MD, MPH
Director
Centers for Disease Control and Prevention (CDC)
1600 Clifton Road
Atlanta, GA 30329

**Re: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees;
Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver
Laboratories (CMS-3326-P)**

Dear Ms. Brooks-LaSure and Dr. Walensky,

The College of American Pathologists (CAP) appreciates the opportunity to comment on the proposed rule entitled, "*Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories.*" As the world's largest organization of board-certified pathologists and the leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists, and the public by fostering and advocating for excellence in the practice of pathology and laboratory medicine worldwide.

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. 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 relate to each other and with the hospital through common ownership or joint management. Moreover, these health care systems are using advances in technology to perform clinical laboratory testing in a myriad of settings that are closer to patients. 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. **Therefore, the CAP supports the CLIA proposals that address practice and technology changes, such as the updates to**



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the Histocompatibility regulations, especially the recognition of virtual crossmatching; the creation of qualification algorithms for testing personnel instead of specific degrees; allowance of respiratory therapists with an associate degree to qualify as a technical consultant; the removal of the physical science degree; and, allowing military trained individuals to qualify as testing personnel once they move to the private sector.

However, the CAP believes the current CLIA requirements for the laboratory director and technical supervisor of the Immunohematology laboratories should be maintained. As such, we are concerned about those proposals that do not address technology or practice changes but are counter to those activities. In addition, we are concerned about the proposal for nurses to be classified as high-complexity laboratory testing personnel in the proposed rule so we will focus our comments on the following areas:

- Laboratory Director Qualifications
 - Doctoral Degree
 - Alternative Qualifying Degree
- Technical Supervisor Qualifications for Immunohematology
- Nurses as clinical laboratory testing personnel

Laboratory Director Qualifications

Doctoral Degree

Physicians are doctors of medicine (MDs) or doctors of osteopathy (DOs). These degrees are awarded based on successful training for the practice of medicine. PhDs are awarded based on successful defense of an academic thesis. The standard MD or DO program structure sees students undertake two years of coursework and classroom-based learning, before undertaking two years of rotational work in a clinical environment (such as a hospital). Receipt of an MD or a DO degree requires successful graduation from a medical school (allopathic schools accredited by the Liaison Committee on Medical Education (LCME); osteopathic schools accredited by the Commission on Osteopathic College Accreditation (COCA). This training, in combination with graduate medical education, prepares physicians to diagnose patients and treat patients – in other words, the practice of medicine.

Pathologists are licensed physicians who are trained in pathology to make medical diagnoses that are based upon macroscopic, cellular (microscopic), molecular and/or laboratory examination of human tissues, cells, body fluids or other samples from the human body. Pathologists direct clinical and anatomic pathology laboratories; perform biopsies; evaluate and diagnose surgical, cytology, and autopsy specimens; interpret clinical laboratory tests; and serve as medical consultants to other physicians. By virtue of their clinical training including medical school and graduate medical education, and specialty certification in the medical disciplines of anatomic and clinical pathology and,



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pathologists are the physicians uniquely best qualified to perform these services.

The CMS is proposing to add a definition for “doctoral degree” to state that it means an earned post-baccalaureate degree with at least 3 years of graduate-level study that includes research related to clinical laboratory testing or advanced study in clinical laboratory science or medical technology. The CMS is considering if the doctorate-level degree should include traditional (for example, Doctor of Philosophy (PhD), doctorate in science (DSc)) and professional (for example, Doctorate in Clinical Laboratory Science (DCLS)) degrees. While the CAP supports the agency’s effort to clarify doctorate-level degrees within CLIA, **we strongly oppose the inclusion of the DCLS degree as a qualifying degree under CLIA.** While the CAP supports the advancement of clinical laboratory professionals in the field of laboratory science, we are concerned that the DCLS degree may cause confusion among the public about the distinctions between a clinical pathologist and DCLS. The proposed rule states that the DCLS will contribute to increasing laboratory efficiency and improving timely access to accurate and appropriate laboratory information. A graduate of a DCLS program will be able to: provide appropriate test selection and interpretation of test results; monitor laboratory data and testing processes; improve the quality, efficiency, and safety of the overall diagnostic testing process; and direct laboratory operations to comply with all state and Federal laws and regulations. We would not consider a DCLS an acceptable doctoral degree. A clinical pathologist is a physician who is trained to render diagnoses, interpret laboratory tests, and provide clinical consultations in the field of laboratory medicine to other physicians. Professional activities of clinical pathologists constitute the practice of medicine. Further, we do not believe it is appropriate to include a professional designation as a qualifying educational category for CLIA. As the agency intends to clarify the doctorate-level requirements, the addition of the DCLS degree would cause confusion.

Alternative Qualifying Degree

The CMS is proposing to add an educational requirement for moderate and high-complexity laboratory director that includes a qualification algorithm for an individual that does not have an earned doctoral degree in a chemical, biological, or clinical laboratory science or medical technology. **The CAP strongly opposes the lowering of educational standards for the laboratory director.** We recognize that degree names and types have changed since the CLIA regulations were first published in 1992 resulting in a challenge for the CMS, state agencies, Exempt States (ES), and Accrediting Organizations (AOs) to determine what types of degrees are considered acceptable degrees; however, **we believe doctorate-level or medical doctor degree should be the minimum educational qualification for laboratory director** given the importance of the role to oversee the overall management and operations of the clinical laboratory.

Technical Supervisor Qualifications for Immunohematology

The CMS is proposing to lower the technical supervisor (TS) requirements for immunohematology to align with other clinical laboratory disciplines. The current



regulation requires that the TS for immunohematology be a doctors of medicine or osteopathy. In the rule, the CMS cited the need to change this requirement because fulfilling the competency assessment requirements (for example, direct observation) can be challenging in rural facilities as the TS may not be onsite as the individual(s) may cover a large geographic area. **The CAP strongly opposes the removal of physicians from the role of TS for immunohematology and believes it would constitute a risk to public health and individuals served the clinical laboratory.** This field is evolving into emerging uses and hazards of therapies (e.g. cellular therapy) in the field of transfusion medicine, which require the expertise of a physician to oversee.

Nurses as Clinical Laboratory Testing Personnel

The CMS is proposing to add an earned doctoral, master's, or bachelor's degree in nursing to qualify as testing personnel under CLIA. In the CAP's 2018 comments to the CMS' request for information (RFI), we recommended the CMS consider the nursing degree as a separate qualifying degree. For the separate qualifying degree, we recommend the CMS create testing personnel criteria that leverage POCT in settings of a hospital or health care facility where specialized or intensive treatment (e.g. 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 (e.g. whole blood glucose). This category would allow nurses to fulfill their roles within the health care 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.

Therefore, the CAP reiterates our recommendations that the CMS create nursing as a separate qualifying degree with criteria:

- **Leveraging POCT in settings of a hospital or health care facility where specialized or intensive treatment (e.g. 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 (e.g. respiratory therapists, interventional radiology technologists, and cardiac catheter technologists with bachelor's degrees).**

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



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continues to evolve, the CMS and interested stakeholders such as the CAP will need to work closely to ensure smarter regulations and policies. Please feel free to contact Helena Duncan, CAP Director, Scientific Regulatory and Health IT Policy at hduncan@cap.org if you have any questions on these comments.

We look forward to discussing these issues with you.

Sincerely,

Emily E. Volk, MD, FCAP
President, College of American Pathologists