PUBLICATION

CMS Enacts New CLIA Regulations Effective January 2025

Authors: Alissa D. Fleming, Tenia L. Clayton, Katherine A. Denney
March 13, 2025

On December 23, 2023, CMS issued its Final Rule, establishing new Clinical Laboratory Improvement Amendments (CLIA) regulations (the Final Rule). Several provisions only became effective December 28, 2024. CMS was driven to implement these updates due to the fact that the requirements have not been updated since 1992, resulting in several terms becoming outdated. We discuss some of these updated terms below along with a high-level summary of many of the significant qualification updates.

Revisions to Definitions Pertinent to Personnel

In addition to the updated education and training requirements discussed further below, CMS has revised or introduced several definitions related to personnel qualifications under CLIA. This effort aims to clarify prior ambiguities regarding the applicable education and training requirements for clinical lab personnel and to establish clear standards for the future. These updates include the following:

1. CMS is updating the definition of "midlevel practitioner" for purposes of CLIA to explicitly include nurse anesthetists and clinical nurse specialists.

2. CMS is adding a definition for "continuing education (CE) credit hours" that includes both "continuing medical education" hours and "continuing education" hours to encompass physician and nonphysician education requirements.

3. CMS is adding a definition for "doctoral degree" to distinguish it from MD, DO, and DPM programs. The definition would include earned post-baccalaureate degrees with at least three years of graduate-level study that includes research related to clinical lab testing or medical technology but would not encompass a Doctor of Veterinary Medicine.

4. CMS is adding a definition for "laboratory training or experience," which means training or experience obtained in a facility subject to and meeting CLIA standards (i.e., conducting nonwaived lab tests). CMS generally intended to ensure that all individuals performing nonwaived lab tests have proper training on the pre-analytic, analytic, and post-analytic phases of testing.

5. CMS is adding a definition for "experience directing or supervising" to clarify that this means experience obtained in a facility subject to and meeting CLIA standards (i.e., conducting nonwaived lab tests).

Personnel Requirements

The new education and training requirements are categorized according to the clinical lab position and the complexity of the lab test. For references to doctoral, master's, and bachelor's degrees, CMS has updated the permitted degrees to include only chemical, biological, clinical or medical lab science, or medical technology degrees across all positions (including those not addressed further below). This change removes "physical science" as a permitted degree. Additionally, the following represents a high-level summary of the Final Rule's updates to requirements related to personnel qualifications and duties:

Lab Directors		
	Changes to Education/Training	***Changes to Duties/Responsibilities***
Moderate Complexity	1. Removed permission previously granted for candidates who can demonstrate qualifications that are equivalent to stated CLIA requirements (e.g., equivalent board certifications). 2. Removed line item previously enumerated for candidates who sought to demonstrate qualifications through a medical residency so as to focus instead on clinical lab training and experience (which could be met under a medical residency program). 3. Expanded options for appropriately qualifying to be a lab director under the pathway requiring a bachelor's degree in chemical, biological, clinical or medical lab science, or medical technology by permitting 120 semester hours from an accredited institution to be equivalent to a bachelor's degree so long as they include one of the following: Opt. 1: 48 semester hours of medical lab science or medical lab technology courses. Opt. 2: 48 semester hours of a science course that includes: • 12 semester hours of chemistry; • 12 semester hours of biology; and • 24 semester hours of chemistry, biology, or medical lab science or medical lab technology. 4. Expanded options for appropriately qualifying to be a lab director under the pathway requiring a master's degree in chemical, biological, clinical or medical lab science, or medical technology by permitting the following to be equivalent	1. **For labs performing provider-performed microscopy procedures**: Must evaluate the competency of all testing personnel through direct observation, monitoring of records/reports, review of test results/worksheets, and other assessments. These evaluations must be conducted and documented at least semiannually during the first year the individual tests patient specimens. Thereafter, they should be performed at least annually. 2. Must be onsite at the lab at least once every six months with at least a four-month interval between visits.

	to a master's degree: Opt. 1: Meet the bachelor's degree equivalency requirements AND have at least 16 semester hours of additional graduate coursework in biology, chemistry, medical technology, or clinical or medical lab science. Opt. 2: Meet the bachelor's degree equivalency requirements AND have at least 16 semester hours in combination with graduate-level coursework in biology, chemistry, medical technology, clinical or medical lab science, and an approved thesis or research project related to lab testing. ***Grandfather Clause?*** Yes (so long as employment is continuous after December 28, 2024).	
High Complexity	1. Removed permission previously granted for candidates who can demonstrate qualifications that are equivalent to stated CLIA requirements (e.g., equivalent board certifications). 2. Removed line item previously enumerated for candidates who sought to demonstrate qualifications through a medical residency so as to focus instead on clinical lab training and experience (which could be met under a medical residency program). 3. Added a requirement that any individual seeking to qualify to be a lab director as an MD, DO, or doctor of podiatric medicine licensed to practice medicine must have at least 20 CE hours in lab practice covering lab director responsibilities in addition to two years of experience directing or supervising high complexity testing. 4. Expanded options for appropriately qualifying to be a lab director with a doctoral degree in chemical, biological, clinical or medical lab science, or	Must be onsite at the lab at least once every six months with at least a four-month interval between visits.

	medical technology by permitting holding a doctoral degree that falls outside the list to be equivalent so long as the individual also has one of the following: Opt. 1. 16 semester hours of doctoral-level coursework in biology, chemistry, medical technology, clinical lab science, or medical lab science. Opt. 2. An approved thesis or research project in biology/chemistry/medical technology/clinical lab science/medical lab science related to lab testing. ***Grandfather Clause?*** Yes (so long as employment is continuous after December 28, 2024).	
Technical Consultants/Supervisors		
	Changes to Education/Training	***Changes to Duties/Responsibilities***
Moderate Complexity (Consultants)	1. Expanded options for appropriately qualifying to be a technical consultant under the pathway requiring a bachelor's degree in chemical, biological, clinical or medical lab science, or medical technology by permitting 120 semester hours from an accredited institution to be equivalent to a bachelor's degree so long as they include one of the following: Opt. 1: 48 semester hours of medical lab science or medical lab technology courses. Opt. 2: 48 semester hours of a science course that includes: • 12 semester hours of chemistry; • 12 semester hours of biology; and • 24 semester hours of chemistry, biology, or medical lab science or medical lab	N/A

	technology. 2. Expanded options for appropriately qualifying to be a technical consultant under the pathway requiring a master's degree in chemical, biological, clinical or medical lab science, or medical technology by permitting the following to be equivalent to a master's degree: Opt. 1: Meet the bachelor's degree equivalency requirements AND have at least 16 semester hours of additional graduate coursework in biology, chemistry, medical technology, clinical or medical lab science. Opt. 2: Meet the bachelor's degree equivalency requirements AND have at least 16 semester hours in combination with graduate-level coursework in biology, chemistry, medical technology, clinical or medical lab science, and an approved thesis or research project related to lab testing. 3. Created a pathway for qualifying to be a technical consultant where the individual has an associate degree in medical lab technology, medical lab science, or clinical lab science and additionally has four years of lab training or experience in nonwaived testing in the relevant specialty or subspecialty for which they will be responsible. 4. Distinguished technical consultant qualifications for blood gas analysis and excluded new pathway through an associate's degree, and added a new pathway for qualifying for those individuals with a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution and at least two years of lab training or experience in blood gas analysis. ***Grandfather Clause?*** Yes (so long as	

	employment is continuous after December 28, 2024).	
High Complexity (Supervisors)	1. Removed permission previously granted for candidates who can demonstrate qualifications that are equivalent to stated CLIA requirements (e.g., equivalent board certifications). 2. Removed mechanism for demonstrating qualifications through certification by the American Society of Cytology. 3. Expanded options for appropriately qualifying to be a technical supervisor under the pathway requiring a master's degree in chemical, biological, clinical or medical lab science, or medical technology by permitting the following to be equivalent to a master's degree: Opt. 1: Meet the bachelor's degree equivalency requirements AND have at least 16 semester hours of additional graduate coursework in biology, chemistry, medical technology, clinical or medical lab science. Opt. 2: Meet the bachelor's degree equivalency requirements AND have at least 16 semester hours in combination with graduate-level coursework in biology, chemistry, medical technology, clinical or medical lab science, and an approved thesis or research project related to lab testing. 4. Expanded options for appropriately qualifying to be a technical supervisor under the pathway requiring a bachelor's degree in chemical, biological, clinical or medical lab science, or medical technology by permitting 120 semester hours from an accredited institution to be equivalent to a bachelor's degree so long as they include one of the following: Opt. 1: 48 semester hours of medical	

	lab technology courses. Opt. 2: 48 semester hours of a science course that includes: • 12 semester hours of chemistry (specific topics required); • 12 semester hours of biology (specific topics required); and • 24 semester hours of chemistry, biology, or medical lab science or medical lab technology. 3. Updated lab training or experience requirements for certain subspecialties to consistently require four years of training or experience in high-complexity testing. ***Grandfather Clause?*** Yes (so long as employment is continuous after December 28, 2024).	
Testing Personnel		
	Changes to Education/Training	***Changes to Duties/Responsibilities***
Moderate Complexity	1. Expanded options for appropriately qualifying to be a member of testing personnel under the pathway requiring a bachelor's degree in chemical, biological, clinical or medical lab science, or medical technology by permitting 120 semester hours from an accredited institution to be equivalent to a bachelor's degree so long as they include one of the following: Opt. 1: 48 semester hours of medical lab science or medical lab technology courses. Opt. 2: 48 semester hours of a science course that includes: • 12 semester hours of chemistry (specific topics required);	N/A

	• 12 semester hours of biology (specific topics required); and • 24 semester hours of chemistry, biology, or medical lab science or medical lab technology. 2. Expanded options for appropriately qualifying to be a member of testing personnel under the pathway requiring a master's degree in chemical, biological, clinical or medical lab science, or medical technology by permitting the following to be equivalent to a master's degree: Opt. 1: Meet the bachelor's degree equivalency requirements AND have at least 16 semester hours of additional graduate coursework in biology, chemistry, medical technology, clinical or medical lab science. Opt. 2: Meet the bachelor's degree equivalency requirements AND have at least 16 semester hours in combination with graduate-level coursework in biology, chemistry, medical technology, clinical or medical lab science, and an approved thesis or research project related to lab testing. 3. Updated the pathway for qualifying to be a member of testing personnel where the individual has an associate degree to require a degree in chemical, biological, clinical or medical lab science, medical lab technology, or nursing. 4. Distinguished testing personnel qualifications for blood gas analysis and added two new pathways: Opt. 1. Earn a bachelor's degree in respiratory therapy or cardiovascular therapy from an accredited institution and have at least one year of lab training or experience in blood gas	

	analysis. Opt. 2. Earn an associate degree related to pulmonary function from an accredited institution and have at least two years of lab training or experience in blood gas analysis. ***Grandfather Clause?*** Yes (so long as employment is continuous after December 28, 2024).	
High Complexity	1. Addition of pathway for qualifying to be a member of testing personnel for high complexity lab tests that permits qualification of individuals with a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical lab science, or medical technology from an accredited institution. 2. Expanded options for appropriately qualifying to be a member of testing personnel for high complexity lab tests with a doctoral degree in chemical, biological, clinical or medical lab science, or medical technology by permitting holding a doctoral degree that falls outside the list to be equivalent so long as the individual also has one of the following: Opt. 1. 16 semester hours of doctoral-level coursework in biology, chemistry, medical technology, clinical lab science, or medical lab science. Opt. 2. An approved thesis or research project in biology/chemistry/medical technology/clinical lab science/medical lab science related to lab testing. 3. Expanded options for appropriately qualifying to be a member of testing personnel for high complexity lab tests with a master's degree in chemical, biological, clinical or medical lab science, or medical technology by permitting the following to be equivalent	

	to a master's degree: Opt. 1: Meet bachelor's degree equivalency requirements AND have at least 16 semester hours of additional graduate coursework in biology, chemistry, medical technology, clinical or medical lab science. Opt. 2: Meet bachelor's degree equivalency requirements AND have at least 16 semester hours in combination with graduate-level coursework in biology, chemistry, medical technology, clinical or medical lab science, and an approved thesis or research project related to lab testing. 4. Expanded options for appropriately qualifying to be a member of testing personnel for high complexity lab tests with a bachelor's degree in chemical, biological, clinical or medical lab science, or medical technology by permitting 120 semester hours from an accredited institution to be equivalent to a bachelor's degree so long as they include one of the following: Opt. 1: 48 semester hours of medical lab technology courses. Opt. 2: 48 semester hours of a science course that includes: • 12 semester hours of chemistry (specific topics required); • 12 semester hours of biology (specific topics required); and • 24 semester hours of chemistry, biology, or medical lab science or medical lab technology.	

Given the broad-sweeping nature of the Final Rule's changes, a number of actions are recommended to promote and maintain compliance. Because the Final Rule became effective in January 2025, such actions should be implemented promptly. Recommended actions include but are not limited to:

1. Assessing and monitoring personnel requirements.

While the Final Rule generally includes a grandfathering clause for the changes to personnel qualification requirements, such grandfathering is limited to individuals who were in their role as of December 28, 2024, and maintain continuous employment. These grandfathered individuals should be monitored so that any lapse in employment is flagged. Additionally, hiring policies and job criteria should be updated to reflect the requirements summarized above.

2. Update policies and procedures.

As noted above, the Final Rule requires laboratory directors to now visit the lab in person at least once per six months with at least four months between such visits. These onsite visits should be planned and documented, including evidence of performing activities that are part of the lab director's responsibilities. These and other changes in the Final Rule necessitate various changes to existing procedures, and such changes should be reflected in written policies and procedures and communicated to relevant individuals to promote and maintain compliance with CLIA.

3. Budget for additional costs.

The Final Rule's changes to personnel requirements and proficiency testing for certain clinical lab personnel will necessitate several costs as a result of the necessary updates to policies and procedures, additional training requirements, and travel and implementation of increased lab director visits. Additionally, the Final Rule incorporates some increased fees and provides a pathway allowing for alternative sanctions rather than being limited to principal sanctions.

The resulting implementation costs from this Final Rule are contemplated to be borne by clinical labs, accrediting organizations, and states that are exempt from CLIA certification and are therefore obligated to ensure their programs implement the updated requirements. Additional costs could also emerge as certain clinical lab personnel are required to acquire further certification or education and seek to pass this cost on to their respective employing labs.

For guidance on implementing policy and procedure changes to ensure compliance with the above and other changes in the Final Rule, please contact Alissa Fleming, Tenia Clayton, Katherine Denney, or any member of the Baker Donelson Health Law team.