

HHS Adopts First Major Update to CLIA Personnel Rules Since 1992

On December 28, 2023, the Centers for Medicare and Medicaid Services (CMS) and the Centers for Disease Control and Prevention (CDC) published a final rule that includes the first significant revision of the CLIA personnel regulations since the CLIA '88 rules were adopted in 1992. The rule also revises the methodology for assessing CLIA fees and adds provisions allowing CMS to impose alternative sanctions on Certificate of Waiver laboratories. The long-awaited final rule follows CMS's 2018 Notice of Inquiry concerning prospective revisions to the CLIA personnel standards, which in turn was followed by a proposed rule issued in July 2022. AMT was among more than 20,500 organizations and individuals that submitted comments in response to the proposed rule.

The final rule is largely consistent with the July 2022 proposed rule, with one major exception. Following is a brief summary of some of the key provisions of the final rule from the perspective of AMT's membership:

BSN Route Nixed in Final Rule

CMS received over 19,750 comments from laboratory personnel groups (including AMT) and individual laboratorians opposing the agency's proposal to allow persons with a bachelor's degree in nursing (BSN) to perform high complexity testing. The July 2022 proposed rule already had acknowledged that a BSN is **not** equivalent to a degree in a biological or chemical science. But the agency had nevertheless proposed to create a separate route by which BSNs could perform high complexity testing – without any additional documented training.

In response to the overwhelming opposition, CMS determined **not** to finalize its proposal to qualify BSNs for high complexity testing. The agency agreed that the breadth and depth of science courses in a nursing curriculum is considerably less than those required for a B.S. in biology or chemistry. Nurses' education also lacks training in fundamental areas of laboratory science such as preanalytic, analytic and postanalytic phases of testing, calibration, quality control, and proficiency testing.

- Nurses can perform high complexity testing **only** if they have completed the requisite additional science coursework and clinical training to meet the equivalent of an associate degree in laboratory science or medical technology.
- Individuals with a nursing degree may still qualify as moderate complexity Testing Personnel, which covers most point-of-care testing, but cannot serve as Lab Directors or Technical Consultants in those settings.

Associate Degree (MLT) Route Added to TC Qualifications

Since the CLIA rules were first adopted in 1992, an anomaly has existed as to who is qualified to perform competency assessments (CA) on high complexity Testing Personnel (TP) and moderate complexity TP. The existing rules allow a General

Supervisor (GS) with an associate degree in medical technology (or equivalent) plus two years' clinical training or experience to perform CA on high complexity TP. However, for moderate complexity TP, the rules require that CA be performed by a Technical Consultant (TC) who has a minimum of a bachelor's degree in a biological or chemical science or laboratory science/technology. Accordingly, under current rules, most MLTs can assess competency of high complexity TP, but cannot perform CA on moderate complexity TP.

The final rule revisions add a route by which individuals with an associate degree in laboratory science or medical technology plus four years' clinical training and/or experience can qualify as TC in a moderate complexity setting. Thus, after the final rule takes effect in December 2024, most MLTs will be qualified to perform CA for both moderate and high complexity TP.

- The TC qualifications were further revised by adding a provision applicable to **blood gas analysis**. To qualify as TC for blood gas analysis, the individual must have a minimum of either a bachelor's degree in a biological or chemical science or in clinical/medical laboratory science or technology, or equivalent; **or** a bachelor's degree in respiratory therapy or cardiovascular pulmonology plus two years' lab training and/or experience in blood gas analysis. (The new associate degree route to qualify as TC does not apply to blood gas analysis.)

“Physical” Science Removed from Personnel Qualifications; Educational Algorithm Adopted for Non-traditional Degrees

CMS finalized its proposal to eliminate a degree in a “physical science” as a route to qualifying for various personnel classifications in nonwaived labs. Henceforth, CMS will recognize bachelor's degrees in a biological or chemical science, or in medical/clinical laboratory technology or science. Individuals who hold a bachelor's degree (or equivalent of 120 semester hours) in physical science or other non-traditional major must meet an “educational algorithm” to qualify for positions that require a minimum of a bachelor's degree.

- Persons who qualified for any position by virtue of a degree in a physical science or other henceforth non-qualifying degree (e.g., nursing) on the effective date of the final rule will be **grandfathered** – i.e., they won't have to satisfy the educational algorithm course requirements – so long as they are employed continuously from the effective date of the revised rules.

Military MLT Training Route Made Permanent for High Complexity TP

CMS finalized its proposal to make permanent the route by which military-trained MLTs can qualify to perform high complexity testing. Specifically, an individual will qualify to perform high complexity testing if they have achieved: “Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical

Laboratory Specialist (Laboratory Technician).” Previously, military-trained technicians qualified only if they had been grandfathered as of April 24, 1995.

New Nomenclature Acknowledged

CMS officially recognized the lab community’s efforts to adopt a uniform nomenclature for the profession. The agency explained: “Several commenters noted the 2022 decision by AMT, ASCP, and ASCLS to change the MT certification designation to MLS. The commenters suggested that medical laboratory science should be used in addition to clinical laboratory science throughout the CLIA personnel qualifications. We agree with the commenters that medical laboratory science should be included in the revised personnel qualifications. We are incorporating the change suggested by the commenters where applicable”

Effective Dates

The revised CLIA fee provisions take effect January 27, 2024. The revised personnel rules do not take effect until a year from the rule’s publication, *i.e.*, Dec. 28, 2024.