People. Trust. Results.
Since 1960

Changes for Lab Directors in the CMS Proposed Rule for 2023

In 1988, the Clinical Laboratory Improvement Amendments (CLIA) were passed to ensure high standards of quality, reliability, and timeliness of results for patient tests at all clinical labs. Over the years, updates have been made to these requirements to keep labs operating at the highest professional level possible.

The CMS made multiple changes in their 2023 proposed rule to the responsibilities and qualifications established by CLIA for lab directors. Although there has been some support for the general attempt to update the standards of CLIA regulations, stakeholders like the American Association for Clinical Chemistry (AACC) have concerns that the expansion of what qualifies someone to be a lab director are inadequate. Groups like the College of American Pathologists (CAP) have also pushed back on the unreasonable proposed change involving on-site visits to labs.

Personnel Qualifications

Since the introduction of CLIA regulations, there have always been aspects of being a lab manager that were allowed to be delegated and elements of the job that must be performed by the director themselves. In the past, direct oversight was required when:

- Ensuring testing systems in the lab provide quality service in every aspect of test performance
- Evaluating physical and environmental conditions of the lab
- Determining if the environment is safe for employees
- Reviewing new test procedures
- Making sure the responsibilities of every employee are specified in writing

Directors were able to delegate tasks if they were shared with a clinical consultant, including the following:

- Ensuring test reports include pertinent information for test interpretation
- Being available for consultation concerning test results and the interpretation of those results as they relate to specific patient conditions

In the proposed rule for 2023, the CMS plans to modify the regulations by implementing a qualification algorithm which makes it possible for people without scientific degrees to qualify for technical supervisions, testing personnel, and laboratory director roles. CMS also proposes adding nursing as a degree that qualifies someone as moderate and high complexity personnel. The AACC believes this is problematic, as it would exempt some personnel from needing important training before performing patient testing. The AACC suggests the following measures as necessary additional requirements to qualify nurses as moderate and high complexity testing personnel:

- Passing a curriculum of required laboratory specific continuing education (CE) courses; and/or
- Passing a competency exam (e.g., ASCP MLS, MLT or equivalent) for certifying staff to work in clinical laboratories as instrument operators and testing personnel

The AACC also strongly objects to the proposed change that allows for “professional doctorates” and those with a “master’s equivalency” to qualify for high complexity lab director positions, which currently require an MD or a board-certified PhD. Overall, the attempt to expand the criteria of these positions to include other qualified individuals is not inherently bad, but stakeholders would like to see a higher standard maintained in qualifying these individuals before they are given positions that require specialized knowledge.

Information provided by APS Medical Billing, October 2022

People. Trust. Results.
Since 1960

On-site Visit Requirements

The other major change the CMS proposes in their 2023 rule relates to how often lab directors are required to visit a lab in person. At this point, lab directors are only required to be on-site at least once every six months in the following states:

- Georgia
- Hawaii
- Maine
- Maryland
- Nevada
- New York
- Oklahoma
- Pennsylvania
- Rhode Island
- Tennessee
- Puerto Rico (Territory)

According to the proposed rule, every lab director would be required to visit each lab they are responsible for overseeing every six months, with at least a 4-month gap between visits. The CMS claims this proposal is inline with recommendations from the clinical laboratory improvement advisory committee (CLIAC). Evidence suggests that labs tend to have higher rates of citations for noncompliance when the lab director does not visit at least once every six months, hence the proposed requirement for semi-regular visits. The CMS will continue to require the lab director to be accessible to the lab via telephone or electronic communication as well.

The College of American Pathologists (CAP) and other advocates have pushed back against this requirement, suggesting that it may be unnecessary or unfairly burdensome for some lab directors, particularly those in rural areas who would have to travel great distances to visit each lab they oversee in person. Since this oversight cannot be delegated, there is no way for lab directors in rural locations to avoid driving very long distances and dedicating large amounts of time to these semi-annual visits.

Although the comment period has closed for this proposed rule, there is still time for stakeholders to react to the proposal — It will not officially be put into place until 2023. As always, APS will continue to monitor any updates on this proposal and advocate for our clients' best interest. If you have any questions as to how this might affect your business, please contact your Practice Manager.