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-25-21-CLIA

DATE: June 23, 2025

TO: State Survey Agency Directors

FROM: Director, Quality, Safety & Oversight Group (QSOG)

SUBJECT: Clinical Laboratory Improvement Amendment (CLIA) Enforcement Discretion and Clarification on Personnel Regulations

Memorandum Summary

- **Enforcement discretion of personnel regulations –** CMS will be exercising enforcement discretion in the following limited circumstances with respect to certain regulatory personnel qualification requirements and plans to address these changes in future notice-and-comment rulemaking:
  - CMS will allow laboratory directors qualifying under §493.1405(b)(2) to have either at least 1 year of experience directing or supervising nonwaived laboratory testing **or** 20 Continuing Education (CE) credit hours in laboratory director responsibilities.
  - CMS will not require the additional 20 CE credit hours currently required under §§493.1405(b)(3)(ii), 493.1405(b)(4)(iv), 493.1405(b)(5)(iv), 493.1443(b)(2)(iii), and 493.1443(b)(3)(iv).
    - As such, any individual previously qualified as a clinical consultant will be able to continue to qualify without taking an additional 20 CE credits;
  - CMS will allow for individuals qualified as technical supervisors under §493.1449(f)(2)(i) to qualify as high complexity laboratory directors for testing in dermatopathology.
- **Clarification of personnel regulations -** In addition, CMS is clarifying and plans to address in future notice-and-comment rulemaking that:
  - "[A]n approved thesis or research project related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings," as required under §§493.1405(b)(3)(i)(B)(2), 493.1405(b)(4)(i)(C)(2), 493.1443(b)(3)(i)(B)(2), and 493.1449(c)(4)(i)(C)(2) does not need to be on human subjects, as most research is performed on animal models.
  - The requirements under §493.1443(b)(3)(iii) for high complexity laboratory directors to require a total of two, not four, years of laboratory training or experience and laboratory experience directing or supervising high complexity testing.

Background:

Enforcement discretion of personnel regulations

The new personnel qualification regulations found in CMS-3326-F went into effect on December 28, 2024. Since the effective date, CMS has received stakeholder feedback that some of the new

personnel qualification regulations are burdensome and unclear. Based on the significant concerns raised by stakeholders, CMS will be exercising enforcement discretion in the following limited circumstances with respect to certain personnel qualification requirements and plans to address these changes in future notice-and-comment rulemaking:

- CMS will allow laboratory directors qualifying under §493.1405(b)(2) to have either at least 1 year of experience directing or supervising nonwaived laboratory testing "or" 20 CE credit hours in laboratory director responsibilities, rather than requiring both;
- CMS will not require the additional 20 CE credit hours currently required under §§ 493.1405(b)(3)(ii), 493.1405(b)(4)(iv), and 493.1405(b)(5)(iv), 493.1443(b)(2)(iii), and 493.1443(b)(3)(iv);
    - As such, any individual previously qualified as a clinical consultant will be able to continue to qualify without taking an additional 20 CE credits;
- CMS will allow for individuals qualified as technical supervisors at §493.1449(f)(2)(i) to qualify as a high complexity laboratory director for testing in dermatopathology; and

Clarification of personnel regulations
CMS is further clarifying and plans to address in future notice-and-comment rulemaking that "an approved thesis or research project related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings," as required under §§493.1405(b)(3)(i)(B)(2), 493.1405(b)(4)(i)(C)(2), 493.1443(b)(3)(i)(B)(2), and 493.1449(c)(4)(i)(C)(2) does not need to be on human subjects, as most research is performed on animal models. In addition, CMS would like to make clear that the requirements under §493.1443(b)(3)(iii) for high complexity laboratory directors to require a total of two, not four, years of laboratory training or experience and laboratory experience directing or supervising high complexity testing.

Discussion:
CMS received feedback from multiple stakeholder groups following the effective date of the new personnel qualification regulations finalized in CMS-3326-F. While CMS did receive comments on the proposed regulations, several of these stakeholders stated that they did not realize the impact the regulatory changes could have on their laboratories.

Depending on the unique circumstances of the stakeholder, the majority of the concerns centered around the laboratory director's requirements for additional experience or 20 CE credit hours under §493.1405 and §493.1443. The enforcement discretion outlined above provides time for CMS to address these stakeholder concerns through notice-and-comment rulemaking without undue burden to laboratories.

Contact:
For questions or concerns relating to this memorandum, please contact LabExcellence@cms.hhs.gov.

Effective Date:
Immediately. Please communicate to all appropriate staff within 30 days.

/s/
David R. Wright
Director, Quality, Safety & Oversight Group

Resources to Improve Quality of Care:

Check out CMS's new Quality in Focus interactive video series. The series of 10–15 minute videos are tailored to provider types and aim to reduce the deficiencies most commonly cited during the CMS survey process, like infection control and accident prevention. Reducing these common deficiencies increases the quality of care for people with Medicare and Medicaid. Learn to:

- *Understand surveyor evaluation criteria*
- *Recognize deficiencies*
- *Incorporate solutions into your facility's standards of care*

See the Quality, Safety, & Education Portal Training Catalog, and select Quality in Focus

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