

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Centers for Medicare & Medicaid Services

## Centers for Disease Control and Prevention

### 42 CFR Part 493

[CMS-2226-F]

RIN 0938-AK24

## Medicare, Medicaid, and CLIA Programs; Laboratory Requirements Relating to Quality Systems and Certain Personnel Qualifications

**AGENCY:** Centers for Disease Control and Prevention (CDC) and Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Final rule.

**SUMMARY:** This final rule revises and responds to comments on certain laboratory requirements issued pursuant to the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Pub. L. 100-578. Specifically, this final rule sets forth requirements for certain quality control (QC) provisions and personnel qualifications; consolidates and reorganizes the requirements for patient test management, QC, and quality assurance; and changes the consensus required for grading proficiency testing challenges.

To ensure a smooth transition to the new provisions for directors of high complexity testing who are not board certified (but who have doctoral degrees), we will not be holding facilities out of compliance with the provisions of the rule concerning directors who are not board certified until the effective date of this new rule, to the extent the facilities are otherwise in compliance with the requirements for laboratory directors.

**EFFECTIVE DATES:** This final rule is effective on April 24, 2003, except § 493.1443(b)(3) is effective on February 24, 2003.

**Compliance Dates:** To ensure a clear transition from the board certification provisions of the former rule at 42 CFR 493.1443(b)(2) that have a compliance date of December 31, 2002 (as set forth in 65 FR 82941), we will not be holding facilities out of compliance with the former rule until the effective date of the parallel provisions of this new rule to the extent that facilities are otherwise in compliance with the regulations for laboratory directors.

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### SUPPLEMENTARY INFORMATION:

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### I. Background

On February 28, 1992, we published a final rule with comment period in the **Federal Register** (57 FR 7002) that set forth the requirements for laboratories that are subject to the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

Under the provisions of the sentence following section 1861(s)(15) through 1861(s)(17) of the Social Security Act, (the Act) any laboratory that wants to be paid for services furnished to Medicare beneficiaries must meet the requirements of section 353 of the Public Health Services Act. Subject to specified exceptions, all laboratories, regardless of whether they receive payment from the Medicare or Medicaid programs must have a current and valid CLIA certificate to test human specimens. The February 28, 1992 final rule with comment period established uniform requirements based on the complexity of testing performed by laboratories regardless of the laboratory's location, size, or type. In the interest of public health, we included requirements in the February 28, 1992 final rule with comment period to ensure the quality of laboratory services.

We recognized that it would take time and resources for laboratories to understand and to implement the new requirements contained in the February 28, 1992 final rule with comment period. This final rule completes the

phase-in of certain requirements where the comments supported taking this action.

The phased-in provision included quality control (QC) requirements applicable to moderate complexity tests and the date by which an individual with a doctoral degree must possess board certification to qualify as a director of a laboratory that performs high complexity testing.

During the phase-in, the Food and Drug Administration (FDA) was to establish a process to review and clear manufacturers' QC instructions for CLIA QC purposes. Because the CLIA program is user fee funded, we decided it would be prudent to wait until the phase-in period ended before implementing the FDA QC review. This afforded us the survey experience necessary to determine whether an additional FDA review process beyond that already in place as part of the premarket review would be of benefit to laboratories. We realized through our experience inspecting laboratories that an additional FDA review would not be of such benefit. We decided to remove this prospective provision. Therefore, we are removing all references to the FDA CLIA QC clearance process that was not implemented.

The phase-in effective dates contained in the February 28, 1992 final rule with comment period were further extended in the final rules with comment period published on December 6, 1994 in the **Federal Register** (59 FR 62606), May 12, 1997 in the **Federal Register** (62 FR 25855), October 14, 1998 in the **Federal Register** (63 FR 55031), and December 29, 2000 in the **Federal Register** (65 FR 82941).

The extensions allowed previously unregulated laboratories time to understand and implement these requirements. The extensions also provided the Department of Health and Human Services (HHS) additional time to issue revised QC requirements, review board certification program requests for approval, and ensure that laboratory directors with a doctoral degree had sufficient time to successfully complete the requirements for board certification.

On December 28, 2001, we published a proposed rule in the **Federal Register** (66 FR 67163) seeking comments on provisions to revise and expand the qualification requirements by which an individual with a doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution may qualify to serve as a director of a laboratory performing high complexity testing. The