

survey agency to ensure that the laboratory makes the improvements necessary to bring it into compliance with the condition level requirements. (The State monitor does not have management authority, that is, cannot hire or fire staff, obligate funds, or otherwise dictate how the laboratory operates. The monitor's responsibility is to oversee whether corrections are made.)

(2) The laboratory must pay the costs of onsite monitoring by the State survey agency.

(i) The costs are computed by multiplying the number of hours of onsite monitoring in the laboratory by the hourly rate negotiated by HCFA and the State.

(ii) The hourly rate includes salary, fringe benefits, travel, and other direct and indirect costs approved by HCFA.

(b) *Procedures.* Before imposing this sanction, HCFA provides notice of sanction and opportunity to respond in accordance with § 493.1810.

(c) *Duration of sanction.* (1) If HCFA imposes onsite monitoring, the sanction continues until HCFA determines that the laboratory has the capability to ensure compliance with all condition level requirements.

(2) If the laboratory does not correct all deficiencies within 12 months, and a revisit indicates that deficiencies remain, HCFA cancels the laboratory's approval for Medicare payment for its services and notifies the laboratory of its intent to suspend, limit, or revoke the laboratory's certificate of compliance, registration certificate, certificate of accreditation, or certificate for PPM procedures.

(3) If the laboratory still does not correct its deficiencies, the Medicare sanction continues until the suspension, limitation, or revocation of the laboratory's certificate of compliance, registration certificate, certificate of accreditation, or certificate for PPM procedures is effective.

[57 FR 7237, Feb. 28, 1992, as amended at 60 FR 20051, Apr. 24, 1995]

**§ 493.1838 Training and technical assistance for unsuccessful participation in proficiency testing.**

If a laboratory's participation in proficiency testing is unsuccessful, HCFA may require the laboratory to under-

take training of its personnel, or to obtain necessary technical assistance, or both, in order to meet the requirements of the proficiency testing program. This requirement is separate from the principal and alternative sanctions set forth in §§ 493.1806 and 493.1807.

**§ 493.1840 Suspension, limitation, or revocation of any type of CLIA certificate.**

(a) *Adverse action based on actions of the laboratory's owner, operator or employees.* HCFA may initiate adverse action to suspend, limit or revoke any CLIA certificate if HCFA finds that a laboratory's owner or operator or one of its employees has—

(1) Been guilty of misrepresentation in obtaining a CLIA certificate;

(2) Performed, or represented the laboratory as entitled to perform, a laboratory examination or other procedure that is not within a category of laboratory examinations or other procedures authorized by its CLIA certificate;

(3) Failed to comply with the certificate requirements and performance standards;

(4) Failed to comply with reasonable requests by HCFA for any information or work on materials that HCFA concludes is necessary to determine the laboratory's continued eligibility for its CLIA certificate or continued compliance with performance standards set by HCFA;

(5) Refused a reasonable request by HCFA or its agent for permission to inspect the laboratory and its operation and pertinent records during the hours that the laboratory is in operation;

(6) Violated or aided and abetted in the violation of any provisions of CLIA and its implementing regulations;

(7) Failed to comply with an alternative sanction imposed under this subpart; or

(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked. (This provision applies only to the owner or operator, not to all of the laboratory's employees.)

(b) *Adverse action based on improper referrals in proficiency testing.* If HCFA determines that a laboratory has intentionally referred its proficiency testing samples to another laboratory for analysis, HCFA revokes the laboratory's CLIA certificate for at least one year, and may also impose a civil money penalty.

(c) *Adverse action based on exclusion from Medicare.* If the OIG excludes a laboratory from participation in Medicare, HCFA suspends the laboratory's CLIA certificate for the period during which the laboratory is excluded.

(d) *Procedures for suspension or limitation—(1) Basic rule.* Except as provided in paragraph (d)(2) of this section, HCFA does not suspend or limit a CLIA certificate until after an ALJ hearing decision (as provided in § 493.1844) that upholds suspension or limitation.

(2) *Exceptions.* HCFA may suspend or limit a CLIA certificate before the ALJ hearing in any of the following circumstances:

(i) The laboratory's deficiencies pose immediate jeopardy.

(ii) The laboratory has refused a reasonable request for information or work on materials.

(iii) The laboratory has refused permission for HCFA or a HCFA agent to inspect the laboratory or its operation.

(e) *Procedures for revocation.* (1) HCFA does not revoke any type of CLIA certificate until after an ALJ hearing that upholds revocation.

(2) HCFA may revoke a CLIA certificate after the hearing decision even if it had not previously suspended or limited that certificate.

(f) *Notice to the OIG.* HCFA notifies the OIG of any violations under paragraphs (a)(1), (a)(2), (a)(6), and (b) of this section within 30 days of the determination of the violation.

**§ 493.1842 Cancellation of Medicare approval.**

(a) *Basis for cancellation.* (1) HCFA always cancels a laboratory's approval to receive Medicare payment for its services if HCFA suspends or revokes the laboratory's CLIA certificate.

(2) HCFA may cancel the laboratory's approval under any of the following circumstances:

(i) The laboratory is out of compliance with a condition level requirement.

(ii) The laboratory fails to submit a plan of correction satisfactory to HCFA.

(iii) The laboratory fails to correct all its deficiencies within the time frames specified in the plan of correction.

(b) *Notice and opportunity to respond.* Before canceling a laboratory's approval to receive Medicare payment for its services, HCFA gives the laboratory—

(1) Written notice of the rationale for, effective date, and effect of, cancellation;

(2) Opportunity to submit written evidence or other information against cancellation of the laboratory's approval.

This sanction may be imposed before the hearing that may be requested by a laboratory, in accordance with the appeals procedures set forth in § 493.1844.

(c) *Effect of cancellation.* Cancellation of Medicare approval terminates any Medicare payment sanctions regardless of the time frames originally specified.

**§ 493.1844 Appeals procedures.**

(a) *General rules.* (1) The provisions of this section apply to all laboratories and prospective laboratories that are dissatisfied with any initial determination under paragraph (b) of this section.

(2) Hearings are conducted in accordance with procedures set forth in subpart D of part 498 of this chapter, except that the authority to conduct hearings and issue decisions may be exercised by ALJs assigned to, or detailed to, the Departmental Appeals Board.

(3) Any party dissatisfied with a hearing decision is entitled to request review of the decision as specified in subpart E of part 498 of this chapter, except that the authority to review the decision may be exercised by the Departmental Appeals Board.

(4) When more than one of the actions specified in paragraph (b) of this section are carried out concurrently, the laboratory has a right to only one hearing on all matters at issue.