

(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.

(b) *Actions that are initial determinations.* The following actions are initial determinations and therefore are subject to appeal in accordance with this section:

(1) The suspension, limitation, or revocation of the laboratory's CLIA certificate by HCFA because of non-compliance with CLIA requirements.

(2) The denial of a CLIA certificate.

(3) The imposition of alternative sanctions under this subpart (but not the determination as to which alternative sanction or sanctions to impose).

(4) The denial or cancellation of the laboratory's approval to receive Medicare payment for its services.

(c) *Actions that are not initial determinations.* Actions that are not listed in paragraph (b) of this section are not initial determinations and therefore are not subject to appeal under this section. They include, but are not necessarily limited to, the following:

(1) The finding that a laboratory accredited by a HCFA-approved accreditation organization is no longer deemed to meet the conditions set forth in subparts H, J, K, M, P, and Q of this part. However, the suspension, limitation or revocation of a certificate of accreditation is an initial determination and is appealable.

(2) The finding that a laboratory determined to be in compliance with condition-level requirements but has deficiencies that are not at the condition level.

(3) The determination not to reinstate a suspended CLIA certificate because the reason for the suspension has not been removed or there is insufficient assurance that the reason will not recur.

(4) The determination as to which alternative sanction or sanctions to impose, including the amount of a civil money penalty to impose per day or per violation.

(5) The denial of approval for Medicare payment for the services of a laboratory that does not have in effect a valid CLIA certificate.

(6) The determination that a laboratory's deficiencies pose immediate jeopardy.

(7) The amount of the civil money penalty assessed per day or for each violation of Federal requirements.

(d) *Effect of pending appeals—(1) Alternative sanctions.* The effective date of an alternative sanction (other than a civil money penalty) is not delayed because the laboratory has appealed and the hearing or the hearing decision is pending.

(2) *Suspension, limitation, or revocation of a laboratory's CLIA certificate—(i) General rule.* Except as provided in paragraph (d)(2)(ii) of this section, suspension, limitation, or revocation of a CLIA certificate is not effective until after a hearing decision by an ALJ is issued.

(ii) *Exceptions.* (A) If HCFA determines that conditions at a laboratory pose immediate jeopardy, the effective date of the suspension or limitation of a CLIA certificate is not delayed because the laboratory has appealed and the hearing or the hearing decision is pending.

(B) HCFA may suspend or limit a laboratory's CLIA certificate before an ALJ hearing or hearing decision if the laboratory has refused a reasonable request for information (including but not limited to billing information), or for work on materials, or has refused permission for HCFA or a HCFA agent to inspect the laboratory or its operation.

(3) *Cancellation of Medicare approval.* The effective date of the cancellation of a laboratory's approval to receive Medicare payment for its services is not delayed because the laboratory has appealed and the hearing or hearing decision is pending.

(4) *Effect of ALJ decision.* (i) An ALJ decision is final unless, as provided in paragraph (a)(3) of this section, one of the parties requests review by the Departmental Appeals Board within 60 days, and the Board reviews the case and issues a revised decision.

(ii) If an ALJ decision upholds a suspension imposed because of immediate jeopardy, that suspension becomes a revocation.

(e) *Appeal rights for prospective laboratories—(1) Reconsideration.* Any prospective laboratory dissatisfied with a denial of a CLIA certificate, or of approval for Medicare payment for its

services, may initiate the appeals process by requesting reconsideration in accordance with §§ 498.22 through 498.25 of this chapter.

(2) *Notice of reopening.* If HCFA reopens an initial or reconsidered determination, HCFA gives the prospective laboratory notice of the revised determination in accordance with § 498.32 of this chapter.

(3) *ALJ hearing.* Any prospective laboratory dissatisfied with a reconsidered determination under paragraph (e)(1) of this section or a revised reconsidered determination under § 498.30 of this chapter is entitled to a hearing before an ALJ, as specified in paragraph (a)(2) of this section.

(4) *Review of ALJ hearing decisions.* Any prospective laboratory that is dissatisfied with an ALJ's hearing decision or dismissal of a request for hearing may file a written request for review by the Departmental Appeals Board as provided in paragraph (a)(3) of this section.

(f) *Appeal rights of laboratories—(1) ALJ hearing.* Any laboratory dissatisfied with the suspension, limitation, or revocation of its CLIA certificate, with the imposition of an alternative sanction under this subpart, or with cancellation of the approval to receive Medicare payment for its services, is entitled to a hearing before an ALJ as specified in paragraph (a)(2) of this section and has 60 days from the notice of sanction to request a hearing.

(2) *Review of ALJ hearing decisions.* Any laboratory that is dissatisfied with an ALJ's hearing decision or dismissal of a request for hearing may file a written request for review by the Departmental Appeals Board, as provided in paragraph (a)(3) of this section.

(3) *Judicial review.* Any laboratory dissatisfied with the decision to impose a civil money penalty or to suspend, limit, or revoke its CLIA certificate may, within 60 days after the decision becomes final, file with the U.S. Court of Appeals of the circuit in which the laboratory has its principal place of business, a petition for judicial review.

(g) *Notice of adverse action.* (1) If HCFA suspends, limits, or revokes a laboratory's CLIA certificate or cancels the approval to receive Medicare payment for its services, HCFA gives

notice to the laboratory, and may give notice to physicians, providers, suppliers, and other laboratory clients, according to the procedures set forth at § 493.1832. In addition, HCFA notifies the general public each time one of these principal sanctions is imposed.

(2) The notice to the laboratory—

(i) Sets forth the reasons for the adverse action, the effective date and effect of that action, and the appeal rights if any; and

(ii) When the certificate is limited, specifies the specialties or subspecialties of tests that the laboratory is no longer authorized to perform, and that are no longer covered under Medicare.

(3) The notice to other entities includes the same information except the information about the laboratory's appeal rights.

(h) *Effective date of adverse action.* (1) When the laboratory's deficiencies pose immediate jeopardy, the effective date of the adverse action is at least 5 days after the date of the notice.

(2) When HCFA determines that the laboratory's deficiencies do not pose immediate jeopardy, the effective date of the adverse action is at least 15 days after the date of the notice.

[57 FR 7237, Feb. 28, 1992; 57 FR 35761, Aug. 11, 1992]

**§ 493.1846 Civil action.**

If HCFA has reason to believe that continuation of the activities of any laboratory, including a State-exempt laboratory, would constitute a significant hazard to the public health, HCFA may bring suit in a U.S. District Court to enjoin continuation of the specific activity that is causing the hazard or to enjoin the continued operation of the laboratory if HCFA deems it necessary. Upon proper showing, the court shall issue a temporary injunction or restraining order without bond against continuation of the activity.

**§ 493.1850 Laboratory registry.**

(a) Once a year HCFA makes available to physicians and to the general public specific information (including information provided to HCFA by the OIG) that is useful in evaluating the performance of laboratories, including the following: