

specialties or subspecialties that are authorized by the laboratory's limited certificate.

**§ 493.1809 Limitation on Medicaid payment.**

As provided in section 1902(a)(9)(C) of the Act, payment for laboratory services may be made under the State plan only if those services are furnished by a laboratory that has a CLIA certificate or is licensed by a State whose licensure program has been approved by the Secretary under this part.

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

**§ 493.1810 Imposition and lifting of alternative sanctions.**

(a) *Notice of noncompliance and of proposed sanction: Content.* If HCFA or its agency identifies condition level noncompliance in a laboratory, HCFA or its agent gives the laboratory written notice of the following:

- (1) The condition level noncompliance that it has identified.
- (2) The sanction or sanctions that HCFA or its agent proposes to impose against the laboratory.
- (3) The rationale for the proposed sanction or sanctions.
- (4) The projected effective date and duration of the proposed sanction or sanctions.
- (5) The authority for the proposed sanction or sanctions.
- (6) The time allowed (at least 10 days) for the laboratory to respond to the notice.

(b) *Opportunity to respond.* During the period specified in paragraph (a)(6) of this section, the laboratory may submit to HCFA or its agent written evidence or other information against the imposition of the proposed sanction or sanctions.

(c) *Notice of imposition of sanction—(1) Content.* HCFA gives the laboratory written notice that acknowledges any evidence or information received from the laboratory and specifies the following:

- (i) The sanction or sanctions to be imposed against the laboratory.
- (ii) The authority and rationale for the imposing sanction or sanctions.
- (iii) The effective date and duration of sanction.

(2) *Timing.* (i) If HCFA or its agent determines that the deficiencies pose immediate jeopardy, HCFA provides notice at least 5 days before the effective date of sanction.

(ii) If HCFA or its agent determines that the deficiencies do not pose immediate jeopardy, HCFA provides notice at least 15 days before the effective date of the sanction.

(d) *Duration of alternative sanctions.* An alternative sanction continues until the earlier of the following occurs:

(1) The laboratory corrects all condition level deficiencies.

(2) HCFA's suspension, limitation, or revocation of the laboratory's CLIA certificate becomes effective.

(e) *Lifting of alternative sanctions—(1) General rule.* Alternative sanctions are not lifted until a laboratory's compliance with all condition level requirements is verified.

(2) *Credible allegation of compliance.* When a sanctioned laboratory submits a credible allegation of compliance, HCFA's agent determines whether—

- (i) It can certify compliance on the basis of the evidence presented by the laboratory in its allegation; or
- (ii) It must revisit to verify whether the laboratory has, in fact, achieved compliance.

(3) *Compliance achieved before the date of revisit.* If during a revisit, the laboratory presents credible evidence (as determined by HCFA or its agent) that it achieved compliance before the date of revisit, sanctions are lifted as of that earlier date.

**§ 493.1812 Action when deficiencies pose immediate jeopardy.**

If a laboratory's deficiencies pose immediate jeopardy, the following rules apply:

(a) HCFA requires the laboratory to take immediate action to remove the jeopardy and may impose one or more alternative sanctions to help bring the laboratory into compliance.

(b) If the findings of a revisit indicate that a laboratory has not eliminated the jeopardy, HCFA suspends or limits the laboratory's CLIA certificate no earlier than 5 days after the date of notice of suspension or limitation. HCFA may later revoke the certificate.