

§ 493.1812

42 CFR Ch. IV (10-1-06 Edition)

agent gives the laboratory written notice of the following:

- (1) The condition level noncompliance that it has identified.
- (2) The sanction or sanctions that CMS 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 CMS 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.* CMS 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 CMS or its agent determines that the deficiencies pose immediate jeopardy, CMS provides notice at least 5 days before the effective date of sanction.

(ii) If CMS or its agent determines that the deficiencies do not pose immediate jeopardy, CMS 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) CMS'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 compli-

ance with all condition level requirements is verified.

(2) *Credible allegation of compliance.* When a sanctioned laboratory submits a credible allegation of compliance, CMS'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 CMS 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) CMS 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, CMS suspends or limits the laboratory's CLIA certificate no earlier than 5 days after the date of notice of suspension or limitation. CMS may later revoke the certificate.

(c) In addition, if CMS has reason to believe that the continuation of any activity by any laboratory (either the entire laboratory operation or any specialty or subspecialty of testing) would constitute a significant hazard to the public health, CMS may bring suit and seek a temporary injunction or restraining order against continuation of that activity by the laboratory, regardless of the type of CLIA certificate the laboratory has and of whether it is State-exempt.

**§ 493.1814 Action when deficiencies are at the condition level but do not pose immediate jeopardy.**

If a laboratory has condition level deficiencies that do not pose immediate jeopardy, the following rules apply:

(a) *Initial action.* (1) CMS may cancel the laboratory's approval to receive Medicare payment for its services.

(2) CMS may suspend, limit, or revoke the laboratory's CLIA certificate.

(3) If CMS does not impose a principal sanction under paragraph (a)(1) or (a)(2) of this section, it imposes one or more alternative sanctions. In the case of unsuccessful participation in proficiency testing, CMS may impose the training and technical assistance requirement set forth at § 493.1838 in lieu of, or in addition to, one or more alternative sanctions.

(b) *Failure to correct condition level deficiencies.* If CMS imposes alternative sanctions for condition level deficiencies that do not pose immediate jeopardy, and the laboratory does not correct the condition level deficiencies within 12 months after the last day of inspection, CMS—

(1) Cancels the laboratory's approval to receive Medicare payment for its services, and discontinues the Medicare payment sanctions as of the day cancellation is effective.

(2) Following a revisit which indicates that the laboratory has not corrected its condition level deficiencies, notifies the laboratory that it proposes to suspend, limit, or revoke the certificate, as specified in § 493.1816(b), and the laboratory's right to hearing; and

(3) May impose (or continue, if already imposed) any alternative sanctions that do not pertain to Medicare payments. (Sanctions imposed under the authority of section 353 of the PHS Act may continue for more than 12 months from the last date of inspection, while a hearing on the proposed suspension, limitation, or revocation of the certificate of compliance, registration certificate, certificate of accreditation, or certificate for PPM procedures is pending.)

(c) *Action after hearing.* If a hearing decision upholds a proposed suspension, limitation, or revocation of a laboratory's CLIA certificate, CMS discontinues any alternative sanctions as of the day it makes the suspension, limitation, or revocation effective.

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

#### § 493.1816 Action when deficiencies are not at the condition level.

If a laboratory has deficiencies, that are not at the condition level, the following rules apply:

(a) *Initial action.* The laboratory must submit a plan of correction that is acceptable to CMS in content and time frames.

(b) *Failure to correct deficiencies.* If, on revisit, it is found that the laboratory has not corrected the deficiencies within 12 months after the last day of inspection, the following rules apply:

(1) CMS cancels the laboratory's approval to receive Medicare payment for its services.

(2) CMS notifies the laboratory of its intent to suspend, limit, or revoke the laboratory's CLIA certificate and of the laboratory's right to a hearing.

#### § 493.1820 Ensuring timely correction of deficiencies.

(a) *Timing of visits.* CMS, the State survey agency or other CMS agent may visit the laboratory at any time to evaluate progress, and at the end of the period to determine whether all corrections have been made.

(b) *Deficiencies corrected before a visit.* If during a visit, a laboratory produces credible evidence that it achieved compliance before the visit, the sanctions are lifted as of that earlier date.

(c) *Failure to correct deficiencies.* If during a visit it is found that the laboratory has not corrected its deficiencies, CMS may propose to suspend, limit, or revoke the laboratory's CLIA certificate.

(d) *Additional time for correcting lower level deficiencies not at the condition level.* If at the end of the plan of correction period all condition level deficiencies have been corrected, and there are deficiencies, that are not at the condition level, CMS may request a revised plan of correction. The revised plan may not extend beyond 12 months from the last day of the inspection that originally identified the cited deficiencies.

(e) *Persistence of deficiencies.* If at the end of the period covered by the plan of correction, the laboratory still has deficiencies, the rules of §§ 493.1814 and 493.1816 apply.