

**§ 493.1814**

**42 CFR Ch. IV (10-1-99 Edition)**

(c) In addition, if HCFA 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, HCFA 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) HCFA may cancel the laboratory's approval to receive Medicare payment for its services.

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

(3) If HCFA 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, HCFA 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 HCFA 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, HCFA—

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

(2) HCFA 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.* HCFA, the State survey agency or other HCFA 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.