

§ 493.1800 Basis and scope.

(a) *Statutory basis.* (1) Section 1846 of the Act—

(i) Provides for intermediate sanctions that may be imposed on laboratories that perform clinical diagnostic tests on human specimens when those laboratories are found to be out of compliance with one or more of the conditions for Medicare coverage of their services; and

(ii) Requires the Secretary to develop and implement a range of such sanctions, including four that are specified in the statute.

(2) The Clinical Laboratories Improvement Act of 1967 (section 353 of the Public Health Service Act) as amended by CLIA '88—

(i) Establishes requirements for all laboratories that perform clinical diagnostic tests on human specimens;

(ii) Requires a Federal certification scheme to be applied to all such laboratories; and

(iii) Grants the Secretary broad enforcement authority, including—

(A) Use of intermediate sanctions;

(B) Suspension, limitation, or revocation of the certificate of a laboratory that is out of compliance with one or more requirements for a certificate; and

(C) Civil suit to enjoin any laboratory activity that constitutes a significant hazard to the public health.

(3) Section 353 also—

(i) Provides for imprisonment or fine for any person convicted of intentional violation of CLIA requirements;

(ii) Specifies the administrative hearing and judicial review rights of a laboratory that is sanctioned under CLIA; and

(iii) Requires the Secretary to publish annually a list of all laboratories that have been sanctioned during the preceding year.

(b) *Scope and applicability.* This subpart sets forth—

(1) The policies and procedures that HCFA follows to enforce the requirements applicable to laboratories under CLIA and under section 1846 of the Act; and

(2) The appeal rights of laboratories on which HCFA imposes sanctions.

§ 493.1804 General considerations.

(a) *Purpose.* The enforcement mechanisms set forth in this subpart have the following purposes:

(1) To protect all individuals served by laboratories against substandard testing of specimens.

(2) To safeguard the general public against health and safety hazards that might result from laboratory activities.

(3) To motivate laboratories to comply with CLIA requirements so that they can provide accurate and reliable test results.

(b) *Basis for decision to impose sanctions.* (1) HCFA's decision to impose sanctions is based on one or more of the following:

(i) Deficiencies found by HCFA or its agents in the conduct of inspections to certify or validate compliance with Federal requirements, or through review of materials submitted by the laboratory (e.g., personnel qualifications).

(ii) Unsuccessful participation in proficiency testing.

(2) HCFA imposes one or more of the alternative or principal sanctions specified in §§ 493.1806 and 493.1807 when HCFA or HCFA's agent finds that a laboratory has condition-level deficiencies.

(c) *Imposition of alternative sanctions.*

(1) HCFA may impose alternative sanctions in lieu of, or in addition to principal sanctions, (HCFA does not impose alternative sanctions on laboratories that have certificates of waiver because those laboratories are not inspected for compliance with condition-level requirements.)

(2) HCFA may impose alternative sanctions other than a civil money penalty after the laboratory has had an opportunity to respond, but before the hearing specified in § 493.1844.

(d) *Choice of sanction: Factors considered.* HCFA bases its choice of sanction or sanctions on consideration of one or more factors that include, but are not limited to, the following, as assessed by the State or by HCFA, or its agents:

(1) Whether the deficiencies pose immediate jeopardy.

(2) The nature, incidence, severity, and duration of the deficiencies or non-compliance.

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(3) Whether the same condition level deficiencies have been identified repeatedly.

(4) The accuracy and extent of laboratory records (e.g., of remedial action) in regard to the noncompliance, and their availability to the State, to other HCFA agents, and to HCFA.

(5) The relationship of one deficiency or group of deficiencies to other deficiencies.

(6) The overall compliance history of the laboratory including but not limited to any period of noncompliance that occurred between certifications of compliance.

(7) The corrective and long-term compliance outcomes that HCFA hopes to achieve through application of the sanction.

(8) Whether the laboratory has made any progress toward improvement following a reasonable opportunity to correct deficiencies.

(9) Any recommendation by the State agency as to which sanction would be appropriate.

(e) *Number of alternative sanctions.* HCFA may impose a separate sanction for each condition level deficiency or a single sanction for all condition level deficiencies that are interrelated and subject to correction by a single course of action.

(f) *Appeal rights.* The appeal rights of laboratories dissatisfied with the imposition of a sanction are set forth in § 493.1844.

[57 FR 7237, Feb. 28, 1992; 57 FR 35761, Aug. 11, 1992, as amended at 60 FR 20051, Apr. 24, 1995]

§ 493.1806 Available sanctions: All laboratories.

(a) *Applicability.* HCFA may impose one or more of the sanctions specified in this section on a laboratory that is out of compliance with one or more CLIA conditions.

(b) *Principal sanction.* HCFA may impose any of the three principal CLIA sanctions, which are suspension, limitation, or revocation of any type of CLIA certificate.

(c) *Alternative sanctions.* HCFA may impose one or more of the following alternative sanctions in lieu of or in addition to imposing a principal sanction, except on a laboratory that has a certificate of waiver.

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(1) Directed plan of correction, as set forth at § 493.1832.

(2) State onsite monitoring as set forth at § 493.1836.

(3) Civil money penalty, as set forth at § 493.1834.

(d) *Civil suit.* HCFA may bring suit in the appropriate U.S. District Court to enjoin continuation of any activity of any laboratory (including a CLIA-exempt laboratory that has been found with deficiencies during a validation survey), if HCFA has reason to believe that continuation of the activity would constitute a significant hazard to the public health.

(e) *Criminal sanctions.* Under section 353(1) of the PHS Act, an individual who is convicted of intentionally violating any CLIA requirement may be imprisoned or fined.

[57 FR 7237, Feb. 28, 1992, as amended at 58 FR 5237, Jan. 19, 1993]

§ 493.1807 Additional sanctions: Laboratories that participate in Medicare.

The following additional sanctions are available for laboratories that are out of compliance with one or more CLIA conditions and that have approval to receive Medicare payment for their services.

(a) *Principal sanction.* Cancellation of the laboratory's approval to receive Medicare payment for its services.

(b) *Alternative sanctions.* (1) Suspension of payment for tests in one or more specific specialties or subspecialties, performed on or after the effective date of sanction.

(2) Suspension of payment for all tests in all specialties and subspecialties performed on or after the effective date of sanction.

§ 493.1808 Adverse action on any type of CLIA certificate: Effect on Medicare approval.

(a) *Suspension or revocation of any type of CLIA certificate.* When HCFA suspends or revokes any type of CLIA certificate, HCFA concurrently cancels the laboratory's approval to receive Medicare payment for its services.

(b) *Limitation of any type of CLIA certificate.* When HCFA limits any type of CLIA certificate, HCFA concurrently limits Medicare approval to only those