Centers for Medicare & Medicaid Services, HHS

§ 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 imprison 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 CMS 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 CMS 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) CMS’s decision to impose sanctions is based on one or more of the following:

(i) Deficiencies found by CMS 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) CMS imposes one or more of the alternative or principal sanctions specified in §§ 493.1806 and 493.1807 when CMS or CMS’s agent finds that a laboratory has condition-level deficiencies.

(c) Imposition of alternative sanctions. (1) CMS may impose alternative sanctions in lieu of, or in addition to principal sanctions, (CMS 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) CMS 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. CMS 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 CMS, or its agents:

(1) Whether the deficiencies pose immediate jeopardy.

(2) The nature, incidence, severity, and duration of the deficiencies or noncompliance.

(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 CMS agents, and to CMS.

(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 CMS 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. CMS 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.

§ 493.1806 Available sanctions: All laboratories.

(a) Applicability. CMS 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. CMS may impose any of the three principal CLIA sanctions, which are suspension, limitation, or revocation of any type of CLIA certificate.

(c) Alternative sanctions. CMS 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:

(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. CMS 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 CMS 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.

§ 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 CMS suspends or revokes any type of CLIA certificate, CMS concurrently cancels the laboratory’s approval to receive Medicare payment for its services.

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

§ 493.1810 Imposition and lifting of alternative sanctions.

(a) Notice of noncompliance and of proposed sanction: Content. If CMS or its agency identifies condition level noncompliance in a laboratory, CMS 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 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.

(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
§ 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 sub specialty 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.

(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 7227, 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 and of the laboratory’s right to a hearing.

§ 493.1826 Suspension of part of Medicare payments.

(a) Application. (1) CMS may impose this sanction if a laboratory—

(i) Is found to have condition level deficiencies with respect to one or more specialties or subspecialties of tests; and

(ii) Agrees (in return for not having its Medicare approval cancelled immediately) not to charge Medicare beneficiaries or their private insurance carriers for the services for which Medicare payment is suspended.

(2) CMS suspends Medicare payment for those specialties or subspecialties of tests for which the laboratory is out of compliance with Federal requirements.

(b) Procedures. Before imposing this sanction, CMS provides notice of sanction and opportunity to respond in accordance with § 493.1810.

(c) Duration and effect of sanction. This sanction continues until the laboratory corrects the condition level deficiencies or CMS cancels the laboratory’s approval to receive Medicare payment for its services, but in no event longer than 12 months.

(1) If the laboratory corrects all condition level deficiencies, CMS resumes Medicare payment effective for all services furnished on or after the date the deficiencies are corrected.

(2) [Reserved]

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

§ 493.1828 Suspension of all Medicare payments.

(a) Application. (1) CMS may suspend payment for all Medicare-approved laboratory services when the laboratory has condition level deficiencies.

(2) CMS suspends payment for all Medicare covered laboratory services when the following conditions are met:

(i) Either—

(A) The laboratory has not corrected its condition level deficiencies included in the plan of correction within 3 months from the last date of inspection; or

(B) The laboratory has been found to have the same condition level deficiencies during three consecutive inspections; and

§ 493.1826 Suspension of part of Medicare payments.

(a) Application. (1) CMS may impose this sanction if a laboratory—

(i) Is found to have condition level deficiencies with respect to one or more specialties or subspecialties of tests; and

(ii) Agrees (in return for not having its Medicare approval cancelled immediately) not to charge Medicare beneficiaries or their private insurance carriers for the services for which Medicare payment is suspended.

(2) CMS suspends Medicare payment for those specialties or subspecialties of tests for which the laboratory is out of compliance with Federal requirements.

(b) Procedures. Before imposing this sanction, CMS provides notice of sanction and opportunity to respond in accordance with § 493.1810.

(c) Duration and effect of sanction. This sanction continues until the laboratory corrects the condition level deficiencies or CMS cancels the laboratory’s approval to receive Medicare payment for its services, but in no event longer than 12 months.

(1) If the laboratory corrects all condition level deficiencies, CMS resumes Medicare payment effective for all services furnished on or after the date the deficiencies are corrected.

(2) [Reserved]

[57 FR 7237, Feb. 28, 1992; 57 FR 35761, Aug. 11, 1992]
(ii) The laboratory has chosen (in return for not having its Medicare approval immediately cancelled), to not charge Medicare beneficiaries or their private insurance carriers for services for which Medicare payment is suspended.

(3) CMS suspends payment for services furnished on and after the effective date of sanction.

(b) Procedures. Before imposing this sanction, CMS provides notice of sanction and opportunity to respond in accordance with §493.1810.

(c) Duration and effect of sanction. (1) Suspension of payment continues until all condition level deficiencies are corrected, but never beyond twelve months.

(2) If all the deficiencies are not corrected by the end of the 12 month period, CMS cancels the laboratory’s approval to receive Medicare payment for its services.

§ 493.1832 Directed plan of correction and directed portion of a plan of correction.

(a) Application. CMS may impose a directed plan of correction as an alternative sanction for any laboratory that has condition level deficiencies. If CMS does not impose a directed plan of correction as an alternative sanction for a laboratory that has condition level deficiencies, it at least imposes a directed portion of a plan of correction when it imposes any of the following alternative sanctions:

(1) State onsite monitoring.

(2) Civil money penalty.

(3) Suspension of all or part of Medicare payments.

(b) Procedures—(1) Directed plan of correction. When imposing this sanction, CMS—

(i) Gives the laboratory prior notice of the sanction and opportunity to respond in accordance with §493.1810;

(ii) Directs the laboratory to take specific corrective action within specific time frames in order to achieve compliance; and

(iii) May direct the laboratory to submit the names of laboratory clients for notification purposes, as specified in paragraph (b)(3) of this section.

(2) Directed portion of a plan of correction. CMS may decide to notify clients of a sanctioned laboratory, because of the seriousness of the noncompliance (e.g., the existence of immediate jeopardy) or for other reasons. When imposing this sanction, CMS takes the following steps—

(i) Directs the laboratory to submit to CMS, the State survey agency, or other CMS agent, within 10 calendar days after the notice of the alternative sanction, a list of names and addresses of all physicians, providers, suppliers, and other clients who have used some or all of the services of the laboratory since the last certification inspection or within any other timeframe specified by CMS.

(ii) Within 30 calendar days of receipt of the information, may send to each laboratory client, via the State survey agency, a notice containing the name and address of the laboratory, the nature of the laboratory’s noncompliance, and the kind and effective date of the alternative sanction.

(iii) Sends to each laboratory client, via the State survey agency, notice of the recission of an adverse action within 30 days of the rescission.

(3) Notice of imposition of a principal sanction following the imposition of an alternative sanction. If CMS imposes a principal sanction following the imposition of an alternative sanction, and for which CMS has already obtained a list of laboratory clients, CMS may use that list to notify the clients of the imposition of the principal sanction.

(c) Duration of a directed plan of correction. If CMS imposes a directed plan of correction, and on revisit it is found that the laboratory has not corrected the deficiencies within 12 months from the last day of inspection, the following rules apply:

(1) CMS cancels the laboratory’s approval for Medicare payment of its services, and notifies the laboratory of CMS’s intent to suspend, limit, or revoke the laboratory’s CLIA certificate.

(2) The directed plan of correction continues in effect until the day suspension, limitation, or revocation of the laboratory’s CLIA certificate.

§ 493.1834 Civil money penalty.

(a) Statutory basis. Sections 1846 of the Act and 353(h)(2)(B) of the PHS Act authorize the Secretary to impose civil
money penalties on laboratories. Section 1846(b)(3) of the Act specifically provides that incrementally more severe fines may be imposed for repeated or uncorrected deficiencies.

(b) Scope. This section sets forth the procedures that CMS follows to impose a civil money penalty in lieu of, or in addition to, suspending, limiting, or revoking the certificate of compliance, registration certificate, certificate of accreditation, or certificate for PPM procedures of a laboratory that is found to have condition level deficiencies.

(c) Basis for imposing a civil money penalty. CMS may impose a civil money penalty against any laboratory determined to have condition level deficiencies regardless of whether those deficiencies pose immediate jeopardy.

(d) Amount of penalty. (1) Factors considered. In determining the amount of the penalty, CMS takes into account the following factors:
  (i) The nature, scope, severity, and duration of the noncompliance.
  (ii) Whether the same condition level deficiencies have been identified during three consecutive inspections.
  (iii) The laboratory's overall compliance history including but not limited to any period of noncompliance that occurred between certifications of compliance.
  (iv) The laboratory's intent or reason for noncompliance.
  (v) The accuracy and extent of laboratory records and their availability to CMS, the State survey agency, or other CMS agent.

(2) Range of penalty amount. (i) For a condition level deficiency that poses immediate jeopardy, the range is $3,050–$10,000 per day of noncompliance or per violation.
  (ii) For a condition level deficiency that does not pose immediate jeopardy, the range is $50–$3,000 per day of noncompliance or per violation.

(3) Decreased penalty amounts. If the immediate jeopardy is removed, but the deficiency continues, CMS shifts the penalty amount to the lower range.

(4) Increased penalty amounts. CMS may, before the hearing, propose to increase the penalty amount for a laboratory that has deficiencies which, after imposition of a lower level penalty amount, become sufficiently serious to pose immediate jeopardy.

(e) Procedures for imposition of civil money penalty—(1) Notice of intent. (i) CMS sends the laboratory written notice, of CMS's intent to impose a civil money penalty.
  (ii) The notice includes the following information:
    (A) The statutory basis for the penalty.
    (B) The proposed daily or per violation amount of the penalty.
    (C) The factors (as described in paragraph (d)(1) of this section) that CMS considered.
    (D) The opportunity for responding to the notice in accordance with §493.1810(c).
    (E) A specific statement regarding the laboratory’s appeal rights.

(2) Appeal rights. (i) The laboratory has 60 days from the date of receipt of the notice of intent to impose a civil money penalty to request a hearing in accordance with §493.1844(g).
  (ii) If the laboratory requests a hearing, all other pertinent provisions of §493.1844 apply.
  (iii) If the laboratory does not request a hearing, CMS may reduce the proposed penalty amount by 35 percent.

(f) Accrual and duration of penalty—(1) Accrual of penalty. The civil money penalty begins accruing as follows:
  (i) 5 days after notice of intent if there is immediate jeopardy.
  (ii) 15 days after notice of intent if there is not immediate jeopardy.

(2) Duration of penalty. The civil money penalty continues to accrue until the earliest of the following occurs:
  (i) The laboratory’s compliance with condition level requirements is verified on the basis of the evidence presented by the laboratory in its credible allegation of compliance or at the time or revisit.
  (ii) Based on credible evidence presented by the laboratory at the time of revisit, CMS determines that compliance was achieved before the revisit. (In this situation, the money penalty stops accruing as of the date of compliance.)
§ 493.1836 State onsite monitoring.

(a) Application. (1) CMS may require continuous or intermittent monitoring of a plan of correction by the State survey agency to ensure that the laboratory makes the improvements necessary to bring it into compliance with the condition level requirements. (The State monitor does not have management authority, that is, cannot hire or fire staff, obligate funds, or otherwise dictate how the laboratory operates. The monitor’s responsibility is to oversee whether corrections are made.)

(2) The laboratory must pay the costs of onsite monitoring by the State survey agency.

(i) The costs are computed by multiplying the number of hours of onsite monitoring in the laboratory by the hourly rate negotiated by CMS and the State.

(ii) The hourly rate includes salary, fringe benefits, travel, and other direct and indirect costs approved by CMS.

(b) Procedures. Before imposing this sanction, CMS provides notice of sanction and opportunity to respond in accordance with § 493.1810.

(c) Duration of sanction. (1) If CMS imposes onsite monitoring, the sanction continues until CMS determines that the laboratory has the capability to ensure compliance with all condition level requirements.

(2) If the laboratory does not correct all deficiencies within 12 months, and a revisit indicates that deficiencies remain, CMS cancels the laboratory’s approval for Medicare payment for its services and notifies the laboratory of its intent to suspend, limit, or revoke the laboratory’s certificate of compliance, registration certificate, certificate of accreditation, or certificate for PPM procedures.

(3) If the laboratory still does not correct its deficiencies, the Medicare sanction continues until the suspension, limitation, or revocation of the laboratory’s certificate of compliance, registration certificate, certificate of accreditation, or certificate for PPM procedures is effective.
§ 493.1838 Training and technical assistance for unsuccessful participation in proficiency testing.

If a laboratory’s participation in proficiency testing is unsuccessful, CMS may require the laboratory to undertake training of its personnel, or to obtain necessary technical assistance, or both, in order to meet the requirements of the proficiency testing program. This requirement is separate from the principal and alternative sanctions set forth in §§ 493.1806 and 493.1807.

§ 493.1840 Suspension, limitation, or revocation of any type of CLIA certificate.

(a) Adverse action based on actions of the laboratory’s owner, operator or employees. CMS may initiate adverse action to suspend, limit or revoke any CLIA certificate if CMS finds that a laboratory’s owner or operator or one of its employees has—

(1) Been guilty of misrepresentation in obtaining a CLIA certificate;
(2) Performed, or represented the laboratory as entitled to perform, a laboratory examination or other procedure that is not within a category of laboratory examinations or other procedures authorized by its CLIA certificate;
(3) Failed to comply with the certificate requirements and performance standards;
(4) Failed to comply with reasonable requests by CMS for any information or work on materials that CMS concludes is necessary to determine the laboratory’s continued eligibility for its CLIA certificate or continued compliance with performance standards set by CMS;
(5) Refused a reasonable request by CMS or its agent for permission to inspect the laboratory and its operation and pertinent records during the hours that the laboratory is in operation;
(6) Violated or aided and abetted in the violation of any provisions of CLIA and its implementing regulations;
(7) Failed to comply with an alternative sanction imposed under this subpart; or
(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked.

(b) Adverse action based on improper referrals in proficiency testing. If CMS determines that a laboratory has intentionally referred its proficiency testing samples to another laboratory for analysis, CMS 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, CMS 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, CMS 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. CMS 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 CMS or a CMS agent to inspect the laboratory or its operation.

(e) Procedures for revocation. (1) CMS does not revoke any type of CLIA certificate until after an ALJ hearing that upholds revocation.

(2) CMS 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. CMS 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) CMS always cancels a laboratory’s approval to receive Medicare payment for its services if CMS suspends or revokes the laboratory’s CLIA certificate.
§ 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 subject to appeal in accordance with this section:

(1) The suspension, limitation, or revocation of the laboratory’s CLIA certificate by CMS because of noncompliance 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 CMS-approved accreditation organization is no longer deemed to meet the conditions set forth in subparts H, J, K, M, 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 CMS 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) CMS 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 CMS or a CMS 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 the 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 CMS reopen an initial or reconsidered determination, CMS 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 CMS suspends, limits, or revokes a laboratory’s CLIA certificate or cancels the approval to receive Medicare payment for its services, CMS gives notice to the laboratory, and may give notice to
§ 493.1846  
physicians, providers, suppliers, and other laboratory clients, according to the procedures set forth at §493.1832. In addition, CMS 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 CMS 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.


§ 493.1846  Civil action.

If CMS 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, CMS 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 CMS 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 CMS makes available to physicians and to the general public specific information (including information provided to CMS by the OIG) that is useful in evaluating the performance of laboratories, including the following:
(i) A list of laboratories that have been convicted, under Federal or State laws relating to fraud and abuse, false billing, or kickbacks.
(ii) A list of laboratories that have had their CLIA certificates suspended, limited, or revoked, and the reason for the adverse actions.
(iii) A list of persons who have been convicted of violating CLIA requirements, as specified in section 353(1) of the PHS Act, together with the circumstances of each case and the penalties imposed.
(iv) A list of laboratories whose adverse actions have been imposed, showing—
(i) The effective date of the sanctions;
(ii) The reasons for imposing them;
(iii) Any corrective action taken by the laboratory; and
(iv) If the laboratory has achieved compliance, the verified date of compliance.
(v) A list of laboratories whose accreditation has been withdrawn or revoked and the reasons for the withdrawal or revocation.
(vi) All appeals and hearing decisions.
(vi) A list of laboratories against which CMS has brought suit under §493.1846 and the reasons for those actions.
(vi) A list of laboratories that have been excluded from participation in Medicare or Medicaid and the reasons for the exclusion.
(b) The laboratory registry is compiled for the calendar year preceding the date the information is made available and includes appropriate explanatory information to aid in the interpretation of the data. It also contains corrections of any erroneous statements or information that appeared in the previous registry.

Subpart S [Reserved]

Subpart T—Consultations

SOURCE: 57 FR 7185, Feb. 28, 1992, unless otherwise noted.