

termination of the laboratory's participation in Medicare and Medicaid for payment, and suspension of, or action to revoke, the laboratory's CLIA certificate in accordance with subpart R of this part.

42. In § 493.1814, the text of the introductory text of paragraph (b) is republished and paragraph (b)(3) is revised to read as follows:

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

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(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—

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(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, certificate for APT tests, or certificate for PPM procedures is pending.)

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43. In § 493.1834, the heading and introductory text of paragraph (f)(2) are republished and paragraphs (b) and (f)(2)(iii) are revised to read as follows:

§ 493.1834 Civil money penalty.

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(b) Scope. This section sets forth the procedures that HCFA 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, certificate for APT tests, or certificate for PPM procedures of a laboratory that is found to have condition level deficiencies.

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(f) Accrual and duration of penalty.

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(2) Duration of penalty. The civil money penalty continues to accrue until the earliest of the following occurs:

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(iii) HCFA suspends, limits, or revokes the laboratory's certificate of compliance, registration certificate, certificate of accreditation, certificate for APT tests, or certificate for PPM procedures.

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44. In § 493.1836, the heading of paragraph (c) is republished and paragraphs (c)(2) and (c)(3) are revised to read as follows:

§ 493.1836 State onsite monitoring.

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(c) Duration and sanction. * * *

(2) If the laboratory does not correct all deficiencies within 12 months, and a revisit indicates that deficiencies remain, HCFA 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, certificate for APT tests, 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, certificate for APT tests, or certificate for PPM procedures is effective.

45. In § 493.2001, the introductory text of paragraph (e) is republished and paragraph (e)(1) is revised to read as follows:

§ 493.2001 Establishment and function of the Clinical Laboratory Improvement Advisory Committee.

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(e) The Clinical Laboratory Improvement Advisory Committee or subcommittee at the request of HHS will review and make recommendations concerning—

(1) Criteria for categorizing tests and examinations of moderate complexity (including the subcategories) and high complexity;

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Authority: Sec. 353 of the Public Health Service Act (42 U.S.C. 263a)

Dated: May 25, 1995.

Bruce C. Vladeck, Administrator, Health Care Financing Administration.

Dated: May 26, 1995.

Philip R. Lee, Assistant Secretary for Health.

Dated: June 5, 1995.

Donna E. Shalala, Secretary.

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