

subpart D, if applicable, and subparts H, J, K, M, and P of this part:

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(4) Permit HHS or its designee upon request to review all information and data necessary to—

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(iii) Determine whether the laboratory is performing tests in addition to procedures specified as PPM procedures; (iv) Collect information regarding the appropriateness of tests specified as PPM procedures; and

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51. In § 493.1777, introductory text to the section is added and the heading and paragraphs (a) and (g) are revised to read as follows:

§ 493.1777 Condition: Inspection of laboratories requesting or issued a certificate of compliance.

Laboratories requesting or issued a certificate of compliance must permit an inspection to assess compliance with part 493 of this chapter. Testing in the subcategory of PPM procedures, may be included in the laboratory's routine or complaint inspection. PPM procedures are assessed for compliance with only the applicable requirements specific to the subcategory of testing.

(a) HHS or its designee may conduct unannounced or announced inspections on at least a biennial basis of any laboratory at any time during its hours of operation. To assess compliance with the requirements of part 493, HHS will inspect a laboratory possessing a registration certificate before issuance of a certificate of compliance.

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(g) Failure to permit an inspection under this subsection will result in the suspension of Medicare and Medicaid payments to the laboratory, or termination of the laboratory's participation in Medicare and Medicaid for payment, and suspension of or action to revoke the laboratory's CLIA certificate of compliance in accordance with subpart R of this part.

§ 493.1804 [Amended]

52. In § 493.1804(b)(2), the word "ore" is revised to read "or".

53. In § 493.1814, 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—

* * * * *

(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.)

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54. 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.

* * * * *

(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, 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—*

* * * * *

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

* * * * *

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

* * * * *

55. 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.

* * * * *

(c) *Duration of sanction.*

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(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, 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.

56. In § 493.2001, paragraph (e) and paragraph (e)(1) are 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 subcategory) and high complexity;

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(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance; Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: December 23, 1994.

Philip R. Lee,
Assistant Secretary for Health.

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

Dated: December 27, 1994.

Donna E. Shalala,
Secretary.

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 61

[CC Docket No. 93-179, FCC 95-133]

Price Cap Rules for Local Exchange Carriers

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This action is taken to incorporate explicitly the "add-back" adjustment into the local exchange carrier (LEC) price cap rules. The explicit add-back rule will first be applied when the LECs file their 1995 access tariffs. It is intended that the explicit add-back rule will ensure that