

§ 493.47

in the notice to the laboratory of denial of the certificate application even if there has been no appeals decision issued.

[57 FR 7143, Feb. 28, 1992, as amended at 58 FR 5223, Jan. 19, 1993; 60 FR 20045, Apr. 24, 1995; 68 FR 3702, Jan. 24, 2003]

§ 493.47 Requirements for a certificate for provider-performed microscopy (PPM) procedures.

(a) A certificate for PPM procedures is required—

(1) Initially for all laboratories performing test procedures specified as PPM procedures; and

(2) For all certificate of waiver laboratories that intend to perform only test procedures specified as PPM procedures in addition to those tests listed in § 493.15(c).

(b) HHS will issue a certificate for PPM procedures if the laboratory—

(1) Complies with the requirements of § 493.43; and

(2) Remits the fee for the certificate, as specified in subpart F of this part.

(c) Laboratories issued a certificate for PPM procedures are subject to—

(1) The notification requirements of § 493.53;

(2) The applicable requirements of this subpart and subparts H, J, K, and M of this part; and

(3) Inspection only under the circumstances specified under §§ 493.1773 and 493.1775, but are not routinely inspected to determine compliance with the requirements specified in paragraphs (c) (1) and (2) of this section.

(d) In accordance with subpart R of this part, HHS will initiate suspension, limitation, or revocation of a laboratory's certificate for PPM procedures for failure to comply with the applicable requirements set forth in this subpart. HHS may also impose certain alternative sanctions. In addition, failure to meet the requirements of this subpart may result in suspension of all or part of payments under Medicare and Medicaid, as specified in subpart R of this part.

(e) A certificate for PPM procedures is valid for a period of no more than 2 years.

[58 FR 5223, Jan. 19, 1993, as amended at 60 FR 20045, Apr. 24, 1995; 68 FR 3702, Jan. 24, 2003; 68 FR 50723, Aug. 22, 2003]

42 CFR Ch. IV (10–1–20 Edition)

§ 493.49 Requirements for a certificate of compliance.

A certificate of compliance may include any combination of tests categorized as high complexity or moderate complexity or listed in § 493.15(c) as waived tests. Moderate complexity tests may include those specified as PPM procedures.

(a) HHS will issue a certificate of compliance to a laboratory only if the laboratory—

(1) Meets the requirements of §§ 493.43 and 493.45;

(2) Remits the certificate fee specified in subpart F of this part; and

(3) Meets the applicable requirements of this subpart and subparts H, J, K, M, and Q of this part.

(b) Laboratories issued a certificate of compliance—

(1) Are subject to the notification requirements of § 493.51; and

(2) Must permit announced or unannounced inspections by HHS in accordance with subpart Q of this part—

(i) To determine compliance with the applicable requirements of this part;

(ii) To evaluate complaints;

(iii) When HHS has substantive reason to believe that tests are being performed, or the laboratory is being operated in a manner that constitutes an imminent and serious risk to human health; and

(iv) To collect information regarding the appropriateness of tests listed in § 493.15 or tests categorized as moderate complexity (including the subcategory) or high complexity.

(c) Failure to comply with the requirements of this subpart will result in—

(1) Suspension, revocation or limitation of a laboratory's certificate of compliance in accordance with subpart R of this part; and

(2) Suspension or denial of payments under Medicare and Medicaid in accordance with subpart R of this part.

(d) A certificate of compliance issued under this subpart is valid for no more than 2 years.

(e) In the event of a noncompliance determination resulting in an HHS action to revoke, suspend or limit the laboratory's certificate of compliance, HHS will—