

(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—

(1) Provide the laboratory with a statement of grounds on which the determination of noncompliance is based; and

(2) Offer an opportunity for appeal as provided in subpart R of this part. If the laboratory requests a hearing within 60 days of the notice of sanction, it retains its certificate of compliance or reissued certificate of compliance until a decision is made by an administrative law judge (ALJ) as provided in subpart R of this part, except when HHS finds that conditions at the laboratory pose an imminent and serious risk to human health or when the criteria at § 493.1840(a) (4) and (5) are met.

(f) For laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of a noncompliance determination even if there has been no appeals decision issued.

(g) A laboratory seeking to renew its certificate of compliance must—

(1) Complete and return the renewal application to HHS 9 to 12 months prior to the expiration of the certificate of compliance; and

(2) Meet the requirements of § 493.43 and paragraphs (a)(2) and (b)(2) of this section.

(h) If HHS determines that the application for the renewal of a certificate of compliance must be denied or limited, HHS will notify the laboratory in writing of the—

(1) Basis for denial of the application; and

(2) Opportunity for appeal as provided in subpart R of this part.

(i) If the laboratory requests a hearing within the time period specified by HHS, the laboratory retains its certificate of compliance or reissued certificate of compliance until a decision is made by an ALJ as provided in subpart R, except when HHS finds that conditions at the laboratory pose an imminent and serious risk to human health.

(j) For laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of nonrenewal of the certificate of compliance even if there has been no appeals decision issued.

17. In § 493.51, the introductory paragraph of paragraph (a) is

republished and the heading, the section's introductory paragraph and paragraphs (a)(5), (b) and (c) are revised to read as follows:

§ 493.51 Notification requirements for laboratories issued a certificate of compliance.

Laboratories issued a certificate of compliance must meet the following conditions:

(a) Notify HHS or its designee within 30 days of any change in—

* * * * *

(5) Technical supervisor (laboratories performing high complexity only).

(b) Notify HHS no later than 6 months after performing any test or examination within a specialty or subspecialty area that is not included on the laboratory's certificate of compliance, so that compliance with requirements can be determined.

(c) Notify HHS no later than 6 months after any deletions or changes in test methodologies for any test or examination included in a specialty or subspecialty, or both, for which the laboratory has been issued a certificate of compliance.

18. In § 493.53, the heading, the introductory paragraph, and paragraph (a) are revised to read as follows:

§ 493.53 Notification requirements for laboratories issued a certificate for provider-performed microscopy (PPM) procedures.

Laboratories issued a certificate for PPM procedures must notify HHS or its designee—

(a) Before performing and reporting results for any test of moderate or high complexity, or both, in addition to tests specified as PPM procedures or any test or examination that is not specified under § 493.15(c), for which it does not have a registration certificate as required in subpart C or subpart D, as applicable, of this part; and

* * * * *

19. The introductory text of § 493.55(a) is revised to read as follows:

§ 493.55 Application for registration certificate and certificate of accreditation.

(a) *Filing of application.* A laboratory may be issued a certificate of accreditation in lieu of the applicable certificate specified in subpart B or subpart C of this part provided the laboratory—

* * * * *

20. In § 493.57, the introductory paragraph and paragraph (b) are revised to read as follows:

§ 493.57 Requirements for a registration certificate.

A registration certificate is required for all laboratories seeking a certificate of accreditation, unless the laboratory holds a valid certificate of compliance issued by HHS.

* * * * *

(b)(1) The laboratory must provide HHS with proof of accreditation by an approved accreditation program—

(i) Within 11 months of issuance of the registration certificate; or

(ii) Prior to the expiration of the certificate of compliance.

(2) If such proof of accreditation is not supplied within this timeframe, the laboratory must meet, or continue to meet, the requirements of § 493.49.

* * * * *

21. In § 493.511, paragraph (h) is revised to read as follows:

§ 493.511 Removal of deeming authority and final determination review.

* * * * *

(h) After HCFA withdraws approval of an accreditation organization's deeming authority, the certificates of accreditation of all affected laboratories continue in effect for 60 days after the laboratory receives notification of the withdrawal of approval. HCFA may extend the period for an additional 60 days for a laboratory if it determines that the laboratory submitted an application for inspection to another approved accreditation organization or an application for the appropriate certificate to HCFA, the State agency, or other HCFA agent before the initial 60-day period ends.

* * * * *

22. Paragraph (j) of § 493.521 is revised to read as follows:

§ 493.521 Removal of CLIA exemption and final determination review.

* * * * *

(j) After HCFA withdraws approval of a State laboratory licensure program, the exempt status of licensed or approved laboratories in the State continues in effect for 60 days after the laboratory receives notification from the State of the withdrawal of HCFA's approval of the program. HCFA may extend this period for an additional 60 days for a laboratory if it determines that the laboratory submitted an application for accreditation to an approved accreditation organization or an application to HCFA for the appropriate certificate before the initial 60-day period ends.

* * * * *

23. Section 493.602 is revised to read as follows: