

§ 493.602

(g) *Withdrawal of approval-effect on laboratory status*—(1) *Accredited laboratory.* After CMS withdraws approval of an accreditation organization's deeming authority, the certificate of accreditation of each affected laboratory continues in effect for 60 days after it receives notification of the withdrawal of approval.

(2) *CLIA-exempt laboratory.* After CMS withdraws approval of a State licensure program, the exempt status of each licensed or approved laboratory in the State continues in effect for 60 days after a laboratory receives notification from the State of the withdrawal of CMS's approval of the program.

(3) *Extension.* After CMS withdraws approval of an accreditation organization or State licensure program, CMS may extend the 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 for the appropriate certificate to CMS or a CMS agent before the initial 60-day period ends.

(h) *Immediate jeopardy to patients.* (1) If at any time CMS determines that the continued approval of deeming authority of any accreditation organization poses immediate jeopardy to the patients of the laboratories accredited by the organization, or continued approval otherwise constitutes a significant hazard to the public health, CMS may immediately withdraw the approval of deeming authority for that accreditation organization.

(2) If at any time CMS determines that the continued approval of a State licensure program poses immediate jeopardy to the patients of the laboratories in that State, or continued approval otherwise constitutes a significant hazard to the public health, CMS may immediately withdraw the approval of that State licensure program.

(i) *Failure to pay fees.* CMS withdraws the approval of a State licensure program if the State fails to pay the applicable fees, as specified in §§ 493.645(a) and 493.646(b).

(j) *State refusal to take enforcement action.* (1) CMS may withdraw approval of a State licensure program if the State

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refuses to take enforcement action against a laboratory in that State when CMS determines it to be necessary.

(2) A laboratory that is in a State in which CMS has withdrawn program approval is subject to the same requirements and survey and enforcement processes that are applied to a laboratory that is not exempt from CLIA requirements.

(k) *Request for reconsideration.* Any accreditation organization or State that is dissatisfied with a determination to withdraw approval of its deeming authority or remove approval of its State licensure program, as applicable, may request that CMS reconsider the determination, in accordance with subpart D of part 488.

Subpart F—General Administration

SOURCE: 57 FR 7138 and 7213, Feb. 28, 1992, unless otherwise noted.

§ 493.602 Scope of subpart.

This subpart sets forth the methodology for determining the amount of the fees for issuing the appropriate certificate, and for determining compliance with the applicable standards of the Public Health Service Act (the PHS Act) and the Federal validation of accredited laboratories and of CLIA-exempt laboratories.

[60 FR 20047, Apr. 24, 1995]

§ 493.606 Applicability of subpart.

The rules of this subpart are applicable to those laboratories specified in § 493.3.

[58 FR 5212, Jan. 19, 1993]

§ 493.638 Certificate fees.

(a) *Basic rule.* Laboratories must pay a fee for the issuance of a registration certificate, certificate for PPM procedures, certificate of waiver, certificate of accreditation, or a certificate of compliance, as applicable. Laboratories must also pay a fee to reapply for a certificate for PPM procedures, certificate of waiver, certificate of accreditation, or a certificate of compliance. The total of fees collected by HHS under the laboratory program must be sufficient to cover the general costs of