

§ 493.602

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(2) A laboratory that is in a State in which CMS has withdrawn program approval is subject to the same requirements and survey and enforcement processes that are applied to a laboratory that is not exempt from CLIA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

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administering the laboratory certification program under section 353 of the PHS Act.

(1) For registration certificates and certificates of compliance, the costs include issuing the certificates, collecting the fees, evaluating and monitoring proficiency testing programs, evaluating which procedures, tests or examinations meet the criteria for inclusion in the appropriate complexity category, and implementing section 353 of the PHS Act.

(2) For a certificate of waiver, the costs include issuing the certificate, collecting the fees, determining if a certificate of waiver should be issued, evaluating which tests qualify for inclusion in the waived category, and other direct administrative costs.

(3) For a certificate for PPM procedures, the costs include issuing the certificate, collecting the fees, determining if a certificate for PPM procedures should be issued, evaluating which procedures meet the criteria for inclusion in the subcategory of PPM procedures, and other direct administrative costs.

(4) For a certificate of accreditation, the costs include issuing the certificate, collecting the fees, evaluating the programs of accrediting bodies, and other direct administrative costs.

(b) *Fee amount.* The fee amount is set annually by HHS on a calendar year basis and is based on the category of test complexity, or on the category of test complexity and schedules or ranges of annual laboratory test volume (excluding waived tests and tests performed for quality control, quality assurance, and proficiency testing purposes) and specialties tested, with the amounts of the fees in each schedule being a function of the costs for all aspects of general administration of CLIA as set forth in § 493.649 (b) and (c). This fee is assessed and payable at least biennially. The methodology used to determine the amount of the fee is found in § 493.649. The amount of the fee applicable to the issuance of the registration certificate or the issuance or renewal of the certificate for PPM procedures, certificate of waiver, certificate of accreditation, or certificate of compliance is the amount in effect at the time the application is received.

Upon receipt of an application for a certificate, HHS or its designee notifies the laboratory of the amount of the required fee for the requested certificate.

[60 FR 20047, Apr. 24, 1995]

§ 493.639 Fee for revised certificate.

(a) If, after a laboratory is issued a registration certificate, it changes its name or location, the laboratory must pay a fee to cover the cost of issuing a revised registration certificate. The fee for the revised registration certificate is based on the cost to issue the revised certificate to the laboratory.

(b) A laboratory must pay a fee to cover the cost of issuing a revised certificate in any of the following circumstances:

(1) The fee for issuing an appropriate revised certificate is based on the cost to issue the revised certificate to the laboratory as follows:

(i) If a laboratory with a certificate of waiver wishes to perform tests in addition to those listed in § 493.15(c) as waived tests, it must, as set forth in § 493.638, pay an additional fee for the appropriate certificate to cover the additional testing.

(ii) If a laboratory with a certificate for PPM procedures wishes to perform tests in addition to those specified as PPM procedures or listed in § 493.15(c) as waived tests, it must, as set forth in § 493.638, pay an additional fee for the appropriate certificate to cover the additional testing.

(2) A laboratory must pay a fee to cover the cost of issuing a revised certificate when—

(i) A laboratory changes its name, location, or its director; or

(ii) A laboratory deletes services or wishes to add services and requests that its certificate be changed. (An additional fee is also required under § 493.643(d) if it is necessary to determine compliance with additional requirements.)

[57 FR 7213, Feb. 28, 1992, as amended at 60 FR 20047, Apr. 24, 1995]

§ 493.643 Fee for determination of program compliance.

(a) *Fee requirement.* In addition to the fee required under § 493.638, a laboratory subject to routine inspections

must pay a fee to cover the cost of determining program compliance. Laboratories issued a certificate for PPM procedures, certificate of waiver, or a certificate of accreditation are not subject to this fee for routine inspections.

(b) *Costs included in the fee.* Included in the fee for determining program compliance is the cost of evaluating qualifications of personnel; monitoring proficiency testing; conducting onsite inspections; documenting deficiencies; evaluating laboratories' plans to correct deficiencies; and necessary administrative costs. HHS sets the fee amounts annually on a calendar year basis. Laboratories are inspected biennially; therefore, fees are assessed and payable biennially. If additional expenses are incurred to conduct follow up visits to verify correction of deficiencies, to impose sanctions, and/or for surveyor preparation for and attendance at ALJ hearings, HHS assesses an additional fee to include these costs. The additional fee is based on the actual resources and time necessary to perform the activities.

(c) *Classification of laboratories that require inspection for purpose of determining amount of fee.* (1) There are ten classifications (schedules) of laboratories for the purpose of determining the fee amount a laboratory is assessed. Each laboratory is placed into one of the ten following schedules based on the laboratory's scope and volume of testing (excluding tests performed for quality control, quality assurance, and proficiency testing purposes).

(i) (A) *Schedule A Low Volume.* The laboratory performs not more than 2,000 laboratory tests annually.

(B) *Schedule A.* The laboratory performs tests in no more than 3 specialties of service with a total annual volume of more than 2,000 but not more than 10,000 laboratory tests.

(ii) *Schedule B.* The laboratory performs tests in at least 4 specialties of service with a total annual volume of not more than 10,000 laboratory tests.

(iii) *Schedule C.* The laboratory performs tests in no more than 3 specialties of service with a total annual volume of more than 10,000 but not more than 25,000 laboratory tests.