

42 C.F.R. § 493.638

Certificate fees.

(a) *Basic rule.* Laboratories must pay a fee that covers the costs incurred for the issuance, renewal, change in certificate type, or reinstatement of a terminated certificate with a gap in service, and other direct administrative costs, as applicable. The total of fees collected by HHS under the laboratory program must be sufficient to cover the general costs of administering the laboratory certification program under section 353 of the PHS Act.

(1) For registration certificates, the fee is a flat fee that includes the costs for issuing the certificates, collecting the fees, and evaluating whether the procedures, tests, or examinations listed on the application fall within the testing allowed for the requested certificate.

(2) For a certificate of waiver, the fee includes the costs for issuing the certificate; collecting the fees; evaluating whether the procedures, tests, or examinations listed on the application fall within the testing appropriate for the requested certificate; and determining whether a laboratory test meets the criteria for a waived test.

(3) For a certificate for PPM procedures, the fee includes the costs for issuing the certificate, collecting the fees; and evaluating whether the procedures, tests, or examinations listed on the application meet the criteria for inclusion in the subcategory of PPM procedures.

(4) For a certificate of accreditation, the fee includes the costs for issuing the certificate, collecting the fees, evaluating the programs of accrediting bodies, and evaluating whether the procedures, tests, or examinations listed on the application fall within the testing appropriate for the requested certificate.

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