

## 42 C.F.R. § 493.37

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### Requirements for a certificate of waiver.

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- (a) HHS will issue a certificate of waiver to a laboratory only if the laboratory meets the requirements of § 493.35.
- (b) Laboratories issued a certificate of waiver—
  - (1) Are subject to the requirements of this subpart and § 493.15(e) of subpart A of this part; and
  - (2) Must permit announced or unannounced inspections by HHS in accordance with subpart Q of this part.
- (c) Laboratories must remit the certificate of waiver fee specified in subpart F of this part.
- (d) In accordance with subpart R of this part, HHS will suspend or revoke or limit a laboratory's certificate of waiver for failure to comply with the requirements of this subpart. In addition, failure to meet the requirements of this subpart will result in suspension or denial of payments under Medicare and Medicaid in accordance with subpart R of this part.

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