
42 C.F.R. § 493.1834

Civil money penalty.

- (a) *Statutory basis.* Sections 1846 of the Act and 353(h)(2)(B) of the PHS Act authorize the Secretary to impose civil money penalties on laboratories. Section 1846(b)(3) of the Act specifically provides that incrementally more severe fines may be imposed for repeated or uncorrected deficiencies.
- (b) *Scope.* This section sets forth the procedures that CMS follows to impose a civil money penalty in lieu of, or in addition to, suspending, limiting, or revoking the certificate of compliance, registration certificate, certificate of accreditation, or certificate for PPM procedures of a laboratory that is found to have condition level deficiencies.
- (c) *Basis for imposing a civil money penalty.* CMS may impose a civil money penalty against any laboratory determined to have condition level deficiencies regardless of whether those deficiencies pose immediate jeopardy.
- (d) *Amount of penalty—(1) Factors considered.* In determining the amount of the penalty, CMS takes into account the following factors:
- (i) The nature, scope, severity, and duration of the noncompliance.
 - (ii) Whether the same condition level deficiencies have been identified during three consecutive inspections.
 - (iii) The laboratory's overall compliance history including but not limited to any period of noncompliance that occurred between certifications of compliance.

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