§ 493.1806 Available sanctions: All laboratories.

(a) Applicability. CMS may impose one or more of the sanctions specified in this section on a laboratory that is out of compliance with one or more CLIA conditions.

(b) Principal sanction. CMS may impose any of the three principal CLIA sanctions, which are suspension, limitation, or revocation of any type of CLIA certificate.

(c) Alternative sanctions. CMS may impose one or more of the following alternative sanctions in lieu of or in addition to imposing a principal sanction, except on a laboratory that has a certificate of waiver:

1. Directed plan of correction, as set forth at § 493.1832.
2. State onsite monitoring as set forth at § 493.1836.
3. Civil money penalty, as set forth at § 493.1834.

(d) Civil suit. CMS may bring suit in the appropriate U.S. District Court to enjoin continuation of any activity of any laboratory (including a CLIA-exempt laboratory that has been found with deficiencies during a validation survey), if CMS has reason to believe that continuation of the activity would constitute a significant hazard to the public health.

(e) Criminal sanctions. Under section 353(1) of the PHS Act, an individual who is convicted of intentionally violating any CLIA requirement may be imprisoned or fined.