

- 493.1832 Directed plan of correction and directed portion of a plan of correction.  
 493.1834 Civil money penalty.  
 493.1836 State onsite monitoring.  
 493.1838 Training and technical assistance for unsuccessful participation in proficiency testing.  
 493.1840 Suspension, limitation, or revocation of any type of CLIA certificate.  
 493.1842 Cancellation of Medicare approval.  
 493.1844 Appeals procedures.  
 493.1846 Civil action.  
 493.1850 Laboratory registry.

#### Subpart S [Reserved]

#### Subpart T—Consultations

- 493.2001 Establishment and function of the Clinical Laboratory Improvement Advisory Committee.

**AUTHORITY:** Sec. 353 of the Public Health Service Act, secs. 1102, 1861(e), the sentence following sections 1861(s)(11) through 1861(s)(16) of the Social Security Act (42 U.S.C. 263a, 1302, 1395x(e), the sentence following 1395x(s)(11) through 1395x(s)(16)).

**SOURCE:** 55 FR 9576, Mar. 14, 1990, unless otherwise noted.

#### Subpart A—General Provisions

**SOURCE:** 57 FR 7139, Feb. 28, 1992, unless otherwise noted.

#### § 493.1 Basis and scope.

This part sets forth the conditions that all laboratories must meet to be certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). It implements sections 1861 (e) and (j), the sentence following section 1861(s)(13), and 1902(a)(9) of the Social Security Act, and section 353 of the Public Health Service Act. This part applies to all laboratories as defined under “laboratory” in § 493.2 of this part. This part also applies to laboratories seeking payment under the Medicare and Medicaid programs. The requirements are the same for Medicare approval as for CLIA certification.

#### § 493.2 Definitions.

As used in this part, unless the context indicates otherwise—

*Accredited institution* means a school or program which—

- (a) Admits as regular student only persons having a certificate of graduation

from a school providing secondary education, or the recognized equivalent of such certificate;

(b) Is legally authorized within the State to provide a program of education beyond secondary education;

(c) Provides an educational program for which it awards a bachelor’s degree or provides not less than a 2-year program which is acceptable toward such a degree, or provides an educational program for which it awards a master’s or doctoral degree;

(d) Is accredited by a nationally recognized accrediting agency or association.

This definition includes any foreign institution of higher education that HHS or its designee determines meets substantially equivalent requirements.

*Accredited laboratory* means a laboratory that has voluntarily applied for and been accredited by a private, nonprofit accreditation organization approved by HCFA in accordance with this part;

*Adverse action* means the imposition of a principal or alternative sanction by HCFA.

*ALJ* stands for Administrative Law Judge.

*Alternative sanctions* means sanctions that may be imposed in lieu of or in addition to principal sanctions. The term is synonymous with “intermediate sanctions” as used in section 1846 of the Act.

*Analyte* means a substance or constituent for which the laboratory conducts testing.

*Approved accreditation organization for laboratories* means a private, nonprofit accreditation organization that has formally applied for and received HCFA’s approval based on the organization’s compliance with this part.

*Approved State laboratory program* means a licensure or other regulatory program for laboratories in a State, the requirements of which are imposed under State law, and the State laboratory program has received HCFA approval based on the State’s compliance with this part.

*Authorized person* means an individual authorized under State law to order tests or receive test results, or both.