

Subparts N–O [Reserved]**Subpart P—Quality Assurance for Moderate Complexity (Including the Subcategory) or High Complexity Testing, or Any Combination of These Tests**

- 493.1701 Condition: Quality assurance; moderate complexity (including the subcategory) or high complexity testing, or any combination of these tests.
- 493.1703 Standard; Patient test management assessment.
- 493.1705 Standard; Quality control assessment.
- 493.1707 Standard; Proficiency testing assessment.
- 493.1709 Standard; Comparison of test results.
- 493.1711 Standard; Relationship of patient information to patient test results.
- 493.1713 Standard; Personnel assessment.
- 493.1715 Standard; Communications.
- 493.1717 Standard; Complaint investigations.
- 493.1719 Standard; Quality assurance review with staff.
- 493.1721 Standard; Quality assurance records.

Subpart Q—Inspection

- 493.1771 Condition: Inspection requirements applicable to all CLIA-certified and CLIA-exempt laboratories.
- 493.1773 Standard: Basic inspection requirements for all laboratories issued a CLIA certificate and CLIA-exempt laboratories.
- 493.1775 Standard: Inspection of laboratories issued a certificate of waiver or a certificate for provider-performed microscopy procedures.
- 493.1777 Standard: Inspection of laboratories that have requested or have been issued a certificate of compliance.
- 493.1780 Standard: Inspection of CLIA-exempt laboratories or laboratories requesting or issued a certificate of accreditation.

Subpart R—Enforcement Procedures

- 493.1800 Basis and scope.
- 493.1804 General considerations.
- 493.1806 Available sanctions: All laboratories.
- 493.1807 Additional sanctions: Laboratories that participate in Medicare.
- 493.1808 Adverse action on any type of CLIA certificate: Effect on Medicare approval.
- 493.1809 Limitation on Medicaid payment.
- 493.1810 Imposition and lifting of alternative sanctions.
- 493.1812 Action when deficiencies pose immediate jeopardy.

- 493.1814 Action when deficiencies are at the condition level but do not pose immediate jeopardy.
- 493.1816 Action when deficiencies are not at the condition level.
- 493.1820 Ensuring timely correction of deficiencies.
- 493.1826 Suspension of part of Medicare payments.
- 493.1828 Suspension of all Medicare payments.
- 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

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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 CMS in accordance with this part;

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

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 CMS'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,

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the requirements of which are imposed under State law, and the State laboratory program has received CMS 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.

Challenge means, for quantitative tests, an assessment of the amount of substance or analyte present or measured in a sample. For qualitative tests, a challenge means the determination of the presence or the absence of an analyte, organism, or substance in a sample.

CLIA means the Clinical Laboratory Improvement Amendments of 1988.

CLIA certificate means any of the following types of certificates issued by CMS or its agent:

(1) *Certificate of compliance* means a certificate issued to a laboratory after an inspection that finds the laboratory to be in compliance with all applicable condition level requirements, or reissued before the expiration date, pending an appeal, in accordance with § 493.49, when an inspection has found the laboratory to be out of compliance with one or more condition level requirements.

(2) *Certificate for provider-performed microscopy (PPM) procedures* means a certificate issued or reissued before the expiration date, pending an appeal, in accordance with § 493.47, to a laboratory in which a physician, midlevel practitioner or dentist performs no tests other than PPM procedures and, if desired, waived tests listed in § 493.15(c).

(3) *Certificate of accreditation* means a certificate issued on the basis of the laboratory's accreditation by an accreditation organization approved by CMS (indicating that the laboratory is deemed to meet applicable CLIA requirements) or reissued before the expiration date, pending an appeal, in accordance with § 493.61, when a validation or complaint survey has found the laboratory to be noncompliant with one or more CLIA conditions.

(4) *Certificate of registration or registration certificate* means a certificate issued or reissued before the expiration date, pending an appeal, in accordance