

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, non-profit 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, non-profit 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,

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.

*Calibration* means a process of testing and adjusting an instrument or test system to establish a correlation between the measurement response and the concentration or amount of the substance that is being measured by the test procedure.

*Calibration verification* means the assaying of materials of known concentration in the same manner as patient samples to substantiate the instrument or test system's calibration throughout the reportable range for patient test results.

*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

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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 with § 493.45, that enables the entity to conduct moderate or high complexity laboratory testing or both until the entity is determined to be in compliance through a survey by CMS or its agent; or in accordance with § 493.57 to an entity that is accredited by an approved accreditation organization.

(5) *Certificate of waiver* means a certificate issued or reissued before the expiration date, pending an appeal, in accordance with § 493.37, to a laboratory to perform only the waived tests listed at § 493.15(c).

*CLIA-exempt laboratory* means a laboratory that has been licensed or approved by a State where CMS has determined that the State has enacted laws relating to laboratory requirements that are equal to or more stringent than CLIA requirements and the State licensure program has been approved by CMS in accordance with subpart E of this part.

*Condition level deficiency* means non-compliance with one or more condition level requirements.

*Condition level requirements* means any of the requirements identified as "conditions" in subparts G through Q of this part.

*Credible allegation of compliance* means a statement or documentation that—

(1) Is made by a representative of a laboratory that has a history of having maintained a commitment to compliance and of taking corrective action when required;

(2) Is realistic in terms of its being possible to accomplish the required corrective action between the date of the exit conference and the date of the allegation; and

(3) Indicates that the problem has been resolved.

*Dentist* means a doctor of dental medicine or doctor of dental surgery licensed by the State to practice dentistry within the State in which the laboratory is located.

*Equivalency* means that an accreditation organization's or a State laboratory program's requirements, taken as a whole, are equal to or more stringent than the CLIA requirements established by CMS, taken as whole. It is acceptable for an accreditation organization's or State laboratory program's requirements to be organized differently or otherwise vary from the CLIA requirements, as long as (1) all of the requirements taken as a whole would provide at least the same protection as the CLIA requirements taken as a whole; and (2) a finding of non-compliance with respect to CLIA requirements taken as a whole would be matched by a finding of noncompliance with the accreditation or State requirements taken as a whole.

*CMS agent* means an entity with which CMS arranges to inspect laboratories and assess laboratory activities against CLIA requirements and may be a State survey agency, a private, non-profit organization other than an approved accreditation organization, a component of HHS, or any other governmental component CMS approves for this purpose. In those instances where all of the laboratories in a State are exempt from CLIA requirements, based on the approval of a State's exemption request, the State survey agency is not the CMS agent.

*FDA-cleared or approved test system* means a test system cleared or approved by the FDA through the pre-market notification (510(k)) or pre-market approval (PMA) process for in-vitro diagnostic use. Unless otherwise stated, this includes test systems exempt from FDA premarket clearance or approval.

*HHS* means the Department of Health and Human Services, or its designee.

*Immediate jeopardy* means a situation in which immediate corrective action is necessary because the laboratory's noncompliance with one or more condition level requirements has already caused, is causing, or is likely to cause,

at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health or safety of the general public. This term is synonymous with imminent and serious risk to human health and significant hazard to the public health.

*Intentional violation* means knowing and willful noncompliance with any CLIA condition.

*Kit* means all components of a test that are packaged together.

*Laboratory* means a facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories.

*Midlevel practitioner* means a nurse midwife, nurse practitioner, or physician assistant, licensed by the State within which the individual practices, if such licensing is required in the State in which the laboratory is located.

*Nonwaived test* means any test system, assay, or examination that has not been found to meet the statutory criteria specified at section 353(d)(3) of the Public Health Service Act.

*Operator* means the individual or group of individuals who oversee all facets of the operation of a laboratory and who bear primary responsibility for the safety and reliability of the results of all specimen testing performed in that laboratory. The term includes—

(1) A director of the laboratory if he or she meets the stated criteria; and

(2) The members of the board of directors and the officers of a laboratory that is a small corporation under subchapter S of the Internal Revenue Code.

*Owner* means any person who owns any interest in a laboratory except for an interest in a laboratory whose stock and/or securities are publicly traded. (That is e.g., the purchase of shares of stock or securities on the New York Stock Exchange in a corporation owning a laboratory would not make a person an owner for the purpose of this regulation.)

*Party* means a laboratory affected by any of the enforcement procedures set forth in this subpart, by CMS or the OIG, as appropriate.

*Performance characteristic* means a property of a test that is used to describe its quality, e.g., accuracy, precision, analytical sensitivity, analytical specificity, reportable range, reference range, etc.

*Performance specification* means a value or range of values for a performance characteristic, established or verified by the laboratory, that is used to describe the quality of patient test results.

*Physician* means an individual with a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine degree who is licensed by the State to practice medicine, osteopathy, or podiatry within the State in which the laboratory is located.

*Principal sanction* means the suspension, limitation, or revocation of any type of CLIA certificate or the cancellation of the laboratory's approval to receive Medicare payment for its services.

*Prospective laboratory* means a laboratory that is operating under a registration certificate or is seeking any of the three other types of CLIA certificates.

*Rate of disparity* means the percentage of sample validation inspections for a specific accreditation organization or State where CMS, the State survey agency or other CMS agent finds noncompliance with one or more condition level requirements but no comparable deficiencies were cited by the accreditation organization or the State, and it is reasonable to conclude that the deficiencies were present at the time of the most recent accreditation organization or State licensure inspection.

*Example:* Assume the State survey agency, CMS or other CMS agent performs 200 sample validation inspections for laboratories accredited by a single accreditation organization or licensed in an exempt State during a validation review period and finds that 60 of the 200 laboratories had one or more condition level requirements out of compliance. CMS reviews the validation and accreditation organization's or State's inspections of the validated laboratories and determines that the State or accreditation organization found comparable deficiencies in 22 of the 60 laboratories and it is reasonable to conclude that deficiencies were present in the remaining 38 laboratories at the time of the accreditation organization's or State's inspection. Thirty-eight divided by 200 equals a 19 percent rate of disparity.

*Referee laboratory* means a laboratory currently in compliance with applicable CLIA requirements, that has had a record of satisfactory proficiency testing performance for all testing events for at least one year for a specific test, analyte, subspecialty, or specialty and has been designated by an HHS approved proficiency testing program as a referee laboratory for analyzing proficiency testing specimens for the purpose of determining the correct response for the specimens in a testing event for that specific test, analyte, subspecialty, or specialty.

*Reference range* means the range of test values expected for a designated population of individuals, e.g., 95 percent of individuals that are presumed to be healthy (or normal).

*Reportable range* means the span of test result values over which the laboratory can establish or verify the accuracy of the instrument or test system measurement response.

*Sample* in proficiency testing means the material contained in a vial, on a slide, or other unit that contains material to be tested by proficiency testing program participants. When possible, samples are of human origin.

*State* includes, for purposes of this part, each of the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands and a political subdivision of a State where the State, acting pursuant to State law, has expressly delegated powers to the political subdivision sufficient to authorize the political subdivision to act for the State in enforcing require-

ments equal to or more stringent than CLIA requirements.

*State licensure* means the issuance of a license to, or the approval of, a laboratory by a State laboratory program as meeting standards for licensing or approval established under State law.

*State licensure program* means a State laboratory licensure or approval program.

*State survey agency* means the State health agency or other appropriate State or local agency that has an agreement under section 1864 of the Social Security Act and is used by CMS to perform surveys and inspections.

*Substantial allegation of noncompliance* means a complaint from any of a variety of sources (including complaints submitted in person, by telephone, through written correspondence, or in newspaper or magazine articles) that, if substantiated, would have an impact on the health and safety of the general public or of individuals served by a laboratory and raises doubts as to a laboratory's compliance with any condition level requirement.

*Target value* for quantitative tests means either the mean of all participant responses after removal of outliers (those responses greater than 3 standard deviations from the original mean) or the mean established by definitive or reference methods acceptable for use in the National Reference System for the Clinical Laboratory (NRSCL) by the National Committee for the Clinical Laboratory Standards (NCCLS). In instances where definitive or reference methods are not available or a specific method's results demonstrate bias that is not observed with actual patient specimens, as determined by a defensible scientific protocol, a comparative method or a method group ("peer" group) may be used. If the method group is less than 10 participants, "target value" means the overall mean after outlier removal (as defined above) unless acceptable scientific reasons are available to indicate that such an evaluation is not appropriate.

*Test system* means the instructions and all of the instrumentation, equipment, reagents, and supplies needed to perform an assay or examination and generate test results.

*Unsatisfactory proficiency testing performance* means failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for a testing event.

*Unsuccessful participation in proficiency testing* means any of the following:

(1) Unsatisfactory performance for the same analyte in two consecutive or two out of three testing events.

(2) Repeated unsatisfactory overall testing event scores for two consecutive or two out of three testing events for the same specialty or subspecialty.

(3) An unsatisfactory testing event score for those subspecialties not graded by analyte (that is, bacteriology, mycobacteriology, virology, parasitology, mycology, blood compatibility, immunohematology, or syphilis serology) for the same subspecialty for two consecutive or two out of three testing events.

(4) Failure of a laboratory performing gynecologic cytology to meet the standard at § 493.855.

*Unsuccessful proficiency testing performance* means a failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for two consecutive or two of three consecutive testing events.

*Validation review period* means the one year time period during which CMS conducts validation inspections and evaluates the results of the most recent surveys performed by an accreditation organization or State laboratory program.

*Waived test* means a test system, assay, or examination that HHS has determined meets the CLIA statutory criteria as specified for waiver under section 353(d)(3) of the Public Health Service Act.

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#### § 493.3 Applicability.

(a) *Basic rule.* Except as specified in paragraph (b) of this section, a laboratory will be cited as out of compliance

with section 353 of the Public Health Service Act unless it—

(1) Has a current, unrevoked or unsuspended certificate of waiver, registration certificate, certificate of compliance, certificate for PPM procedures, or certificate of accreditation issued by HHS applicable to the category of examinations or procedures performed by the laboratory; or

(2) Is CLIA-exempt.

(b) *Exception.* These rules do not apply to components or functions of—

(1) Any facility or component of a facility that only performs testing for forensic purposes;

(2) Research laboratories that test human specimens but do not report patient specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of individual patients; or

(3) Laboratories certified by the Substance Abuse and Mental Health Services Administration (SAMHSA), in which drug testing is performed which meets SAMHSA guidelines and regulations. However, all other testing conducted by a SAMHSA-certified laboratory is subject to this rule.

(c) *Federal laboratories.* Laboratories under the jurisdiction of an agency of the Federal Government are subject to the rules of this part, except that the Secretary may modify the application of such requirements as appropriate.

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#### § 493.5 Categories of tests by complexity.

(a) Laboratory tests are categorized as one of the following:

(1) Waived tests.

(2) Tests of moderate complexity, including the subcategory of PPM procedures.

(3) Tests of high complexity.

(b) A laboratory may perform only waived tests, only tests of moderate complexity, only PPM procedures, only tests of high complexity or any combination of these tests.

(c) Each laboratory must be either CLIA-exempt or possess one of the following CLIA certificates, as defined in § 493.2: