

Subpart E—Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program

SOURCE: 63 FR 26732, May 14, 1998, unless otherwise noted.

§ 493.551 General requirements for laboratories.

(a) *Applicability.* HCFA may deem a laboratory to meet all applicable CLIA program requirements through accreditation by a private nonprofit accreditation program (that is, grant deemed status), or may exempt from CLIA program requirements all State licensed or approved laboratories in a State that has a State licensure program established by law, if the following conditions are met:

(1) The requirements of the accreditation organization or State licensure program are equal to, or more stringent than, the CLIA condition-level requirements specified in this part, and the laboratory would meet the condition-level requirements if it were inspected against these requirements.

(2) The accreditation program or the State licensure program meets the requirements of this subpart and is approved by HCFA.

(3) The laboratory authorizes the approved accreditation organization or State licensure program to release to HCFA all records and information required and permits inspections as outlined in this part.

(b) *Meeting CLIA requirements by accreditation.* A laboratory seeking to meet CLIA requirements through accreditation by an approved accreditation organization must do the following:

(1) Obtain a certificate of accreditation as required in subpart D of this part.

(2) Pay the applicable fees as required in subpart F of this part.

(3) Meet the proficiency testing (PT) requirements in subpart H of this part.

(4) Authorize its PT organization to furnish to its accreditation organization the results of the laboratory's participation in an approved PT program for the purpose of monitoring the lab-

oratory's PT and for making the annual PT results, along with explanatory information required to interpret the PT results, available on a reasonable basis, upon request of any person. A laboratory that refuses to authorize release of its PT results is no longer deemed to meet the condition-level requirements and is subject to a full review by HCFA, in accordance with subpart Q of this part, and may be subject to the suspension or revocation of its certificate of accreditation under § 493.1840.

(5) Authorize its accreditation organization to release to HCFA or a HCFA agent the laboratory's PT results that constitute unsuccessful participation in an approved PT program, in accordance with the definition of "unsuccessful participation in an approved PT program," as specified in § 493.2 of this part, when the laboratory has failed to achieve successful participation in an approved PT program.

(6) Authorize its accreditation organization to release to HCFA a notification of the actions taken by the organization as a result of the unsuccessful participation in a PT program within 30 days of the initiation of the action. Based on this notification, HCFA may take an adverse action against a laboratory that fails to participate successfully in an approved PT program.

(c) *Withdrawal of laboratory accreditation.* After an accreditation organization has withdrawn or revoked its accreditation of a laboratory, the laboratory retains its certificate of accreditation for 45 days after the laboratory receives notice of the withdrawal or revocation of the accreditation, or the effective date of any action taken by HCFA, whichever is earlier.

§ 493.553 Approval process (application and reapplication) for accreditation organizations and State licensure programs.

(a) *Information required.* An accreditation organization that applies or re-applies to HCFA for deeming authority, or a State licensure program that applies or re-applies to HCFA for exemption from CLIA program requirements of licensed or approved laboratories within the State, must provide the following information: