Centers for Medicare & Medicaid Services, HHS

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(3) Submit the certificate of accreditation fee specified in subpart F of this part.
(i) If HHS determines that the renewal application for a certificate of accreditation is to be denied or limited, HHS will notify the laboratory in writing of—
(1) The basis for denial of the application;
(2) Whether the laboratory is eligible for a certificate as defined in subpart C of this part;
(3) The opportunity for appeal on HHS’s action to deny the renewal application for certificate of accreditation as provided in subpart R of this part. If the laboratory requests a hearing within the time frame specified by HHS, it retains its certificate of accreditation or reissued certificate of accreditation until a decision is made by an administrative law judge as provided in subpart R of this part, unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health; and
(4) Suspension of payments under Medicare or Medicaid for those laboratories receiving payments under the Medicare or Medicaid programs.

§ 493.63 Notification requirements for laboratories issued a certificate of accreditation.

Laboratories issued a certificate of accreditation must:
(a) Notify HHS and the approved accreditation program within 30 days of any changes in—
(1) Ownership;
(2) Name;
(3) Location; or
(4) Director.
(b) Notify the approved accreditation program no later than 6 months after performing any test or examination within a specialty or subspecialty area that is not included in the laboratory’s accreditation, so that the accreditation organization can determine compliance and a new certificate of accreditation can be issued.
(c) Notify the accreditation program no later than 6 months after of any deletions or changes in test methodologies for any test or examination included in a specialty or subspecialty, or both, for which the laboratory has been issued a certificate of accreditation.

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. CMS 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 CMS.
(3) The laboratory authorizes the approved accreditation organization or State licensure program to release to CMS 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.
§ 493.553 Approval process (application and reapplication) for accreditation organizations and State licensure programs.

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

(1) A detailed comparison of the individual accreditation, or licensure or approval requirements with the comparable condition-level requirements; that is, a crosswalk.

(2) A detailed description of the inspection process, including the following:
   (i) Frequency of inspections.
   (ii) Copies of inspection forms.
   (iii) Instructions and guidelines.
   (iv) A description of the review and decision-making process of inspections.
   (v) A statement concerning whether inspections are announced or unannounced.
   (vi) A description of the steps taken to monitor the correction of deficiencies.

(3) A description of the process for monitoring PT performance, including action to be taken in response to unsuccessful participation in a CMS-approved PT program.

(4) Procedures for responding to and for the investigation of complaints against its laboratories.

(5) A list of all its current laboratories and the expiration date of their accreditation or licensure, as applicable.

(6) Procedures for making PT information available (under State confidentiality and disclosure requirements, if applicable) including explanatory information required to interpret PT results, on a reasonable basis, upon request of any person.

(b) CMS action on an application or reapplication. If CMS receives an application or reapplication from an accreditation organization, or State licensure program, CMS takes the following actions:

(1) CMS determines if additional information is necessary to make a determination for approval or denial of the application and notifies the accreditation organization or State to afford it an opportunity to provide the additional information.

(2) CMS may visit the accreditation organization or State licensure program offices to review and verify the