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

(1) HCFA 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) HCFA may visit the accreditation organization or State licensure program offices to review and verify the policies and procedures represented in its application and other information, including, but not limited to, review and examination of documents and interviews with staff.

(3) HCFA notifies the accreditation organization or State licensure program indicating whether HCFA approves or denies the request for deeming authority or exemption, respectively, and the rationale for any denial.

(c) *Duration of approval.* HCFA approval may not exceed 6 years.

(d) *Withdrawal of application.* The accreditation organization or State licensure program may withdraw its application at any time before official notification, specified at § 493.553(b)(3).

§ 493.555 Federal review of laboratory requirements.

HCFA's review of an accreditation organization or State licensure program includes, but is not limited to, an evaluation of the following:

(a) Whether the organization's or State's requirements for laboratories are equal to, or more stringent than, the condition-level requirements for laboratories.

(b) The organization's or State's inspection process to determine the comparability of the full inspection and complaint inspection procedures and

requirements to those of HCFA, including, but not limited to, inspection frequency and the ability to investigate and respond to complaints against its laboratories.

(c) The organization's or State's agreement with HCFA that requires it to do the following:

(1) Notify HCFA within 30 days of the action taken, of any laboratory that has—

(i) Had its accreditation or licensure suspended, withdrawn, revoked, or limited;

(ii) In any way been sanctioned; or

(iii) Had any adverse action taken against it.

(2) Notify HCFA within 10 days of any deficiency identified in an accredited or CLIA-exempt laboratory if the deficiency poses an immediate jeopardy to the laboratory's patients or a hazard to the general public.

(3) Notify HCFA, within 30 days, of all newly—

(i) Accredited laboratories (or laboratories whose areas of specialty/subspecialty testing have changed); or

(ii) Licensed laboratories, including the specialty/subspecialty areas of testing.

(4) Notify each accredited or licensed laboratory within 10 days of HCFA's withdrawal of the organization's deeming authority or State's exemption.

(5) Provide HCFA with inspection schedules, as requested, for validation purposes.

§ 493.557 Additional submission requirements.

(a) *Specific requirements for accreditation organizations.* In addition to the information specified in §§ 493.553 and 493.555, as part of the approval and review process, an accreditation organization applying or reapplying for deeming authority must also provide the following:

(1) The specialty or subspecialty areas for which the organization is requesting deeming authority and its mechanism for monitoring compliance with all requirements equivalent to condition-level requirements within the scope of the specialty or subspecialty areas.

(2) A description of the organization's data management and analysis system

with respect to its inspection and accreditation decisions, including the kinds of routine reports and tables generated by the systems.

(3) Detailed information concerning the inspection process, including, but not limited to the following:

(i) The size and composition of individual accreditation inspection teams.

(ii) Qualifications, education, and experience requirements that inspectors must meet.

(iii) The content and frequency of training provided to inspection personnel, including the ability of the organization to provide continuing education and training to inspectors.

(4) Procedures for removal or withdrawal of accreditation status for laboratories that fail to meet the organization's standards.

(5) A proposed agreement between HCFA and the accreditation organization with respect to the notification requirements specified in § 493.555(c).

(6) Procedures for monitoring laboratories found to be out of compliance with its requirements. (These monitoring procedures must be used only when the accreditation organization identifies noncompliance. If noncompliance is identified through validation inspections, HCFA or a HCFA agent monitors corrections, as authorized at § 493.565(d)).

(7) A demonstration of its ability to provide HCFA with electronic data and reports in compatible code, including the crosswalk specified in § 493.553(a)(1), that are necessary for effective validation and assessment of the organization's inspection process.

(8) A demonstration of its ability to provide HCFA with electronic data, in compatible code, related to the adverse actions resulting from PT results constituting unsuccessful participation in PT programs as well as data related to the PT failures, within 30 days of the initiation of adverse action.

(9) A demonstration of its ability to provide HCFA with electronic data, in compatible code, for all accredited laboratories, including the area of specialty or subspecialty.

(10) Information defining the adequacy of numbers of staff and other resources.

(11) Information defining the organization's ability to provide adequate funding for performing required inspections.

(12) Any facility-specific data, upon request by HCFA, which includes, but is not limited to, the following:

(i) PT results that constitute unsuccessful participation in a HCFA-approved PT program.

(ii) Notification of the adverse actions or corrective actions imposed by the accreditation organization as a result of unsuccessful PT participation.

(13) An agreement to provide written notification to HCFA at least 30 days in advance of the effective date of any proposed change in its requirements.

(14) An agreement to disclose any laboratory's PT results upon reasonable request by any person.

(b) *Specific requirements for a State licensure program.* In addition to requirements in §§ 493.553 and 493.555, as part of the approval and review process, when a State licensure program applies or reapplies for exemption from the CLIA program, the State must do the following:

(1) Demonstrate to HCFA that it has enforcement authority and administrative structures and resources adequate to enforce its laboratory requirements.

(2) Permit HCFA or a HCFA agent to inspect laboratories in the State.

(3) Require laboratories in the State to submit to inspections by HCFA or a HCFA agent as a condition of licensure or approval.

(4) Agree to pay the cost of the validation program administered in that State as specified in §§ 493.645(a) and 493.646(b).

(5) Take appropriate enforcement action against laboratories found by HCFA not to be in compliance with requirements equivalent to CLIA requirements.

(6) Submit for Medicare and Medicaid payment purposes, a list of the specialties and subspecialties of tests performed by each laboratory.

(7) Submit a written presentation that demonstrates the agency's ability to furnish HCFA with electronic data in compatible code, including the crosswalk specified in § 493.553(a)(1).

(8) Submit a statement acknowledging that the State will notify HCFA

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through electronic transmission of the following:

(i) Any laboratory that has had its licensure or approval revoked or withdrawn or has been in any way sanctioned by the State within 30 days of taking the action.

(ii) Changes in licensure or inspection requirements.

(iii) Changes in specialties or subspecialties under which any licensed laboratory in the State performs testing.

(9) Provide information for the review of the State's enforcement procedures for laboratories found to be out of compliance with the State's requirements.

(10) Submit information that demonstrates the ability of the State to provide HCFA with the following:

(i) Electronic data and reports in compatible code with the adverse or corrective actions resulting from PT results that constitute unsuccessful participation in PT programs.

(ii) Other data that HCFA determines are necessary for validation and assessment of the State's inspection process requirements.

(11) Agree to provide HCFA with written notification of any changes in its licensure/approval and inspection requirements.

(12) Agree to disclose any laboratory's PT results in accordance with a State's confidentiality requirements.

(13) Agree to take the appropriate enforcement action against laboratories found by HCFA not to be in compliance with requirements comparable to condition-level requirements and report these enforcement actions to HCFA.

(14) If approved, reapply to HCFA every 2 years to renew its exempt status and to renew its agreement to pay the cost of the HCFA-administered validation program in that State.

§ 493.559 Publication of approval of deeming authority or CLIA exemption.

(a) *Notice of deeming authority or exemption.* HCFA publishes a notice in the FEDERAL REGISTER when it grants deeming authority to an accreditation organization or exemption to a State licensure program.

(b) *Contents of notice.* The notice includes the following:

(1) The name of the accreditation organization or State licensure program.

(2) For an accreditation organization:

(i) The specific specialty or subspecialty areas for which it is granted deeming authority.

(ii) A description of how the accreditation organization provides reasonable assurance to HCFA that a laboratory accredited by the organization meets CLIA requirements equivalent to those in this part and would meet CLIA requirements if the laboratory had not been granted deemed status, but had been inspected against condition-level requirements.

(3) For a State licensure program, a description of how the laboratory requirements of the State are equal to, or more stringent than, those specified in this part.

(4) The basis for granting deeming authority or exemption.

(5) The term of approval, not to exceed 6 years.

§ 493.561 Denial of application or re-application.

(a) *Reconsideration of denial.* (1) If HCFA denies a request for approval, an accreditation organization or State licensure program may request, within 60 days of the notification of denial, that HCFA reconsider its original application or application for renewal, in accordance with part 488, subpart D.

(2) If the accreditation organization or State licensure program requests a reconsideration of HCFA's determination to deny its request for approval or reapproval, it may not submit a new application until HCFA issues a final reconsideration determination.

(b) *Resubmittal of a request for approval— accreditation organization.* An accreditation organization may resubmit a request for approval if a final reconsideration determination is not pending and the accreditation program meets the following conditions:

(1) It has revised its accreditation program to address the rationale for denial of its previous request.

(2) It demonstrates that it can provide reasonable assurance that its accredited facilities meet condition-level requirements.