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 laboratory’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 a notification of the actions taken by the organization as a result of the 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.

(c) Withdrawal of laboratory accreditation. After an accreditation organization has withdrawn or revoked its accreditation of a laboratory, the laboratory must provide the following information:

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 laboratory’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 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.

6. Authorize its accreditation organization to release to HCFA a notice 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 must provide the following information:

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 laboratory’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 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 must provide the following information:

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 laboratory’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 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 must provide the following information:

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 laboratory’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 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 must provide the following information:

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 laboratory’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 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 must provide the following information:
§ 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) Reaccredited laboratories (or laboratories whose areas of specialty/subspecialty testing have changed).

§ 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
§ 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.

(iii) 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:
§ 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 reapplication.

(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.

(3) It resubmits the application in its entirety.

(c) Resubmittal of request for approval—State licensure program. The State licensure program may resubmit a request for approval if a final reconsideration determination is not pending and it has taken the necessary action to address the rationale for any previous denial.

§ 493.563 Validation inspections—Basis and focus.

(a) Basis for validation inspection—Laboratory with a certificate of accreditation. (1) HCFA or a HCFA agent may conduct an inspection of an accredited laboratory that has been issued a certificate of accreditation on a representative sample basis or in response to a substantial allegation of noncompliance.

(2) HCFA uses the results of these inspections to validate the accreditation organization’s accreditation process.

(b) Laboratory in a State with an approved State licensure program. (1) HCFA or a HCFA agent may conduct an inspection of any laboratory in a State with an approved State licensure program on a representative sample basis or in response to a substantial allegation of noncompliance.

(ii) The results of these inspections are used to validate the appropriateness of the exemption of that State’s licensed or approved laboratories from CLIA program requirements.

(b) Validation inspection conducted on a representative sample basis. (1) If HCFA or a HCFA agent conducts a validation inspection on a representative sample basis, the inspection is comprehensive, addressing all condition-level requirements, or it may be focused on a specific condition-level requirement.

(2) The number of laboratories sampled is sufficient to allow a reasonable estimate of the performance of the accreditation organization or State.

(c) Validation inspection conducted in response to a substantial allegation of noncompliance. (1) If HCFA or a HCFA agent conducts a validation inspection in response to a substantial allegation of noncompliance, the inspection focuses on any condition-level requirement that HCFA determines to be related to the allegation.

(2) If HCFA or a HCFA agent substantiates a deficiency and determines that the laboratory is out of compliance with any condition-level requirement, HCFA or a HCFA agent conducts a full CLIA inspection.

(d) Inspection of operations and offices. As part of the validation review process, HCFA may conduct an onsite inspection of the operations and offices to verify the following:

(1) The accreditation organization’s representations and to assess the accreditation organization’s compliance with its own policies and procedures.

(2) The State’s representations and to assess the State’s compliance with its own policies and procedures, including verification of State enforcement actions taken on the basis of validation inspections performed by HCFA or a HCFA agent.

(e) Onsite inspection of an accreditation organization. An onsite inspection of an accreditation organization may include, but is not limited to, the following:

(1) A review of documents.
(2) An audit of meetings concerning the accreditation process.
(3) Evaluation of accreditation inspection results and the accreditation decision-making process.
(4) Interviews with the accreditation organization’s staff.
(f) Onsite inspection of a State licensure program. An onsite inspection of a State licensure program office may include, but is not limited to, the following:
(1) A review of documents.
(2) An audit of meetings concerning the licensure or approval process.
(3) Evaluation of State inspection results and the licensure or approval decision-making process.
(4) Interviews with State employees.
§ 493.565 Selection for validation inspection—laboratory responsibilities.
A laboratory selected for a validation inspection must do the following:
(a) Authorize its accreditation organization or State licensure program, as applicable, to release to HCFA or a HCFA agent, on a confidential basis, a copy of the laboratory’s most recent full, and any subsequent partial inspection.
(b) Authorize HCFA or a HCFA agent to conduct a validation inspection.
(c) Provide HCFA or a HCFA agent with access to all facilities, equipment, materials, records, and information that HCFA or a HCFA agent determines have a bearing on whether the laboratory is being operated in accordance with the requirements of this part, and permit HCFA or a HCFA agent to copy material or require the laboratory to submit material.
(d) If the laboratory possesses a valid certificate of accreditation, authorize HCFA or a HCFA agent to monitor the correction of any deficiencies found through the validation inspection.
§ 493.567 Refusal to cooperate with validation inspection.
(a) Laboratory with a certificate of accreditation. (1) A laboratory with a certificate of accreditation that refuses to cooperate with a validation inspection by failing to comply with the requirements in §493.565—
(i) Is subject to full review by HCFA or a HCFA agent, in accordance with this part; and
(ii) May be subject to suspension, revocation, or limitation of its certificate of accreditation under this part.
(2) A laboratory with a certificate of accreditation is again deemed to meet the condition-level requirements by virtue of its accreditation when the following conditions exist:
(i) The laboratory withdraws any prior refusal to authorize its accreditation organization to release a copy of the laboratory’s current accreditation inspection, PT results, or notification of any adverse actions resulting from PT failure.
(ii) The laboratory withdraws any prior refusal to allow a validation inspection.
(iii) HCFA finds that the laboratory meets all the condition-level requirements.
(b) CLIA-exempt laboratory. If a CLIA-exempt laboratory fails to comply with the requirements specified in §493.565, HCFA notifies the State of the laboratory’s failure to meet the requirements.
§ 493.569 Consequences of a finding of noncompliance as a result of a validation inspection.
(a) Laboratory with a certificate of accreditation. If a validation inspection results in a finding that the accredited laboratory is out of compliance with one or more condition-level requirements, the laboratory is subject to—
(1) The same requirements and survey and enforcement processes applied to laboratories that are not accredited and that are found out of compliance following an inspection under this part; and
(2) Full review by HCFA, in accordance with this part; that is, the laboratory is subject to the principal and alternative sanctions in §493.1806.
(b) CLIA-exempt laboratory. If a validation inspection results in a finding that a CLIA-exempt laboratory is out of compliance with one or more condition-level requirements, HCFA directs the State to take appropriate enforcement action.
§ 493.571 Disclosure of accreditation, State and HCFA validation inspection results.

(a) Accreditation organization inspection results. HCFA may disclose accreditation organization inspection results to the public only if the results are related to an enforcement action taken by the Secretary.

(b) State inspection results. Disclosure of State inspection results is the responsibility of the approved State licensure program, in accordance with State law.

(c) HCFA validation inspection results. HCFA may disclose the results of all validation inspections conducted by HCFA or its agent.

§ 493.573 Continuing Federal oversight of private nonprofit accreditation organizations and approved State licensure programs.

(a) Comparability review. In addition to the initial review for determining equivalency of specified organization or State requirements to the comparable condition-level requirements, HCFA reviews the equivalency of requirements in the following cases:

(1) When HCFA promulgates new condition-level requirements.

(2) When HCFA identifies an accreditation organization or a State licensure program whose requirements are no longer equal to, or more stringent than, condition-level requirements.

(3) When an accreditation organization or State licensure program adopts new requirements.

(4) When an accreditation organization or State licensure program adopts changes to its inspection process, as required by § 493.575(b)(1), as applicable.

(5) Every 6 years, or sooner if HCFA determines an earlier review is required.

(b) Validation review. Following the end of a validation review period, HCFA evaluates the validation inspection results for each approved accreditation organization and State licensure program.

(c) Reapplication procedures. (1) Every 6 years, or sooner, as determined by HCFA, an approved accreditation organization must reapply for continued approval of deeming authority and a State licensure program may reapply for continued approval of a CLIA exemption. HCFA provides notice of the materials that must be submitted as part of the reapplication procedure.

(2) An accreditation organization or State licensure program that does not meet the requirements of this subpart, as determined through a comparability or validation review, must furnish HCFA, upon request, with the reapplication materials HCFA requests. HCFA establishes a deadline by which the materials must be submitted.

(d) Notice. (1) HCFA provides written notice, as appropriate, to the following:

(i) An accreditation organization indicating that its approval may be in jeopardy if a comparability or validation review reveals that it is not meeting the requirements of this subpart and HCFA is initiating a review of the accreditation organization's deeming authority.

(ii) A State licensure program indicating that its CLIA exemption may be in jeopardy if a comparability or validation review reveals that it is not meeting the requirements of this subpart and that a review is being initiated of the CLIA exemption of the State's laboratories.

(2) The notice contains the following information:

(i) A statement of the discrepancies that were found as well as other related documentation.

(ii) An explanation of HCFA's review process on which the final determination is based and a description of the possible actions, as specified in § 493.575, that HCFA may impose based on the findings from the comparability or validation review.

(iii) A description of the procedures available if the accreditation organization or State licensure program, as applicable, desires an opportunity to explain or justify the findings made during the comparability or validation review.

(iv) The reapplication materials that the accreditation organization or State licensure program must submit and the deadline for that submission.
§ 493.575 Removal of deeming authority or CLIA exemption and final determination review.

(a) HCFA review. HCFA conducts a review of the following:

(1) A deeming authority review of an accreditation organization’s program if the comparability or validation review produces findings, as described at § 493.573. HCFA reviews, as appropriate, the criteria described in §§ 493.555 and 493.557(a) to reevaluate whether the accreditation organization continues to meet all these criteria.

(2) An exemption review of a State’s licensure program if the comparability or validation review produces findings, as described at § 493.573. HCFA reviews, as appropriate, the criteria described in §§ 493.555 and 493.557(b) to reevaluate whether the licensure program continues to meet all these criteria.

(3) A review of an accreditation organization or State licensure program, at HCFA’s discretion, if validation review findings, irrespective of the rate of disparity, indicate widespread or systematic problems in the organization’s accreditation or State’s licensure process that provide evidence that the requirements, taken as a whole, are no longer equivalent to CLIA requirements, taken as a whole.

(4) A review of the accreditation organization or State licensure program whenever validation inspection results indicate a rate of disparity of 20 percent or more between the findings of the organization or State and those of HCFA or a HCFA agent for the following periods:

(i) One year for accreditation organizations.

(ii) Two years for State licensure programs.

(b) HCFA action after review. Following the review, HCFA may take the following action:

(1) If HCFA determines that the accreditation organization or State has failed to adopt requirements equal to, or more stringent than, CLIA requirements, HCFA may give a conditional approval for a probationary period of its deeming authority to an organization 30 days following the date of HCFA’s determination, or exempt status to a State within 30 days of HCFA’s determination, both not to exceed 1 year, to afford the organization or State an opportunity to adopt equal or more stringent requirements.

(2) If HCFA determines that there are widespread or systematic problems in the organization’s or State’s inspection process, HCFA may give conditional approval during a probationary period, not to exceed 1 year, effective 30 days following the date of the determination.

(c) Final determination. HCFA makes a final determination as to whether the organization or State continues to meet the criteria described in this subpart and issues a notice that includes the reasons for the determination to the organization or State within 60 days after the end of any probationary period. This determination is based on an evaluation of any of the following:

(1) The most recent validation inspection and review findings. To continue to be approved, the organization or State must meet the criteria of this subpart.

(2) Facility-specific data, as well as other related information.

(3) The organization’s or State’s inspection procedures, surveyors’ qualifications, ongoing education, training, and composition of inspection teams.

(4) The organization’s accreditation requirements, or the State’s licensure or approval requirements.

(d) Date of withdrawal of approval. HCFA may withdraw its approval of the accreditation organization or State licensure program, effective 30 days from the date of written notice to the organization or State of this proposed action, if improvements acceptable to HCFA have not been made during the probationary period.

(e) Continuation of validation inspections. The existence of any validation review, probationary status, or any other action, such as a deeming authority review, by HCFA does not affect or limit the conduct of any validation inspection.

(f) Federal Register notice. HCFA publishes a notice in the Federal Register containing a justification for removing the deeming authority from an accreditation organization, or the CLIA-exempt status of a State licensure program.
§ 493.602 Scope of subpart.

The rules of this subpart are applicable to those laboratories specified in §493.3.

§ 493.606 Applicability of subpart.

The rules of this subpart are applicable to those laboratories specified in §493.3.

§ 493.638 Certificate fees.

(a) Basic rule. Laboratories must pay a fee for the issuance of a registration certificate, certificate for PPM procedures, certificate of waiver, certificate of accreditation, or a certificate of compliance, as applicable. Laboratories must also pay a fee to reapply for a certificate for PPM procedures, certificate of waiver, certificate of accreditation, or a certificate of compliance. The total of fees collected by HHS under the laboratory program must be...