

§ 493.555

42 CFR Ch. IV (10–1–04 Edition)

(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 re-application.* 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 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) CMS notifies the accreditation organization or State licensure program indicating whether CMS approves or denies the request for deeming authority or exemption, respectively, and the rationale for any denial.

(c) *Duration of approval.* CMS 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.

CMS'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 CMS, including, but not limited to, inspection fre-

quency and the ability to investigate and respond to complaints against its laboratories.

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

(1) Notify CMS 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(i) Had its accreditation or licensure suspended, withdrawn, revoked, or limited;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 CMS 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 CMS, 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 CMS's withdrawal of the organization's deeming authority or State's exemption.

(5) Provide CMS 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