Estimated Burden Hours Per Respondent/Recordkeeper:

Recordkeeping—7 hours, 39 minutes
Learning about the law or the form—35 minutes
Preparing and sending the form to the IRS—45 minutes

Frequency of Response: Annually.

Estimated Total Reporting/Recordkeeping Burden: 899 hours.

Clearance Officer: Garrick Shear (202) 535–4297, Internal Revenue Service, Room 5571, 1111 Constitution Avenue, NW. Washington, DC 20224.

OMB Reviewer: Milo Sunderhauf (202) 395–6880, Office of Management and Budget, Room 3001, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Department Reports, Management Officer.

[FR Doc. 92–18150 Filed 7–30–92; 8:45 am]

BILLING CODE 4830–01–M

Bureau of Engraving and Printing

Privacy Act of 1974; Amendment to Existing System of Records Notice

AGENCY: Bureau of Engraving and Printing, Treasury.

ACTION: Notice of Amendment to Privacy Act System of Records Notice, Treasury/BEP .021.

SUMMARY: The Bureau of Engraving and Printing (BEP) is making several amendments to the description of an existing system of records, Treasury/BEP .021, Investigative Files, to reflect: (1) The automation of the system of records; and (2) a change in the retention schedule of two categories of records.

EFFECTIVE DATE: This notice will be adopted without further publication in the **Federal Register** on August 31, 1992, unless modified by a subsequent notice to incorporate comments received from the public.

FOR FURTHER INFORMATION CONTACT: Lawrence F. Zenker, Disclosure Officer, Bureau of Engraving and Printing, Room 321–12A, 14th and C Streets, SW., Washington, DC 20228, Telephone: (202) 874–2687.

SUPPLEMENTARY INFORMATION: In accordance with the Privacy Act of 1974, the Department of the Treasury reviewed all Privacy Act systems of records and published all systems notices on April 17, 1992. This publication affects only the notice for the system maintained by the Bureau of Engraving and Printing, Treasury/BEP .021.

Treasury/BEP .021, Investigative Files, is being amended to reflect that the system has been automated. As a consequence, changes are reflected in the storage description for this system. Additionally, changes have been made under "Retention and Disposal" because the retention schedule for this system of records has been increased.

* * * * *

Treasury/BEP .021

SYSTEM NAME:

Investigative Files—Treasury/BEP.

* * * * *

STORAGE:

File Folders, 3x5 Index Cards, 5x8 Index Cards, Loose-Leaf Binders, Ledgers, Recording tape, Computer Database Programs, and Microfiche.

* * * * *

RETENTION AND DISPOSAL:

Destroyed within 90 days following notification of an employee's death, or, within five years after separation or transfer of incumbent employee; or, five years after expiration of contractual relationship. Product Discrepancy Investigative Reports and Bank Letter Investigative Reports are retained indefinitely.

* * * * *

Dated: July 23, 1992.

David M. Nummy,

Assistant Secretary (Management).

[FR Doc. 92–18151 Filed 7–30–92; 8:45 am]

BILLING CODE 4840–01–M

Internal Revenue Service

Tax Counseling for the Elderly (TCE) Program; Availability of Application Packages

AGENCY: Internal Revenue Service, Treasury.

ACTION: Availability of TCE application packages.

SUMMARY: This document provides notice of the availability of application Packages for the 1993 Tax Counseling for the Elderly (TCE) Program.

DATES: Application packages are available from the IRS at this time. The deadline for submitting an application package to the IRS for the 1993 Tax Counseling for the Elderly (TCE) Program is September 8, 1992.

ADDRESSES: Application Packages may be requested by contacting: Program Manager, Tax Counseling for the Elderly Program. Internal Revenue Service Management and Operations Branch (T:T:M) 1111 Constitution Ave., NW., room 7207, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Ms. Karen Haag, Management and Operations Branch (T:T:M) room 7207, Internal Revenue Service, 1111 Constitution Ave., NW., room 7207, Washington, DC 20224. The non-toll-free telephone number is: (202) 622–7664.

SUPPLEMENTARY INFORMATION: Authority for the Tax Counseling for the Elderly (TCE) Program is contained in section 163 of the Revenue Act of 1978, Pub. L. No. 95–600, 92 Stat. 12810, November 6, 1978. Regulations were published in the **Federal Register** at 44 72113 on December 13, 1979. Section 163 gives the Internal Revenue Service authority to enter into cooperative agreements with private or public non-profit agencies or organizations to establish a network of trained volunteers to provide free tax information and return preparation assistance to elderly individuals. Elderly individuals are defined as individual age 60 and over at the close of their taxable year.

Cooperative agreements will be entered into based upon competition among eligible agencies and organizations. Because applications are being solicited before the FY 1993 budget has been approved, cooperative agreements will be entered into subject to appropriation of funds. Once funded, sponsoring agencies and organizations will receive a grant from the IRS for administrative expenses and to reimburse volunteers for expenses incurred in training and in providing tax return assistance. The Tax Counseling for the Elderly (TCE) Program is referenced in the Catalog of Federal Domestic Assistance in § 21.006.

John J. Mannion,

Chief, Management and Operations Branch.

[FR Doc. 92–18059 Filed 7–30–92; 8:45 am]

BILLING CODE 4830–01–M

Sunshine Act Meetings

Federal Register
Vol. 57, No. 148
Friday, July 31, 1992

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Agency Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 10:33 a.m. on Tuesday, July 28, 1992, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider the following:

Matters relating to the probable failure of certain insured banks.

Recommendations concerning administrative enforcement proceedings.

Recommendation regarding the liquidation of a depository institution's assets acquired by the Corporation in its capacity as receiver, liquidator, or liquidating agent of those assets:

Case No. 47,818—Silverado Banking, Savings and Loan Association, Denver Colorado

Matters relating to the Corporation's supervisory activities.

In calling the meeting, the Board determined, on motion of Director C.C. Hope, Jr. (Appointive), seconded by Chairman William Taylor, and concurred in by Director Stephen R. Steinbrink (Acting Comptroller of the Currency), Vice Chairman Andrew C. Hove, Jr., and Director T. Timothy Ryan, Jr. (Office of Thrift Supervision), that Corporation business required its consideration of the matters on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), (c)(9)(B), and (c)(10) of the "Government in the sunshine Act" (5 U.S.C. 552b(c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), (c)(9)(B), and (c)(10)).

The meeting was held in the Board Room of the FDIC Building located at 550-17th Street, N.W., Washington, D.C.

Dated: July 28, 1992.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Deputy Executive Secretary.

[FR Doc. 92-18239 Filed 7-29-92; 10:05 am]

BILLING CODE 6714-01-M

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

TIME AND DATE: 10:00 a.m., Tuesday, August 4, 1992.

PLACE: Room 600, 1730 K Street, NW, Washington, DC.

STATUS: Open.

MATTERS TO BE CONSIDERED: The Commission will consider and act upon the following:

1. *Island Creek Coal Co. v. Roy Farmer et al,* Docket No. VA 91-31-C (Issues include whether the judge erred in concluding that Roy Farmer had good cause for filing out of time a complaint for compensation brought under 30 U.S.C. § 821.)

Any person attending this meeting who requires special accessibility features and/or auxiliary aids, such as sign language interpreters, must inform the Commission in advance of those needs. Subject to 29 CFR § 2706.150(a)(3) and § 2706.160(e).

CONTACT PERSON FOR MORE INFO: Jean Ellen (202) 653-5629/(202) 708-9300 for TDD Relay/1-800-877-8339 for toll free.

Dated: July 28, 1992.

Jean H. Ellen,

Agenda Clerk.

[FR Doc. 92-18325 Filed 7-29-92; 3:05 am]

BILLING CODE 6735-01-M

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

TIME AND DATE: 10:00 a.m., Wednesday, August 5, 1992.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, N.W., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED.

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any time carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204. You may call (202) 452-3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: July 29, 1992.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 92-18244 Filed 7-29-92; 10:23am]

BILLING CODE 6210-01-M

federal register

Friday
July 31, 1992

Part II

Department of Health and Human Services

Health Care Financing Administration

42 CFR Part 493 and 498

Clinical Laboratories Improvement Act Program; Accreditation and Exemption; Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 493 and 498

[HSQ-181-F]

RIN 0938-AE62

Clinical Laboratories Improvement Act Program; Granting and Withdrawal of Deeming Authority to Private Nonprofit Accreditation Organizations and of CLIA Exemption Under State Laboratory Programs

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: This rule permits HCFA to approve or disapprove accreditation organizations and State laboratory programs and thereby determine that laboratories accredited by a HCFA-approved private, nonprofit accreditation organization are deemed to meet the requirements set forth in 42 CFR part 493 of the regulations, which implement section 353 of the Public Health Service Act (PHSA) or, in the case of State laboratory programs, are exempt from the requirements. Section 353 of the PHSA was enacted by the Clinical Laboratories Improvement Act of 1967 (CLIA '67) and was amended by the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

EFFECTIVE DATE: This rule is effective August 31, 1992, except for the definitions of "accredited laboratory", "CLIA-exempt laboratory", and "HCFA agent", found in § 493.2, which will be effective on September 2, 1992.

FOR FURTHER INFORMATION, CONTACT: Irene Gibson, (410) 966-6768.

SUPPLEMENTARY INFORMATION:

Background

Under section 353 of the Public Health Service Act (PHSA), as enacted by the Clinical Laboratories Improvement Act of 1967 (CLIA '67), laboratories engaged in testing specimens in interstate commerce had to meet Federal requirements established under the CLIA '67 program in order to become or remain licensed to engage in interstate commerce. HCFA established the requirements, called "conditions," and standards, and was responsible for assuring that they were met. The Federal conditions under the CLIA program for granting licenses to laboratories were similar to the conditions of participation or for coverage that a laboratory had to meet in order to participate in Medicare or Medicaid. Each condition was usually comprised of one or more standards, which enumerated activities, outcomes, or other requirements that, upon evaluation by HCFA, its agents, or a State survey agency under contract with HCFA, served as the basis for determining compliance with a particular condition. If the laboratory failed to comply with any CLIA condition, we initiated an adverse action to revoke, suspend or limit the laboratory's CLIA license.

Section 353(d)(2) of the PHSA, as enacted by CLIA '67, stated that the provisions of section 353 requiring licensing did not apply to a laboratory in a hospital accredited by the Joint Commission on the Accreditation of Hospitals, later renamed the Joint Commission on the Accreditation of Healthcare Organizations (Joint Commission), or the American Osteopathic Association (AOA), or to an interstate laboratory inspected or accredited by either the Commission on Inspection and Accreditation of the College of American Pathologists (CAP) or by any other accreditation organization approved by the Secretary for this purpose. The accreditation standards applied by these organizations had to be equal to or more stringent than the requirements of section 353 and the regulations implementing it. In addition, there had to be adequate provision for assuring that the standards continued to be met by each accredited laboratory of a given accreditation organization. Section 353(l) of the PHSA, as enacted by CLIA '67, provided that where a State had enacted laws that set forth standards equal to or more stringent than the provisions of Section 353 or the regulations under that section, the Secretary could exempt laboratories in that State from compliance with that section.

HCFA, with the necessary scientific and technical support as needed from the Centers for Disease Control and the Food and Drug Administration of the Public Health Service (PHS), administers the CLIA program for HHS.

Three significant events occurred affecting clinical laboratories, both under the CLIA program and under Medicare and Medicaid. First, on October 31, 1988, Pub. L. 100-578, the Clinical Laboratory Improvement Amendments of 1988 (CLIA), was enacted. CLIA made every laboratory in the country that tests human specimens for health reasons subject to Federal regulation whether or not it participates in the Medicare or Medicaid program and whether or not it tests specimens in interstate commerce. CLIA also established test complexity as the basis for evaluating satisfactory performance in laboratory testing. (See discussion below under "Legislation".) Second, on March 14, 1990, we published in the **Federal Register** (55 FR 9538) final rules that consolidated and recodified regulations for the Medicare and Medicaid programs and for interstate laboratories into a new 42 CFR part 493. These rules were effective September 10, 1990. As of that date we have a single set of regulations for laboratories that are subject to Medicare or Medicaid or that test specimens in interstate commerce.

Third, on February 28, 1992 we published in the **Federal Register** (57 FR 7002) final rules that establish the performance requirements that laboratories must meet in order to be certified by HHS as in compliance with CLIA requirements and that supersede the March 14, 1990 regulations. With certain exceptions, the performance requirements are effective September 1, 1992.

Legislation

As stated earlier, on October 31, 1988, Congress enacted the Clinical Laboratory Improvement Amendments of 1988, which replaced in its entirety Section 353 of the PHSA. CLIA continues to provide for the accreditation of laboratories by accreditation organizations or exemption of laboratories from CLIA requirements when States apply requirements equal to or more stringent than the **Federal Register** requirements. These subsections were effective January 1, 1990. The content of the current CLIA provision concerning State licensure remains the same as under CLIA '67; however, the accreditation provision is much more detailed.

Section 353(e) states that a laboratory may be accredited for purposes of obtaining a CLIA certificate if the laboratory meets the standards of an approved accreditation organization and authorizes the organization to submit to the Secretary, State agency, or other designated HCFA agent, records or other information the Secretary requires.

According to the statute at section 353(e), the Secretary may approve a private, nonprofit organization for the accreditation of laboratories if the accreditation organization—

• Agrees to inspect a laboratory for purposes of accreditation at a frequency determined by the Secretary, using inspectors qualified to evaluate laboratory methodologies used in the performance of laboratory examinations and other test procedures;

• Applies standards equal to or more stringent than the standards issued by the Secretary in determining whether or not to accredit a laboratory;

• Provides adequate assurance that the standards of the accreditation organization continue to be met by the laboratories it accredits;

• Agrees to submit to the Secretary the name of any laboratory accredited by the organization that has had its accreditation denied, suspended, withdrawn, or revoked or that has had any other adverse action taken against it by the accreditation organization within 30 days of the action taken;

• Agrees to notify the Secretary at least 30 days before it changes its standards; and

• Agrees to notify each laboratory accredited by the organization within 10 days of a decision by the Secretary to withdraw his or her approval of the accreditation organization.

CLIA requires the Secretary to promulgate criteria and procedures for approving an accreditation organization and for withdrawing approval if it is determined that the accreditation organization does not meet Federal requirements. The statute does not specifically require the promulgation of specific criteria for the exemption of laboratories in a State. The decision whether or not to exempt all laboratories in a State from CLIA is discretionary with the Secretary.

Under CLIA, if the Secretary withdraws the approval of an accreditation organization, the certificate of any laboratory accredited by the organization continues in effect for 60 days after the laboratory receives notification of the withdrawal of the approval. The Secretary may extend the period for an additional period of time (which we have specified to be 60 days) if the laboratory submits to HCFA in a timely manner an application for accreditation by another accreditation organization or an application for a CLIA certificate based on an inspection for compliance with CLIA conditions by the State agency or other HCFA agent.

Under CLIA, if an accreditation organization withdraws or revokes the accreditation of a laboratory, the certificate of the laboratory will continue in effect—

• For 45 days after the laboratory receives notice of the withdrawal or revocation of the accreditation, or

• Until the effective date of any action taken by the Secretary under section 353(i) of the PHSA.

The performance of each approved accreditation organization or licensure agency is to be evaluated by HCFA annually. A sufficient number of accredited or licensed laboratories is to be inspected to allow a reasonable estimate of the performance of that organization.

The Secretary is to prepare and submit annually, to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate, a report that describes the results of the evaluations conducted under section 353(e)(2)(D) of the PHSA.

Proposed Revisions to the Regulations

On August 20, 1990, we published a proposed rule to implement sections 353(e) and 353(p) of the PHSA as amended by CLIA (55 FR 33936). We proposed to add a new subpart E to 42 CFR part 493 to implement these sections. We proposed to institute the same requirements for both private accreditation organizations and for State licensure agencies. Although the statute does not require us to judge both by the same standards, we stated that we do not believe that it is reasonable to use different standards, since both entities function to assure us that laboratories meet statutory requirements for health and safety. The proposed regulations, therefore, addressed granting exemptions to and removing exemptions from specific State licensure agencies and the laboratories they license and were based on the statutory framework provided for private nonprofit accreditation organizations. The rationale for this approach was that we believe Congress could not have intended to allow the Secretary to grant exemptions to State licensure agencies without applying objective criteria to the State licensure programs, or to allow the Secretary to grant initial approvals without periodically re-evaluating those approvals. Based on the premise of the necessity of objective periodic re-evaluation, we used the list of statutory criteria provided for accreditation organizations because it is comprehensive and, we believe, conducive to maintaining the integrity of the deeming/exemption programs.

A. Requirements for Accreditation and Licensure Organizations

We proposed to include a general section, § 493.501, that would state the basic premise of the subpart: if a private nonprofit accreditation organization or State licensure agency for laboratories provides reasonable assurance to us that it requires the laboratories it accredits or licenses to meet requirements equal to or more stringent than CLIA conditions, we may deem its laboratories to be in compliance with CLIA, Medicare and Medicaid condition-level requirements. In new § 493.507, we would require that the laboratories be subject to validation inspections (surveys) performed by HCFA or its designee (see discussion on § 493.507) and authorize their accreditation organization or licensure agency to release to HCFA such records and reports as required by this regulation.

In § 493.503 we proposed to require each laboratory deemed to meet CLIA requirements under new subpart E to authorize its accreditation organization or State licensure agency to submit to us annually a copy of the laboratory's quarterly or semi-annual (if applicable) proficiency testing results for the purpose of establishing a system to make the proficiency testing results available, on a reasonable basis, upon request as required by section 353(f)(3) of CLIA. In case of a laboratory's failure to achieve successful participation in the proficiency testing program, the laboratory would be required to authorize its accreditation organization or State licensure agency to submit a report of test results to HCFA within 30 days of the notice of the failure. We would require submission of these results because section 353(f)(3) of CLIA requires that every laboratory issued a CLIA certificate must participate successfully in a proficiency testing program acceptable to HCFA for each specialty and subspecialty of test it performs. Failure to participate successfully or refusal to participate in a proficiency testing program would result in the laboratory's loss of deemed status and could possibly lead to suspension, revocation or limitation of the laboratory's CLIA certification if an inspection by a HCFA agent or the State survey agency found the laboratory's performance level warrants any of these actions.

In proposed § 493.504 we proposed to require that if an accreditation organization or licensure agency revokes or withdraws its accreditation or licensure from a laboratory, the certification would continue in effect until: (1) The effective date of a HCFA action to revoke, suspend, or limit a CLIA certificate or (2) 45 days after the laboratory receives notice of withdrawal or revocation of accreditation or licensure as required by the statute.

B. Definitions

In § 493.502, we proposed to define the following terms:

"Approved laboratory accreditation organization" would be defined as a

private, nonprofit accreditation organization or State licensure agency that has formally applied for and received HCFA's approval based on the organization's compliance with Federal requirements in accordance with this subpart.

"CLIA conditions" would mean the requirements laboratories must meet to receive a CLIA certificate.

"HCFA agent" would mean an entity other than the State survey agency with which HCFA may contract to perform inspections and review the functions of laboratories. A HCFA agent may be a professional organization, another component within HHS, or any other group that HCFA approves for this purpose.

"Rate of disparity" would mean the percent of validation inspections in which HCFA, the State survey agency or HCFA agent finds noncompliance with one or more conditions, but no comparable condition-level deficiencies were cited by the accreditation organization or licensure agency.

"State survey agency" would mean the State health agency or other appropriate State or local agency used by HCFA to perform inspections and review functions under CLIA.

"Substantial allegation" would mean a complaint from any of a variety of sources (including complaints submitted in person, by telephone, through written correspondence, or in newspaper or magazine articles) that reflects on the health and safety of individuals served by a laboratory and raises doubts as to a laboratory's compliance with any CLIA condition.

"Validation review period" would be the period after the end of a fiscal year during which HCFA conducts a review of the validation surveys for the previous fiscal year.

We also proposed to revise the definition in § 493.2 of "accredited laboratory" to delete the names of currently approved accreditation organizations and licensure agencies and to state simply that an accredited laboratory is one approved by an accreditation organization or licensure agency meeting the requirements of subpart E.

C. Approved Laboratory Accreditation and State Licensure Programs

In our proposed rule we noted that we had recently published a proposed rule (55 FR 20896, May 21, 1990) identifying regulatory requirements that laboratories would need to meet to satisfy CLIA requirements. Once those proposed requirements were included in an effective final rule, we intended to add a new section to subpart E to indicate that laboratories accredited or licensed by specified entities would be deemed to meet all CLIA conditions, with the exception of any requirement under section 353 of the PHSA that HCFA identifies in the future as being more stringent or more precise than the requirements of the accreditation organization or State licensure agency. The laboratory would not initially be deemed to meet the more stringent requirement(s), but would have to actually demonstrate that it meets these requirements.

We stated our intent to publish a notice in the **Federal Register** containing the name of each approved accreditation organization or State licensure agency and our basis for granting deeming authority to that accreditation or licensure organization. The notice would describe how the organization provides reasonable assurance to HCFA that laboratories accredited or licensed by the organization or agency meet CLIA requirements.

D. Federal Review of Accreditation Organizations and Licensure Agencies

We proposed to add § 493.506, outlining the process for Federal review and approval of accreditation organizations and licensure agencies. The regulations at § 493.506 would specify that HCFA's review of a private, nonprofit accreditation organization or State licensure agency will include, but not be limited to, an analysis of the following items.

HCFA would evaluate the equivalency of the requirements of the accreditation organization or State licensure agency to comparable HCFA requirements. In order to receive HCFA approval, each accreditation organization or State licensure agency would have to be able to demonstrate adequately that each of its requirements is as stringent as those of HCFA. We particularly invited comments regarding how accreditation organizations and State licensure agencies might be able to demonstrate that certain standards, although different from the Federal approach, are indeed equally as stringent as Federal CLIA requirements in terms of protecting individuals served by the laboratory. We also invited comments on the feasibility of the development of a comprehensive crosswalk by which to compare the standards of an accreditation organization or State licensure agency to those of HCFA. We would perform a detailed review of the accreditation or licensure organization's inspection process. Finally, we would assure that the organization's agreement provides for furnishing required services.

In reviewing the accreditation or licensure organization's inspection process, we would evaluate the following items:

- The composition of the inspection team, qualifications of the surveyors, and the ability of the organization to provide continuing education to surveyors in order to insure that the accreditation or licensure organization employs qualified surveyors who are able to perform accurate inspections, as required by section 353(e)(2)(A)(i) of the PHSA;
- The comparability of the comprehensive inspection and complaint inspection procedures of the accreditation organization or licensure agency, including those for routine inspection frequency as required by section 353(e)(2)(A)(ii) of the PHSA, to those of HCFA;
- The organization's or agency's procedures for monitoring laboratories to assure that the laboratories continue to meet its standards, as required by section 353(e)(2)(A)(iii) of the PHSA;
- The ability of the organization or agency to provide HCFA the necessary reports in electronic data in ASCII-comparable code, which can be electronically transmitted into the HCFA computer network, thus eliminating excess paperwork and staff time and facilitating the effective validation and assessment of the organization's inspection process as required by section 353(e)(2)(D) of the PHSA.
- The ability of the organization or agency to provide to HCFA annually reports of adverse actions resulting from PT results constituting unsuccessful participation in PT programs, and the PT failures within 30 days of the adverse action.
- The ability of the organization or agency to provide adequate funding to perform required inspections.

In assuring that the organization's or agency's agreement provides for furnishing all required services, we proposed to verify that it contain the following items. The organization or agency would agree to provide HCFA—

- Within 30 days of the action taken, the name of any laboratory accredited or licensed by the organization or State that has had its accreditation or State licensure denied, suspended, withdrawn, or revoked, or that has had any other adverse action taken against it by the organization. (This is not the same as suspension or revocation of a CLIA certificate, which are actions that can be taken by HCFA after a

laboratory's accreditation is suspended, withdrawn or revoked by the accreditation organization or if, after an inspection by the survey agency or other HCFA agent, the laboratory is found out of compliance with CLIA conditions and remains out of compliance.)

- As required by section 353 of the PHSA, documentation that each laboratory accredited or licensed by the organization or agency is notified within 10 days of HCFA's withdrawal of the recognition of the organization's deeming authority;
- An inspection schedule to facilitate the conducting of HCFA validation inspections; and
- Annually, facility-specific data to include but not be limited to the results of the laboratory's quarterly or semi-annual (if applicable) proficiency testing, except for the proficiency testing results of a laboratory that failed to achieve satisfactory results within 30 days of a notice of failure. This report could be incorporated within the report of the action taken by the accreditation organization or licensure agency resulting from the failure to achieve satisfactory proficiency testing results.

The regulations at § 493.501 would further provide for HCFA to publish a notice in the **Federal Register** containing the names of any private, nonprofit accreditation organization or State licensure agencies to which HCFA has given deeming authority, the basis for the granting of deeming authority to each organization, and a description of how each organization provides to HCFA reasonable assurance that laboratories accredited or licensed by each organization or agency meet CLIA requirements.

E. Validation Inspections

1. Basis for Inspection

We proposed at § 493.507 that we may require an inspection of an accredited laboratory by HCFA, its agents, or the State survey agency, in order to validate the process used by the laboratory's accreditation organization. We would inspect laboratories on a selective-sample basis or in response to substantial allegations of one or more deficiencies. Inspections conducted on a sample basis would be comprehensive, address all CLIA conditions, and be sufficient in number to allow a reasonable evaluation of the performance of each accreditation organization or State licensure agency. Inspections conducted in response to a substantial allegation of noncompliance would focus on any condition that HCFA determines is related to the allegation. If the State survey agency or other HCFA agent substantiates an allegation and HCFA determines that the laboratory is out of compliance with any CLIA condition, the State survey agency or other HCFA agent would conduct an inspection of all CLIA conditions.

Section 353(e)(2)(B) of the PHSA states that the Secretary shall promulgate criteria and procedures for approving an accreditation organization and for withdrawing approval of organizations that do not meet the requirements of Section 353(e)(2)(A) of PHSA. The validation process would establish the mechanism by which a determination is made that the accreditation organization no longer meets the requirements of Section 353(e)(2)(A) and that the approval of that organization's deeming authority should be withdrawn.

2. Effect of Selection for Inspection

The regulations at § 493.507(b) would specify the additional requirements for a laboratory selected for a validation inspection. The requirements would be consistent with the Secretary's statutory obligation to promulgate procedures for withdrawing the approval of an accreditation organization or State licensure agency and would be consistent with existing validation procedures applicable to accredited providers currently participating in the Medicare program under deemed status.

We proposed that a laboratory selected for a validation inspection must:

- Authorize its accreditation organization or licensure agency to release to HCFA, the State survey agency or designated HCFA agent, a copy of the laboratory's most recent full accreditation or licensure inspection, and any subsequent partial inspection;
- Authorize the validation inspection to take place at the facility; and
- Authorize HCFA, the State survey agency or any designated HCFA agent to monitor the correction of any deficiencies found through the validation inspection, to insure that they are corrected in a timely manner.

We proposed to require a copy of the laboratory's full inspection and any subsequent partial inspections for the purpose of comparing the findings of the accreditation organization or State licensure agency with those that HCFA may identify during the validation inspection. (The accreditation inspection would be disclosable to the public only if it is related to an enforcement action taken by the Secretary.)

3. Refusal to Cooperate with Inspection

We additionally proposed to require that if a laboratory selected for a validation inspection fails to provide the necessary authorizations for the validation inspection to be performed, it would no longer be deemed to meet CLIA conditions. This is because section 353(e)(1)(B) of the PHSA states that a laboratory may be accredited (deemed to meet CLIA conditions) if it, among other factors, authorizes the accreditation organization to submit to the Secretary required information. Failure to cooperate with the survey would either directly or indirectly result in a failure to provide necessary information to the Secretary and would result in a loss of deemed status. Instead, it would be subject to an inspection of all CLIA conditions by HCFA, the State survey agency or other designated HCFA agent in accordance with 42 CFR part 493, subpart N, and might also be subject to suspension, revocation, or limitation of its CLIA certificate as specified in the statute and in accordance with proposed § 493.1806 (April 2, 1991, 56 FR 13439) for failure to meet the requirements in part 493.

4. Consequences of the Finding of Noncompliance

We proposed at § 493.507(d) that if a validation inspection results in a finding that a laboratory is out of compliance with one or more CLIA conditions, the laboratory would no longer be deemed to be in compliance with CLIA conditions. Specifically, the laboratory would then be subject to the requirements at 42 CFR part 493 applied to laboratories that are not deemed under CLIA, and to a full review by HCFA, the State survey agency or other designated HCFA agent in accordance with 42 CFR part 493, subpart N. As authorized by the statute, the laboratory could also be subject to suspension, revocation, or limitation of its CLIA certificate as specified at § 493.1706.

5. Reinstatement

We proposed at § 493.507(e) that an accredited or State licensed laboratory would once again be deemed to meet CLIA conditions only if it withdraws any prior refusal to authorize its accreditation organization or licensure agency to release to HCFA a copy of its current accreditation or licensure inspection or notification of any adverse actions resulting from PT results, or withdraws any prior refusal to allow a validation inspection. Furthermore, HCFA, the survey agency, or other HCFA agent, via an onsite inspection and review of documentation, would

have to find the laboratory in compliance with all CLIA conditions.

F. Removal of HCFA Approval of Accreditation Organization's or Licensure Agency's Deeming Authority

The proposed regulations at §§ 493.509 and 493.511 would set forth specific criteria and procedures for removing the approval of a private, nonprofit accreditation organization or State licensure agency. The criteria and procedures would call for a review of the accreditation organization's or licensure agency's requirements to verify their comparability with HCFA and CLIA conditions. We would compare the results of the validation inspection with the most recent accreditation inspection to determine whether any disparities exist.

We would perform a deeming authority review whenever such review is warranted by our findings with respect to the comparability of requirements or the rate of disparity of findings. If our review indicated variance with our requirements, we could grant a conditional approval. If it indicated poor performance, we could provide for a probationary period of up to one year. At the end of the probationary period, the organization could keep its HCFA approval, or its approval could be withdrawn. If the deeming authority of an organization were no longer recognized, we would issue a notice in the **Federal Register** and allow accredited providers and suppliers opportunity to obtain HCFA certification. This proposed process is more fully discussed below.

1. Comparability Review (Section 493.509(a))

In addition to comparing the equivalency of an accreditation organization's accreditation requirements or a State licensure agency's licensing requirements to the comparable HCFA requirements when such an organization or agency applies for deeming authority or exemption from CLIA requirements, we also proposed to conduct a comparability review whenever new CLIA conditions are promulgated or an accreditation or licensure organization proposes to adopt new requirements. This would implement section 353(e)(2)(A)(ii) of the PHSA, which requires an accreditation organization's requirements to be equal to or more stringent than the requirements established by HCFA.

We would identify accreditation organizations and State licensure agencies whose procedures and requirements are not comparable with CLIA conditions, in order to safeguard physicians, laboratories, and the general public.

2. Validation Review (Section 493.509(b))

Following the end of a validation review period, we would identify any accreditation organizations or licensure agencies for which either or both of the following situations exist: (1) Validation inspection results indicate a rate of disparity of 20 percent or more between certifications of the accreditation organization or licensure agency and certifications of HCFA, the State survey agency or other HCFA agent; and (2) Validation inspection results over a period of two or more years indicate a pattern of increasing disparity between the certifications of the accreditation organization or licensure agency and certifications of HCFA, the State survey agency or other HCFA agent.

We solicited public comment regarding use of the 20 percent rate of disparity.

3. Notice (Section 493.509(c))

The regulations would specify that if the validation or comparability review finds that an accreditation organization or licensure agency is not meeting the requirements of this regulation, we would inform the organization in writing that its approval may be in jeopardy. The proposed notice would contain the following information:

- A statement identifying the CLIA requirements for which disparity was found, and the instance, rate, and patterns (if any) of the disparity;
- An explanation of the validation review on which our decision is based;
- A description of the procedures available for the organization to follow to explain or refute the findings of the validation review (that is, who to contact and the time frame for doing so); and
- A description of possible actions that may be imposed based on the findings of the validation review.

4. Deeming Authority Review (Section 493.511)

We would conduct a deeming authority review of an accreditation organization or licensure agency if the comparability or validation review produces findings of lack of comparability between requirements or disparity between accreditation and validation inspection results. We would review, as appropriate, the comparability of accreditation organization or State licensure requirements to ours and the procedures for inspecting and monitoring laboratories to reevaluate if the accreditation organization or licensure agency continues to meet Federal criteria.

In § 493.511 (b) and (c) we proposed that if we determine, following the deeming authority review, that the accreditation organization or licensure agency had failed to adopt requirements comparable to ours, the organization could be given a conditional approval of its deeming authority for a probationary period of up to six months during which it could adopt comparable requirements.

If we determined, following the deeming authority review, that the rate of disparity identified during the validation review indicates poor performance by the accreditation organization or licensure agency, we would take a number of actions. First, HCFA could provide the accreditation organization or licensure agency conditional approval of its deeming authority for a probationary period of up to one year (whether or not there are also noncomparable requirements) effective 30 days following the date of the determination. We would require the accreditation organization or licensure agency to release to us any facility-specific data we require for continued monitoring. We would require the accreditation organization or licensure agency to provide us with an inspection schedule for the purpose of intermittent onsite monitoring during the probationary period of the organization's inspection process by HCFA staff, State surveyors, HCFA agents, or all three.

The difference in the probationary periods would be based on the amounts of time we feel are necessary to correct disparity due to lack of comparability between requirements or disparity caused by poor performance on the part of the accreditation organization or State licensure agency. We could require additional validation inspections of laboratories as part of the process of monitoring the correction process on the part of the accreditation organization or licensure agency.

5. Action Following the Probationary Period

The proposed regulations further stated that within 60 days after the end of any probationary period, we would conduct a final determination review and make a final determination as to whether or not an accreditation organization or licensure agency continues to meet the criteria at § 493.506 and issue an appropriate notice (including reasons for this determination) to the accreditation organization or licensure agency.

This determination would be based on one or more of the following:

- The evaluation of the most recent validation inspection and review findings;
- The evaluation of facility-specific data and related information;
- The evaluation of the accreditation organization's or licensure agency's surveyors in terms of qualifications, continuing education, composition of the inspection team, and similar items;
- The evaluation of inspection procedures;
- The accreditation or licensure requirements.

The regulations would specify that if the accreditation organization or licensure agency has not made acceptable improvements during the probationary period, we may remove approval of deeming authority. HCFA review or action would not in any way affect or limit the conducting of any validation inspection. We would publish in the **Federal Register** a notice containing a justification for removal of deeming authority from an accreditation organization or licensure agency.

6. Continuation of Validity of CLIA Certificate (Section 493.511(g))

The proposed regulations would further provide for the CLIA certificate of affected laboratories to continue in effect for 60 days after the laboratory receives notification that its accreditation organization's or licensure agency's authorization to grant deemed status was being removed. Such a period would allow us the time to inspect to see if the affected laboratories meet CLIA requirements. The proposed regulations specified that we could extend this period for an additional 60 days if the laboratory submitted a timely application for accreditation by another approved accreditation organization or exemption by an approved licensure agency or submitted a timely application to HCFA for a CLIA certificate so that the laboratory's compliance with CLIA conditions can be determined.

G. Report

We proposed to prepare and submit a report annually to Congress that describes the results of the selective-sample validation inspection conducted under § 493.507 and the reviews conducted under § 493.509. The report would include the name of any accreditation organization or licensure agency that is given conditional approval during a probationary period by us.

H. Technical Revisions

We proposed to remove § 493.1701(b)(4) and § 493.1708 as they would be superseded by the new subpart E.

Comments and Responses

We received comments from 32 commenters in response to the proposed rule published on August 20, 1990. Commenters included professional associations, laboratories, accreditation organizations, State and City governments and consumers. While many of the commenters expressed overall support for the proposed regulation and/or approval of HCFA's "deeming" process, there was an array of concerns that we have summarized below.

Note: We have revised several terms for clarity and use these new terms in our responses to comments:

"CLIA-exempt" replaces "State-exempt";
"State laboratory program" or "State program" replaces "State licensure agency" and "State licensure program";
"Approved State laboratory program" or "approved State program" replaces "approved State licensure agency", "State exemption" and "exempt State"; and
"Condition level requirement" replaces "CLIA condition".

General Comments

We have summarized below those comments that do not pertain to a single section of the proposed regulations, but rather relate to the policies included in the proposed rule in general.

Expression of Support

Comment: Many commenters expressed overall support for the proposed regulations and the process by which HCFA will grant deeming authority to private nonprofit accreditation organizations or grant recognition to State licensure laws. (Hereafter, the term "deeming authority" will be used in the case of private nonprofit accreditation organizations, and the term "exemption" will apply to laboratories in States with approved State programs.)

Response: We appreciate the support we have received for this rule and are committed to the development of regulations that are reflective of the accreditation related aspects of the CLIA provisions and that will implement the law effectively.

Related Regulations

Comment: Several commenters recommended that HCFA publish all CLIA-related regulations simultaneously, in their entirety, in order to allow for a complete review and a chance to comment on all CLIA regulations at one time.

Response: We recognize that publishing CLIA regulations simultaneously would have facilitated a thorough review of the implementation of all CLIA legislation by enabling the reader to review related regulatory provisions at the same time. However, to do so would have ultimately resulted in some CLIA regulations being delayed; for example, three of these regulations were published on February 28, 1992. (HSQ–176–FC—Regulations Implementing the Clinical Laboratory Improvement Amendments of 1988, 57 FR 7002, HSQ–177–F—Fee collection, 57 FR 7188, and HSQ–179–F—Enforcement Procedures for Laboratories, 57 FR 7218). We have cross-referenced other regulatory documents with **Federal Register** numbers and publication dates and agency control numbers to assist the reader in locating related material.

General Comments on Impact

Comment: One commenter stated that applying the same standards to the approval of accreditation agencies under section 353(e)(2) of the PHSA and to the granting of exemptions based on State laws under section 353(p)(2) of the Act conflicts with the statutory provisions and will cause significant implementation problems. The commenter believed that the PHSA provides for the granting of exemptions based on a review of State licensure law and not through the recognition of State licensure agencies.

Response: The commenter is correct in that there are different statutory provisions concerning deeming authority for approved accreditation organizations and approval of exemption from CLIA requirements of all laboratories in a State whose laws regarding the regulation of laboratories are equal to or more stringent than those specified in CLIA. While we have always recognized that there are differences in the statutory provisions with respect to both types of entities, we continue to believe that in all cases the protection of the health and safety of individuals using these laboratories, as well as that of the general public, is the paramount consideration in determining whether to approve a request for deeming authority by an accreditation organization or to approve a State's request for an exemption from CLIA requirements.

There are two major differences between deeming through accreditation and exemption under State law that must be considered in developing and implementing effective regulations: Accreditation is voluntary while State

licensure and regulation are mandatory and imposed under the force of law; and accreditation is national in scope while exemptions from CLIA requirements can be approved only on a State-by-State basis. Thus, while all licensed or approved laboratories in an approved State will be exempt from CLIA requirements, should the State satisfy us as to the equivalency of its requirements, the criteria we will use in making that determination will not differ substantially from those used in determining whether to approve a request for deeming authority by a private accreditation organization. However, we are aware that the unique characteristics of individual State laws and enforcement mechanisms may require more flexibility in our deliberations regarding these States. Therefore, we have accepted the commenter's suggestion and have included separate regulatory provisions for accreditation organizations and States in this final rule to implement these programs in a manner that is consistent with the respective treatment accorded to each under the statute. The provisions that apply to approved State programs are included in this final rule at §§ 493.513, 493.515, 493. 517, 493.519 and 493.521. It will still be necessary for a State that wishes all laboratories in that State to be exempt from the CLIA requirements to apply for approval of its State laboratory program and to demonstrate that its requirements for laboratories, imposed under State law, are equal to or more stringent than the CLIA requirements.

Approved State laboratory programs will be required to apply for the renewal of their approval every two years. There are a number of reasons that this reapplication procedure is necessary. First, while the approval of an accreditation organization is not time limited, the CLIA certificate of accreditation furnished to accredited laboratories is valid for two years. At the end of that time each laboratory determines whether to obtain a new certificate of accreditation or to apply for a regular certificate on the basis of a State survey agency inspection. In either case, the laboratory's approval under CLIA is good for two years. In the case of approved State laboratory programs, all of the laboratories in the State are exempt from CLIA requirements as long as the State's approval is in effect. To ensure that the treatment of both types of laboratories is comparable, we will approve a State laboratory program for a two year period.

Additionally, there are substantial costs involved in the administration of a laboratory certification or exemption program under an accreditation or State program. In the case of accredited laboratories, these costs are borne directly by the laboratories as reflected in the fees paid for the certificate of accreditation. The costs of administering approved State programs must be paid by the States, who may pass through these costs to the laboratories in the form of licensing fees or through some other mechanism. In any case, for a State laboratory program to receive approval for exemption of its laboratories, the State must agree to pay to HCFA the costs associated with the program. Some of these costs are general administrative costs involved in evaluating the initial application for approval, the costs of the validation program, and the cost of investigating complaints. We will recalculate these costs every two years, and we feel it could pose an unrealistic fiscal burden to expect a State to commit to make payments of an unknown amount for an indefinite period of time. By approving the State programs for a two year period, each State will have the opportunity to decide if it wishes to continue as an approved program or to have the laboratories in the State seek CLIA certification through accreditation or directly through inspection by the State survey agency.

The new regulation sections reflect the statutory framework for State laboratory programs and provide that it is up to the Secretary, through HCFA, to determine whether State laws are equal to or more stringent than CLIA requirements. Once we make that determination with respect to the laws of any State, a decision to exempt laboratories in that State from CLIA remains discretionary with HCFA.

Thus, HCFA will impose reasonable conditions, specified in this final rule, designed to ensure enforcement with equivalent CLIA requirements, on the decision to exempt the laboratories of any State. Once a State has satisfied these reasonable conditions and we have decided to exempt the laboratories of that State, by definition the laboratories in that State are not subject to Federal standards or enforcement. While these laboratories would be exempt from CLIA requirements, we can seek an injunction in Federal court under section 353(j) of CLIA with respect to individual laboratories found to have serious deficiencies that the State is unwilling to address, or we can withdraw approval of the State's laboratory program at any time. With respect to the reasonable conditions reflected in the new regulatory sections, in addition to establishing that its laws regarding laboratory requirements are equal to or more stringent than those imposed by CLIA, a State requesting exemption from CLIA must:

- Demonstrate that it has adequate enforcement authority and the administrative structure and resources adequate to enforce its State standards;
- Permit HCFA or its agents to perform validation inspections of laboratories in the State;
- Agree to pay the cost of these validation inspections; and
- Agree to take appropriate enforcement action against laboratories found by HCFA or its agents not to be in compliance with standards equivalent to CLIA standards.

We believe that most States enforce their laboratory laws through a licensure mechanism, but we have included in our definitions of State licensure and State licensure agency in § 493.2 language that allows for approval mechanisms other than licensure that may be employed by a State for the enforcement of its standards for laboratories.

When HCFA approves a State laboratory program, laboratories in that State will not have the option of seeking CLIA certification through accreditation. Laboratories that are exempt from CLIA, by definition, must comply with the requirements of their approved State laboratory program. Only if an approved State program were to recognize an accreditation program as having requirements equivalent to its own, and provided for the "deeming" of State requirements through accreditation under State law, would accreditation be of any consequence.

Requirements for both the accreditation organizations and State laboratory programs are generally the same. Below we summarize the differences in requirements for State laboratory programs.

1. Section 493.503, Proficiency testing requirements for laboratories with deemed status, specifies the proficiency testing (PT) requirements of laboratories with deemed status. In § 493.515, Federal review of laboratory requirements of State laboratory programs, we permit the States with an approved State laboratory program to govern the PT requirements independently. However, we note that HCFA will hold the States to the same requirements when conducting a comparability review.

2. Section 493.504, Revocation of accreditation, specifies the statutory requirements (criteria) to permit continued recognition of a laboratory by HCFA, after an accreditation

organization withdraws its accreditation. There exist no comparable requirements for State laboratory programs because only the State has the authority to issue a license or approve a laboratory in that State. The regulation requires that a laboratory must be licensed or approved if a State has a program for licensure or approval that is recognized by the Secretary.

3. Paragraph (a) of § 493.506, Federal review and initial approval of private, nonprofit accreditation organizations, permits an accreditation organization to request approval for all specialties and subspecialties or for specific ones. A State laboratory program must govern a laboratory in its entirety.

4. Section 493.507(d), Consequences of a finding of noncompliance, provides that if a validation inspection results in a finding of noncompliance, the laboratory is subject to the same requirements applied to laboratories that are not accredited. However, in the case of States, § 493.517(d) (also "Consequences of a finding of noncompliance") specifies that if a validation inspection results in a finding of noncompliance, a laboratory's State license or approval will continue to be recognized. We will refer the deficiencies to the State and require the State to take the appropriate enforcement action against the laboratory. We will then monitor the State to ensure that the recommended action is being enforced. If the State refuses to take the appropriate action, § 493.521, Removal of CLIA-exemption and final determination review, permits HCFA to remove recognition of the State laboratory program.

5. Section 493.507(e), Reinstatement, specifies the criteria HCFA will use to determine if an accredited laboratory's deemed status should be reinstated. There exists no similar requirement under the State laboratory program provisions since HCFA has no authority to remove a laboratory's State license or approval.

6. Sections 493.511, Deeming authority review and final determination review, and 493.521, Removal of CLIA exemption and final determination review, provide for a reconsideration when HCFA removes approval for recognition of an accreditation organization or State program.

7. Section 493.521(g) specifies that HCFA will cancel the approval of an approved State laboratory program if the State does not pay the applicable estimated costs of validation surveys. Approved States are obligated to pay applicable fees to the Federal goverment, whether or not these costs are passed on to the laboratories in licensing fees or by some other mechanism. In the case of accredited laboratories, validation costs are dispersed among all laboratories holding a certification of accreditation.

Comment: One commenter urged HCFA to reconsider the proposed rule. This party believed there would be significant, unnecessary adverse impacts on access to care as a result of the proposed rule. The implication of this comment was that requirements for obtaining a CLIA certificate are too strict, thereby limiting the number of laboratories that could receive one. If this happened, patients' access to laboratories also would be limited.

Response: The impact on access to care is not within the purview of this rule. However, it has been our objective under CLIA to develop regulations that provide an appropriate balance between the concern for access to care and the need to protect the public from inaccurate and potentially dangerous testing. The rule that addresses these issues was entitled "Regulations Implementing the Clinical Laboratory Improvement Amendments of 1988" (HSQ–176–F) and was published in the **Federal Register** on February 28, 1992 (57 FR 7002). In that rule we establish conditions that laboratories must meet to receive a CLIA certificate.

Comment: One commenter stated that HCFA should make it clear in the final rule that obtaining certification via accreditation by a "deemed" private organization is voluntary, not mandatory.

Response: We have accepted this suggestion. We have reflected this policy in the definition of accredited laboratory at § 493.2.

Comment: One commenter stated that, based on many years of experience in laboratory inspection and accreditation, the commenter's position is that no private, nonprofit organization or State licensure agency has the capacity to accredit or certify laboratories in the context of this regulation.

Response: We cannot make any predictions about which accreditation organizations or State laboratory programs will or will not be approved for CLIA purposes until a comparability review is performed to determine the equivalency of an accreditation organization's or State laboratory program's requirements and procedures to those of HCFA. Our commitment is that only quality laboratories be permitted to perform services. If an accreditation organization wishes to be granted deeming authority, it must have appropriate procedures for assuring that the standards are met by the accredited laboratory. Similarly, HCFA will closely examine the requirements established under State law for any State that requests exemption of its laboratories from CLIA.

Comment: One commenter stated that there should be an opportunity for public comment at the time an accreditation organization applies for deeming authority. The commenter believes that this is part of Congressional intent in drafting the accreditation provisions of CLIA and may be required under law.

Response: To provide for public comment each time any accreditation organization or State applies for deeming authority or exemption from CLIA requirements, respectively, would unduly complicate our task of implementing CLIA due to the large numbers of laboratories coming under regulation for the first time. We have sought public comments on our interpretation of the statute and resulting regulatory policies. We considered all comments and either incorporated changes into our final regulations or explained why we were not doing so. We believe our final regulations are reflective of public opinion. We will publish in the **Federal Register** the name of each approved accreditation organization or State laboratory program and our basis for granting deeming authority or approval to that organization or program. In addition, the **Federal Register** document will describe how the organization or program provides reasonable assurance to HCFA that laboratories accredited or licensed (or approved) by it can be deemed to meet condition level requirements or exempted from meeting them.

Comment: A few commenters stated that there is no mention of any fee that will be charged to the accreditation organization to cover the costs of HCFA's review and approval process of an accreditation organization's requirements.

Response: Unlike the provision of CLIA that fees be collected to monitor laboratory compliance (see 57 FR 7118, published on February 28, 1992 for our final rule on this subject), the law provides no authority to charge fees for approval of accreditation organizations. The costs associated with the requests by an organization to be granted "deeming authority" and the costs of validation inspections will be reflected in the fees collected from laboratories for the issuance of certificates of accreditation.

Comment: One commenter believed that HCFA should carefully scrutinize State programs, since they are much

more vulnerable to political forces attempting to dilute or eliminate regulations necessary to fulfill CLIA requirements.

Response: We are required by law to scrutinize the laboratory requirements of States as well as those of private, nonprofit accreditation organizations. We are committed to assuring that all organizations granted deeming authority and all States whose laboratories are granted exemption meet the applicable Federal criteria for such approval as set forth in §§ 493.506 through 493.515, and that all laboratories accredited by an approved organization or licensed or approved in a State with an approved State laboratory program meet condition level requirements that we have determined to be comparable to CLIA's.

Comment: One commenter recommended that a task force of HCFA, the States of New York and Pennsylvania and private accreditation organizations be formed to establish the final "deeming authority" regulations.

Response: The nature of the process by which we respond to comments on a published notice of proposed rulemaking offers an efficient and effective means to request and obtain input from a broad spectrum of the public. To include only a few members of the public on a task force to draft final regulations would, at best, be soliciting repetitive comments, and would, at worst, be contrary to the intent of the Administrative Procedure Act. Such an approach could allow an inequitable opportunity for certain parties to influence the agency's reaction to public comments and the ultimate formulation of policy.

Comment: One commenter believed that approval of accrediting organizations would add another bureaucratic level that would decrease efficiency while increasing costs.

Response: We disagree with this comment. Accreditation is strictly voluntary on the part of each laboratory. Therefore, the number of accreditation organizations approved would not in itself cause laboratories to incur additional costs or otherwise decrease efficiency.

Comment: One commenter stated that the proposed regulation should be modified to ensure that States with strong clinical laboratory statutes receive deemed status.

Response: States that have strong clinical laboratory statutes and apply for HCFA approval will be granted such an approval if by "strong" the commenter means that State requirements are such that we find them to be equal to or more stringent than the condition level requirements set forth in applicable sections of part 493.

Comment: One commenter stated that State licensing laws should be recognized simply based on the States' assurance that they provide an equivalent level of protection for patients. Another commenter stated that an accurate evaluation of equivalency under § 493.506(a) is absolutely essential for deemed status to operate appropriately and that reliance upon the accreditation organization or State alone to provide reasonable assurance is not sufficient.

Response: We do not believe it is appropriate to accept a State laboratory program's or a private accreditation organization's assertion that its standards are at least equivalent to Federal requirements. In either case, we are obliged to consider whether an organization's or State's standards are "equal to or more stringent" than those set forth in CLIA. In addition, we believe that for us to make this determination properly we need not only review substantive and procedural requirements of these entities to determine "equivalency", but we must also assess the efficacy of these standards and procedures, as applied by organizations and States on a continuing basis.

Application Process

Comment: Several commenters stated that the actual process for applying for deemed status is not outlined in the regulation.

Response: In response to the comment we have inserted the application process for accreditation organizations at § 493.501(c) and for States seeking approval of their laboratory programs at § 493.513(c). Accreditation organizations or States wishing to apply to HCFA for "deeming authority" or for "exemption", respectively, must provide the following information:

- The specialty(ies) or subspecialty(ies) for which an accreditation organization is requesting "deeming authority";
- A detailed comparison of individual laboratory requirements of the accreditation organization or State with the comparable condition level requirements; i.e., a crosswalk. The crosswalk will be used to help establish that the body of an organization's or State's requirements are equivalent to the body of applicable CLIA requirements. Where accreditation standards or State requirements differ in detail from specific condition level requirements, the organization or State must demonstrate how its standards are at least equal to CLIA's either by a comparison to the most nearly equivalent CLIA requirement or by demonstrating how a less stringent requirement in one instance is offset by more stringent requirements in a related area. We will make every effort to accept reasonable differences and encourage innovative approaches provided that the accreditation organization or State requirements substantiate the equivalency of the entire body of standards;
- A detailed description of the inspection process, including:

—The frequency of inspections;
—Copies of inspection forms;
—The review and decision-making process;
—The surveyor guidelines and/or instructions;
—The steps taken to monitor the correction of deficiencies;

- A description of the process for monitoring unsuccessful participation in a proficiency testing program, including action to be taken in response to proficiency testing failures;
- A description of the accreditation organization's or State's data management and analysis system with respect to its inspection process;
- Procedures for the removal or withdrawal of accreditation status or of State licensure or approval for laboratories that fail to meet the organization's or State laboratory program's standards;
- Current procedures employed to investigate and respond to complaints against accredited or exempt State licensed or approved facilities;
- Duration of a laboratory's accreditation, including a list of all those currently accredited; and
- In the case of approved State programs, a list of all licensed or approved laboratories, the expiration date of each laboratory's licensure or approval, and each laboratory's specialties and subspecialties. (This information is necessary for the laboratories in the State to be paid for claims under Medicare or Medicaid.)

Private accreditation organizations must also provide:

- Detailed information about the kinds of personnel (surveyors or inspectors) who perform inspections, including:

—The size and composition of individual accreditation or inspection teams;
—The education and experience requirements those inspectors must meet; and
—The content and frequency of the in-service training provided to inspection personnel;

• Procedures for providing PT information in response to public requests for such information; and

• A proposed agreement that stipulates the accreditation organization will comply with the specific notification procedures included in this rule.

HCFA will notify an organization or State if it finds that additional information is required.

Each accreditation organization or State will receive a written notice from the HCFA Administrator stating whether the request for "deeming authority" or CLIA-exemption of the laboratories in a State has been approved or denied. Approval of accreditation organization and State laboratory programs is for a six year term, at a maximum. We established this six year term of approval because we believe it would be irresponsible and unreasonable simply to approve an organization or laboratory program for an indefinite amount of time and not provide for further comprehensive reviews. Since HCFA has discretionary authority with respect to the approval of accreditation organizations and State laboratory programs, we must be able to impose reasonable conditions, such as the six year term, in order to ensure the health and safety of the patients and the general public.

A notice will also be published in the Federal Register indicating the accreditation organizations for which deeming authority and the States for which exemption was approved, and the rationale for these decisions.

All requests for "deeming authority" or "exemption" should be mailed to: Administrator, Health Care Financing Administration, Room 700 East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland 21207.

Compliance Costs

Comment: One commenter stated that the added expense of having to comply with provisions of both CLIA '67 and CLIA may cause small laboratories to close.

Response: This comment does not come directly under the purview of this rule. The issue of costs to laboratories of meeting CLIA requirements is related to HSQ–176–FC—Regulations Implementing the Clinical Laboratory Improvement Amendments of 1988, published February 28, 1992 (57 FR 7002). Certificate and compliance determination fees that laboratories must pay are specified in HSQ–177–F, Fee Collection, published February 28, 1992 (57 FR 7188).

Comment: One commenter believed that many accreditation programs will withdraw (not seek HCFA approval), rather than expend time, effort, and costs to comply with HCFA requirements.

Response: We recognize that some accreditation programs may have to revise their requirements and procedures in order to meet the requirements of CLIA. However, HCFA is charged with carrying out the law and implementing regulations that will reflect what we believe to be the most effective means of carrying out the purposes of the CLIA statute. By evaluating accreditation and State requirements taken as a whole, the approval process has the flexibility necessary to accommodate some differences in individual requirements while recognizing the equivalency of one body of standards to another body of standards.

Comment: One commenter believed that the public would be better served by a return to basics similar to those presented in CLIA '67; thus, all laboratories could be brought under some type of oversight, which in and of itself would improve the quality of health care in this country.

Response: We disagree with the commenter's suggestion that the public interest would be better served by implementing only minimal requirements for all laboratories. CLIA already provides that virtually every laboratory will be brought under oversight, and the requirements implemented must address the condition level requirements for laboratory performance specified in the statute. Additionally, this rule does not establish laboratory requirements but rather provides a mechanism for assessing the equivalency of accreditation organization and State licensure or approval requirements as compared to the Federal requirements.

Comment: One commenter stated that facilities that perform only limited testing as part of routine nursing services and are not reimbursed separately by Medicare or Medicaid would be required to comply with rules disproportionate to the extent of testing performed. One commenter believed that nursing facilities and intermediate care facilities for the mentally retarded that obtain their laboratory services from outside entities may encounter reduced access to certified laboratories especially in rural areas. Many of these facilities currently obtain laboratory services from physicians' offices or small independent laboratories. If the number of waivered tests or tests of moderate complexity are unrealistically limited, residents' access to services and timely follow-up care will be unnecessarily jeopardized.

Response: These two comments do not come directly under the purview of this rule. The issues concerning accessibility to laboratory services and waivered test requirements are related to the rule published on February 28, 1992 (57 FR 7002), specifying the conditions laboratories have to meet to be given a CLIA certificate.

Staff Availability

Comment: One commenter believed that the implementation of this regulation should be delayed until HCFA can address the problems of a shrinking personnel pool in the laboratory field.

Response: This comment does not come under the purview of this regulation if the commenter is referring to a diminishing source of personnel to staff clinical laboratories. The participation requirements published in the previously cited rule address personnel requirements for laboratories. However, if the commenter is referring to the unavailability of staff for accreditation organizations, we can only respond that the personnel inspecting the operation of a laboratory must be qualified by training and experience to perform any survey of laboratories.

Hospital Laboratories

Comment: One commenter stated that HCFA's involvement in hospital laboratory accreditation should be no greater than maintaining and reviewing the records provided by the various certifying agencies that already exist.

Response: We do not accept this suggestion. HCFA is responsible for ensuring that any hospital laboratory, accredited or not, is in compliance with the provisions of CLIA. It is true that HCFA will have to review the aforementioned records in order to validate findings used by the laboratory's accreditation organization or a State's inspection program. It will also be necessary for HCFA to inspect laboratories on a representative sample basis or in response to substantial allegations of deficiencies.

Comment: One commenter stated that since New York City's Laboratory Improvement Program was the first of any in this country to regulate clinical laboratories, "city licensure agency" should be allowed to act as an accreditation organization. One commenter submitted an application to HCFA for recognition as an accreditation agency.

Response: Regarding the commenter's remarks with respect to whether a city

licensure agency can act as an accreditation organization, any entity that meets the definition of an approved accreditation organization as specified at § 493.2 of this regulation may be accepted for approval of deeming authority. A city licensure agency could not be approved as an accreditation organization because the definition reflects the statutory requirement that approved accrediting bodies be private nonprofit organizations. However, HCFA may grant a CLIA exemption to laboratories licensed by a local government such as a city, provided that the city's requirements are determined by HCFA to be equal to or more stringent than CLIA requirements, and the city's authority for the regulation or licensure of laboratories has been explicitly delegated pursuant to State law. In such cases, we will view the local governmental entity as acting in its jurisdiction on behalf of the State in which it is undertaking responsibilities the State would be performing had it not explicitly empowered the local entity to perform the State's tasks. We have included a definition of State at § 493.2 to allow for such exemptions. If HCFA concludes that a State's laws authorize recognition of a local entity for State licensure or approval purpose, we will first advise the State of our conclusion and will not take any steps to recognize or approve a local entity unless the State concurs that HCFA is correctly interpreting State law.

Specific Comments

Following are comments we received on specific regulatory sections:

Section 493.501 General Requirements

Comment: One commenter requested § 493.501(a)(1)(i) be revised to require that accredited or licensed laboratories meet the specific CLIA program requirements in part 493.

Response: We cannot accept this recommendation. Laboratories deemed to meet CLIA requirements by virtue of accreditation by an approved accreditation organization will be issued a certificate of accreditation by HCFA that certifies "deemed" compliance with applicable CLIA requirements. Such a certificate indicates that the accreditation organization's requirements are equal to or more stringent than those of HCFA, and that accreditation by that organization provides reasonable assurance that the laboratory would meet CLIA requirements if inspected for them. In the absence of a CLIA inspection, such compliance is "deemed" or presumed.

On the other hand, laboratories inspected by a State that has had its laboratory program approved by HCFA are exempt from all provisions of section 353 of the Public Health Service Act, including the requirement at section 353(b) that the laboratory have a certificate that certifies compliance, or the presumption of compliance as in the case of laboratories accredited by an approved organization. Should a State have its requirements approved, then its requirements are applied in lieu of those promulgated by the Secretary in regulations pursuant to the CLIA statute. This is because HCFA has determined that the laboratories in that State satisfy a set of requirements equal to or more stringent than those specified in Federal regulation. Therefore, it would be inconsistent with the intent of the statute to require, in regulations, compliance with specific Federal requirements when the law permits compliance with equivalent or more stringent standards in the case of both accredited laboratories and CLIA exempt laboratories.

Section 493.502 Definitions

Comment: One commenter stated that the lack of definitions for general terms such as "conditions", "standards", and "requirements" causes some confusion throughout the proposed rule. The commenter stated that the term "CLIA conditions", as defined in the proposed rule, is confusing because these "conditions" that HCFA mandates are broadly stated and more analogous to the properly used term "standards", while "standards" are used in the context of very specific and detailed mandates. The commenter thought that the definition for "CLIA conditions" should be eliminated and wherever the term is used throughout subpart E, it should be replaced with "conditions and/or standards * * *"

Response: As a result of the issues raised in the above comment, we have amended the text by deleting the definition of the term "CLIA conditions" (since the definition in the enforcement procedures regulation (57 FR 2178) concerning condition level requirements is adequate) and we have clarified that the terminology describing levels of requirements may differ between that used in applicable subparts of part 493 and that used by accreditation organizations or State laboratory programs. (What we referred to as "CLIA conditions" in the proposed rule we refer to as "condition level requirements" throughout this final rule.) Because each organization can organize and identify its requirements in the manner it feels is most appropriate, the organization can establish that its requirements taken as a whole provide equal to or more stringent requirements.

We have also eliminated the proposed definitions section for this subpart, previously proposed as § 493.502, and have included all definitions at § 493.2, which is the definitions section for part 493.

Comment: A few commenters stated that the definition specified in the regulation for "HCFA agent" is not consistent with the statute.

Response: The term "HCFA agent" is not included in the CLIA legislation. HCFA made an administrative decision, based on the authority in section 353(o) of the PHSA, to provide for a "HCFA agent" for the purpose of broadening the types of entities that may be used by HCFA or a State survey agency for performing laboratory inspections. HCFA agents will be required to use HCFA forms, inspection processes and guidelines. The authority of these agents will be limited. That is, HCFA agents will provide HCFA with the laboratory inspection results and HCFA or the State survey agency will be responsible for the certifications. The definition of "HCFA agent" is included in § 493.2 of the text.

Comment: One commenter stated that proprietary organizations that would be eligible to assume survey and validation duties on behalf of HCFA should be excluded from the definition of "HCFA agents".

Response: The law explicitly states at section 353(o) of the PHSA, "In carrying out this section [section 353] the Secretary may, pursuant to agreement, use the services or facilities of any Federal or State or local public agency or *nonprofit private organization* * * *." (Emphasis added) We are including in the definition of "HCFA agent" the requirement that any "private" HCFA agent must be a nonprofit entity.

Comment: Three commenters stated that HCFA's definition of "deemed status" was unclear.

Response: We accept this comment and have included further clarification at § 493.501 of this rule.

Section 493.503 Proficiency Testing Requirements of Laboratories With Deemed Status

Comment: Many commenters believed that there was no need for the accreditation organization to report proficiency testing (PT) results to HCFA. The PT organizations already do this, so this reporting by the accreditation organizations would be duplicative.

Response: Based on the comments we received, we attempted to eliminate any

duplication in the processing of test results as reflected in the proposed regulations. We have revised § 493.506 to specify that, in the case of an accredited laboratory, the accreditation organization will handle the disclosure. HCFA will receive from accreditation organizations only those PT results that constitute unsuccessful participation in the PT program and adverse action resulting from PT results constituting unsuccessful participation in PT programs. In the case of CLIA-exempt laboratories, States are required to notify HCFA only of the action(s) taken by the State as a result of that unsuccessful participation.

Therefore, we will not require the PT organizations to submit test results to HCFA from accredited laboratories. We will, instead, require that the PT organization submit test data on an ongoing basis to applicable accreditation organizations or State laboratory programs so that the accreditation organizations or State programs can maintain the test results, as necessary, to respond to disclosure requests from the public, and so that they can monitor and take necessary accreditation or licensure or approval actions. HCFA intends to include this change in its future regulations implementing CLIA '88 (HSQ–176–FC, 57 FR 7002) when we issue technical corrections to that rule.

Comment: Six commenters believed that the 30-day time period for reporting PT failures is too short.

Response: We have clarified the regulation at §§ 493.506 and 493.515 to indicate that HCFA is to receive notification of actions taken by accreditation organizations and State laboratory programs resulting from PT failures within 30 days of the imposition of the adverse action.

Comment: Two commenters believed that an accreditation organization should be prevented from restricting participation in PT programs to its own PT service. The commenter recommended that an accreditation organization should permit participation in any CLIA-approved PT program.

Response: We do not accept this recommendation. We believe that an accreditation organization or a State should have the authority to determine which CLIA-approved proficiency testing program it will use to meet CLIA's PT requirements. We will not evaluate an accreditation organization's or State's requirements in any way other than to determine equivalency to Federal requirements, including PT requirements. Whatever criteria an accreditation organization or State uses for selecting a HCFA-approved proficiency testing program to achieve equivalency is left to the discretion of those entities.

Comment: One commenter asked if the proposed rule intended that in the case of PT failures, accreditation organizations and State licensure agencies had to require onsite PT.

Response: No. State laboratory programs and accreditation organizations are expected to impose the same PT requirements as specified in the final laboratory standards regulations, HSQ–176–FC, Regulations Implementing the Clinical Laboratory Improvement Amendments of 1988 (57 FR 7002). Since the PT provisions in that rule require enrollment by all laboratories with certificates in a HCFA-approved PT program, the accreditation organization or State laboratory program must impose the same requirement.

Section 493.504 Revocation of Accreditation or State Licensure

Comment: One commenter stated that the accreditation status of a laboratory should not be affected by the suspension, revocation, or limitation of that laboratory's CLIA certificate. Another comment expressed concern regarding the timing of notification to HCFA of the removal of accreditation from a laboratory for serious deficiencies that could endanger laboratory patients or the public.

Response: We do not require that the suspension, revocation or limitation of a laboratory's certificate of accreditation by us have any affect on a laboratory's status with respect to its accreditation organization. However, as a practical matter, if the laboratory's certificate of accreditation is suspended, limited or revoked, the laboratory cannot test specimens in any area covered by the sanction. Thus, being accredited in these circumstances is meaningless.

In addition, since the statute requires an approved accreditation organization to notify HCFA within 30 days of the time it revokes a laboratory's accreditation, we will also require an approved organization or State laboratory program to notify HCFA within 10 days of the time it identifies a laboratory that has deficiencies that would be considered to be an immediate jeopardy or a hazard to the public health. We are also making a technical correction at § 493.504 to remove the incorrect citation of § 493.1704 we proposed. We have also deleted reference to the CLIA '67 term "letter of exemption". We have also changed the title in the final rule so that the section does not apply to State laboratory programs.

Section 493.506 Federal Review and Initial Approval of Private Nonprofit Accreditation Organizations and State Licensure Agencies

Comment: Several commenters believed that accreditation organizations should be granted deeming authority for specialties (e.g., blood banks, cytology).

Response: We accept this comment. HCFA will allow accreditation organizations to be granted "deeming authority" for certain specialties and subspecialties (i.e., blood banking, cytology). However, this does not relieve these accreditation organizations from accountability for monitoring compliance with other related requirements that are equivalent to CLIA requirements. For example, an accreditation organization approved for blood banking would be responsible for monitoring quality control, quality assurance, personnel requirements, recordkeeping, etc. as they pertain to blood banking. The text of this rule at § 493.506 is being amended to reflect this clarification. We have also revised the title to show that the provision no longer applies to State laboratory programs.

Comment: One commenter stated that the language in proposed § 493.506(c)(4)(ii), "each analyte and", should be deleted because the rules established under the CLIA enforcement rule published on February 28, 1992 (57 FR 7218) specifically refer to suspension and termination of approval only of specialties and subspecialties.

Response: We have accepted this comment and have revised this provision to require the accreditation organization to provide only those PT results to HCFA that constitute unsuccessful participation in the PT program and to provide notification of the adverse action(s) taken by that accreditation organization or State laboratory program. References to "each analyte" have been removed from this rule. Limitation of a CLIA certificate of accreditation constitutes suspension or termination of specialties or subspecialties.

Comment: One commenter stated that proposed § 493.506(c)(1) appears to give the accreditation organization the power to deny, suspend, withdraw, or revoke a deemed laboratory's certificate of accreditation. The commenter recommended that the wording be changed to limit the authority of an accreditation organization to withdrawing accreditation and

providing the information to HCFA. If it is truly HCFA's intent to allow the accreditation organization to revoke a certificate of accreditation, then the appeal and hearing opportunities stated in proposed §§ 493.622 and 493.626 (published August 3, 1990, 55 FR 31770) should be repeated in this section.

Response: The intent of proposed § 493.506(c)(1), (redesignated as § 493.506(b)(3)(i) in this final rule) was to convey that accreditation organizations can withdraw a laboratory's accreditation. We do not allow accreditation organizations to deny, suspend, or revoke laboratory certificates, which are issued only by the Department of Health and Human Services. We are revising § 493.506(b)(3)(i) to clarify this provision.

Comment: Two commenters expressed concern that certain accreditation organizations that obtain approval or States whose laboratory program is approved may wish to impose stricter standards than those developed by HCFA. The commenters believed that the statement "an accreditation body's standards must be equal to or more stringent than those under CLIA" has been abused over the past ten years.

Response: An accreditation organization or a State is explicitly permitted in accordance with sections 353(e)(2)(A)(ii) and (p)(2) of the PHSA to establish standards that are equal to or more stringent than the standards issued by the Secretary. Since facilities are free to seek accreditation or be surveyed under our rules, we see no need to prohibit accreditation organizations from establishing more stringent standards than those of the Secretary. Additionally, the statute specifically provides that nothing in section 353 of the Public Health Service Act shall affect the power of any State to enact and enforce laws relating to these matters that are not inconsistent with the CLIA statute or implementing regulations.

Comment: One commenter stated that data requested in "ASCII code" may not be included in the computer system of the accreditation organization and would therefore be a major cost factor for revising or writing the computer programs. Another commenter stated that the requirement to transmit data in "ASCII-comparable code" is meaningless without specifications for format and variety of other specifications and details.

Response: All references to ASCII code may be interpreted as the ability to generate standard electronic data files that are capable of being processed on mainframe computers. For example, EBCDIC STANDARD 6250 BPI tape is an acceptable alternative to ASCII. File formats, record layouts, edits and procedures are being designed. When these formats are finalized, we will advise accreditation organizations applying for deeming authority and States applying for approval of their laboratory programs that data be submitted to HCFA electronically, either on magnetic tape or through electronic data transmission. We also wish to point out that in the final rule we do not require the accreditation organization or State to submit the quarterly or semiannual PT results except for the PT failures that constitute unsuccessful participation in a specialty or subspecialty. This is a change from the provision in the proposed rule that required the submission of all PT results.

Comment: One commenter indicated that approved PT programs should be required in § 493.506 to supply data to the deeming authority in electronic form in ASCII-comparable code. Otherwise, other excess paperwork that HCFA would like to eliminate to save staff time would accrue to the deeming authority.

Response: Specific requirements for information transmission for PT programs do not come under the purview of this rule. The accreditation organizations, States, and PT programs will negotiate these items.

Comment: One commenter stated that § 493.506(c)(4)(i) should be deleted. The language is duplicative of the information specified in § 493.506(b)(4).

Response: We disagree with this comment. Although proposed §§ 493.506(b)(4) and 493.506(c)(4)(i) (redesignated as §§ 493.506(b)(2)(iv) and 493.506(b)(3)(iv)(A) in this final rule) contain similar language, these provisions address different requirements. Specifically, proposed § 493.506(b)(4) establishes, as one criterion that an accreditation organization must meet to be granted "deeming authority," the ability to provide data electronically. Proposed § 493.506(c)(4) specifies the information an accreditation organization must agree to provide to be granted deeming authority. However, as previously stated we do not require all PT results to be submitted to HCFA. We have revised the requirement in this final rule to require notification of only the unsuccessful participation in a PT program and any resulting adverse action.

Comment: Two commenters indicated that many States may have the equipment to submit reports electronically but would require a reasonable period of time to establish a system for obtaining PT results by a medium that is compatible with that of the States.

Response: We are not specifying the media by which States or accreditation organizations communicate with PT organizations. We only require that data transmitted to HCFA be submitted electronically and within the designated time. We will permit a reasonable time for states and organizations to refine their electronic communication systems.

Comment: One commenter recommended that proposed § 493.506(c)(5) (redesignated in this final rule as § 493.506(b)(3)(v)) be modified so that agencies or organizations would be required to give us advance notice of changes in their "standards" rather than their "requirements."

Response: We do not accept this comment. We feel it is important that the accreditation or State laboratory program agree to notify HCFA of changes to any requirements, including its standards.

Comment: One commenter stated that under proposed § 493.506(c)(4) the requests by HCFA for data from accreditation organizations should be discrete (i.e., HCFA should not be able to request any type of data it wants at any time it wants).

Response: We do not agree that our regulations should list all specific data needs. Our interest is in obtaining sufficient data to monitor the approved accreditation organizations' surveys of facilities and to obtain the results of such surveys. The specific data needed may vary from time to time and any list of specific items may become out-of-date. Further, we need to know, the responsiveness of the organizations to cited deficiencies, and we may need to request special data quickly, depending on the circumstances. We will not make unreasonable requests, but only those necessary to monitor the organization and the laboratories they accredit.

Comment: One commenter stated that an accreditation organization's inspectors should be approved by HCFA solely by virtue of their experience and the complexity of the laboratories they inspect, instead of by HCFA's qualifications.

Response: This rule does not specify any HCFA-mandated inspector qualifications. The qualifications an accreditation organization sets for inspectors will be evaluated by HCFA as part of the approval process and will consider the complexity of laboratories inspected. The accreditation organization must employ individuals with sufficient training and experience to provide us with reasonable assurance

that laboratories surveyed by its surveyors meet the applicable requirements.

Comment: Two commenters believed that HCFA should not approve accreditation organizations that require more stringent educational and experience requirements for inspectors or surveyors than HCFA does for its surveyors.

Response: We disagree. Accreditation organizations and States have the right to make this determination.

Comment: Several commenters stated that HCFA should clarify how the adequacy of staffing, finances and other resources of an organization or State will be determined.

Response: We do not believe this level of detail should be included in regulations; rather it is a subject for operating guidelines. We intend to review the number of staff, and the financial resources of an organization to determine its ability to conduct timely surveys, respond to complaints, report to HCFA as required, train surveyors, and perform the administrative functions necessary to support the number of laboratories accredited by the organization. In addition, we have included provisions for both the initial evaluation of applications and for validation activities that permit HCFA to go onsite to the accreditation or State program offices to verify information supplied by these bodies and to observe their operations more closely.

Comment: One commenter believed that deemed status should be limited to those organizations that have structured surveying programs in place, similar to the State survey agencies. Deemed status should not be given to organizations that have indicated a serious conflict between consultation and the enforcement of requirements.

Response: Each accreditation organization is reviewed on its own merits. To ensure that each program continues to meet CLIA requirements, we will be performing annual validation reviews on each accreditation organization approved. As part of those validation reviews, we will evaluate their ability to monitor the correction of deficiencies.

Comment: One commenter stated that under § 493.506 the statement "HCFA's review of a private, nonprofit accreditation organization or State licensure agency includes, but is not necessarily limited to, an evaluation of the following:" does not indicate that the organization or agency must have the ability to provide proficiency testing specimens when onsite PT testing is conducted as required in § 493.807 of the May 21, 1990 proposed rule.

Response: The organization or agency seeking approval is not required to provide additional PT specimens when onsite monitoring of PT testing is conducted. There may be onsite monitoring by HCFA or its agent of a laboratory's testing of PT specimens when the laboratory has not participated successfully in PT and wishes to be reinstated.

Comment: In the preamble of the proposed rule, we specifically invited comments on how accreditation organizations and State laboratory programs might be able to demonstrate that certain standards, although different from the Federal approach, are indeed equally as stringent as Federal CLIA requirements in terms of protecting individuals served by a laboratory. We also invited comments on the feasibility of the development of a comprehensive crosswalk by which to compare the standards of an accreditation organization or a State to those of HCFA. We received 20 such comments, and they are summarized below.

- Eight commenters were in favor of a crosswalk comparison of CLIA requirements to those requirements of an accreditation organization. One State said that a comparative analysis of standards of accreditation organizations and State licensure agencies with those established by HCFA is not only feasible, but essential to assure consistency among groups providing deemed status.
- One commenter was undecided. The commenter believed that HCFA should publish for comment more detailed criteria governing which programs would be considered to be equivalent and which inspection processes would be considered comparable.
- Eleven commenters argued against the crosswalk comparison of HCFA requirements to those requirements of an accreditation organization. Listed below is a summary of several of the comments received that were opposed to the development of a comprehensive crosswalk.
- One commenter stated that a crosswalk or line-by-line comparative approach is a rigid mechanism that would treat all requirements as having equal importance and would not allow the organizations or agencies to make exceptions or variations that respond to a particular laboratory's needs or circumstances.
- One commenter stated that HCFA should reconsider the standards-level approach to assessing equivalency and the competency of private accrediting organizations and instead evaluate the ability of the accrediting organization to identify good and bad performance.
- One commenter indicated a concern that such a comparison would require accreditation organizations to adopt requirements virtually identical to those of HCFA, thus eroding the individuality of established programs.
- One commenter stated that the regulations should allow approved accreditation organizations to carry out their programs according to their own methods and that HCFA should simply accept accreditation awarded by their programs.

Response: We appreciate the recommendations of the commenters. We acknowledge that there is a significant amount of concern among the commenters with respect to how an accreditation organization's or a State's requirements will be reasonably compared to those requirements established by HCFA. To eliminate much of this concern, we have defined the term "equivalency" at § 493.2 to mean that an accreditation organization's or a State's requirements, taken as a whole, are equal to or more stringent than the CLIA requirements established by HCFA, taken as whole. It is acceptable for an accreditation organization's or State's requirements to be organized differently or otherwise vary from the CLIA requirements as long as (1) all of the requirements taken as a whole provide at least the same protection as the CLIA requirements taken as a whole; and (2) a finding of noncompliance with respect to CLIA requirements taken as a whole is matched by a finding of noncompliance with the accreditation or State requirements taken as a whole. We have also included a requirement that accreditation organizations applying for deeming authority, or States applying for approval of their laboratory programs, must include in their application materials a crosswalk that provides a detailed analysis that demonstrates how accreditation or licensure or approval requirements, taken as a whole, are equal to or more stringent than the condition level requirements, taken as a whole.

Comment: One commenter expressed concern that HCFA has designed criteria that essentially would use the private accrediting body merely to enforce the Federal certification standards without recognizing the independent value of the private accreditation process.

Response: As indicated above, private accreditation organization or State laboratory requirements must reasonably compare to and provide the same protection or greater as the

corresponding requirements established by HCFA. Accreditation organization and States will enforce their own requirements, which may be essentially similar to Federal requirements.

Comment: One commenter stated that the proposed rule offers private accreditation organizations little incentive to seek deeming authority and would create disincentives for laboratories to continue to seek private accreditation because they would have to submit to two largely duplicative surveys.

Response: The duplicative surveys to which the commenter referred would only be an issue in the case of a sample validation survey or a complaint survey. These surveys will represent only a small percent of the accredited or CLIA-exempt laboratories and are necessary to ensure that the accreditation program is operating properly and that the laboratories are capable of providing accurate and reliable test results and that the health of individuals served by the laboratory and that of the general public is not adversely affected by laboratory operations and by testing procedures that do not meet the standards set forth in part 493. The decision of whether to seek approval of deeming authority is at the discretion of the individual accreditation organization. In a similar way, the decision to seek accreditation and be inspected by an accreditation organization rather than the State survey agency is at the discretion of each laboratory.

Section 493.507 Validation Inspections

Comment: Three commenters believed that validation of an accreditation organization should be done by an objective party instead of the State agency, one commenter suggesting the Office of the Inspector General as a more objective party. Additionally, another commenter recommended that HCFA should delete references to "the State agency" and "HCFA agent" throughout § 493.507 and state unequivocally that "all validation inspections will be performed by HCFA personnel who have scientific and technical education and training as well as inspection experience equivalent to that specified in approved accreditation organizations."

Response: For the purpose of evaluating the survey procedures of private, nonprofit accreditation organizations, the State survey agency is an objective party and is more familiar with HCFA survey regulations and procedures than HHS components such as the Office of the Inspector General (which does not specifically deal with ongoing inspection of facilities for compliance with HCFA program participation requirements). In the case of a State that has been granted approval of its laboratory program, we will not have it or any other State agency within that State conduct validation surveys to evaluate its own operation. To clarify these requirements, we have included definitions of State survey agency and HCFA agent at § 493.2. Therefore, as necessary, we will exercise the authority at section 353(o) of the PHSA, by which the Secretary can enter into agreement with other governmental or nonprofit organizations to assist HCFA in performing validation inspections. In addition, HCFA may utilize its own Federal surveyors for validation surveys of CLIA-exempt laboratories or accredited laboratories. State agencies, HCFA, and HCFA agents will possess the necessary scientific and technical education and experience and receive the necessary training to evaluate each accreditation organization objectively.

Comment: One commenter indicated that laboratories in exempt States should be exempt from the validation process.

Response: As previously stated, we believe Congress did not intend to allow the Secretary to approve a State laboratory program without imposing reasonable conditions to ensure enforcement with equivalent requirements or without periodically re-evaluating these approvals. We believe it is a reasonable condition to re-evaluate the State's requirements through validation inspections and to remove our approval of a State laboratory program if the State's requirements are no longer equal to or more stringent than the CLIA requirements. Although section 353(p)(2) allows the Secretary to exempt clinical laboratories in a State whose requirements are equal to or more stringent than the CLIA requirements, such exemptions remain discretionary with the Secretary. Accordingly, we believe it is consistent with the statute to have in place a system that will enable us to determine if exemptions, once granted, continue to satisfy statutory requirements. If we determine that they do not, the exemptions should be revoked. We believe that the performance of validation inspections provides us with the most effective means of assuring that objective.

Comment: One commenter indicated that language pertaining to validation inspection is too rigid. Specifically, the commenter thought we ought to change the policy embodied in the statement, "If a validation inspection results in a finding that the laboratory is out of compliance with one or more CLIA conditions, the laboratory is no longer deemed to meet the CLIA condition." Deemed status should only be lifted if a laboratory fails to comply with major conditions.

Response: We cannot accept this recommendation. All condition level requirements are considered major. On the other hand, if an accreditation organization or State has received approval of an accreditation or regulatory structure that is not exact in its replication of CLIA requirements, but that compensates in other areas so that its overall standards are at least equivalent to those established under CLIA (for example, a lower standard than CLIA is offset by a more stringent standard elsewhere in the requirements pertaining to the same CLIA conditions), HCFA would accommodate those distinctions in making its validation conclusions.

Comment: One commenter recommended that § 493.507(a) be rewritten to reflect more accurately the statutory authority provided under CLIA as follows: "HCFA may require the inspection of an accredited laboratory for any reason, including to validate its organization's accreditation process or in response to substantial allegations of deficiencies."

Response: We accept this recommendation; accordingly, we have revised the text at § 493.507(a). Additionally, HCFA may inspect any laboratory exempt from CLIA under an approved State laboratory program to enable HCFA to make a continuing assessment of the ability of the State program to assure its requirements, taken as a whole, are at least as stringent as CLIA requirements, taken as a whole.

Comment: One commenter recommended that the sample size for validation inspections be at least five percent.

Response: Because the statute does not require a particular sample size for validation surveys, we will not at this point establish such a sample size through regulations.

Comment: One commenter stated that there was no time limit within which a proposed validation inspection would have to occur.

Response: Historically, such time limits for validation surveys of other accredited facilities (i.e., hospitals) have been included within HCFA's internal operating instructions. We intend for this to be the case with laboratories as well. These types of timeframes and procedures that we impose on our

agents are subject to frequent change as a function of varying workloads, staff resources and other considerations. HCFA must reserve the right to alter such procedures expeditiously as situations warrant. At the current time, the guidelines provided in our instruction manual for the interval between an accreditation survey or inspection and a corresponding validation survey or inspection of a hospital is 60 days. We anticipate establishing a similar guideline for accredited or exempt laboratories in our operating instructions.

Comment: One commenter suggested that when a validation inspection is performed in response to a substantial allegation as noted in proposed § 493.507(a)(2), HCFA should notify the accreditation organization responsible for accrediting the laboratory in question.

Response: Historically, whenever an allegation of noncompliance with health and safety requirements is made against an accredited facility, HCFA notifies the accreditation organization unless the complaint pertains to things such as billing that have nothing to do with accreditation requirements. The Joint Commission on Accreditation of Healthcare Organizations is currently an approved deeming authority for the Medicare hospital program. It recently requested that it only be notified when an inspection or survey has been conducted and only of those survey results when a condition level deficiency is substantiated. The request was made to decrease unnecessary paperwork. These new notification policies will apply to all approved accredited providers and suppliers.

Comment: One commenter stated that §§ 493.507(b)(1), 493.507(b)(2), 493.507(b)(3), 493.507(c), 493.507(e)(1) and 493.507(e)(2) are redundant with § 493.501. The commenter recommended deletion of these redundant sections.

Response: The language contained in the sections referenced in the comment above is required as part of the general format of the regulation. Section 493.501 summarized general requirements of the regulation that are subsequently addressed in greater detail.

Comment: One commenter indicated that under § 493.507(a)(2), "Validation Inspections", the requirement for a "full" CLIA inspection for a deficiency may be too extreme, depending upon the interpretation of noncompliance with any CLIA condition.

Response: As part of the substantial allegation validation survey process, HCFA has always required a full survey to be performed if the survey agency substantiates that a facility is out of compliance with a condition. The rationale is that if one condition is out of compliance at the time of the validation survey, other conditions may also be out of compliance and may have existed undetected at the time of the accreditation or State laboratory program survey.

Comment: One commenter indicated that under § 493.507(d), "Consequences of the findings of noncompliance," the statement "finding that the laboratory is out of compliance with one or more CLIA conditions" is not clear as to exactly what conditions are meant and whether this refers to severe deficiencies found on inspection or other factors mentioned in subpart N.

Response: The statement "* * * finding that the laboratory is out of compliance with one or more CLIA conditions" means that a laboratory is found through a validation inspection to be out of compliance with one or more condition level requirements.

Comment: One commenter expressed concern about HCFA's proposed review (oversight) of accreditation organizations. The commenter wanted to know HCFA's plan to control for bias and other differing interpretations of Federal standards by the oversight inspection team.

Response: The State survey agency or other HCFA agent will not have access to the accreditation survey information before performing the validation survey in order to insure the objectivity of the surveyors or oversight inspection team. To further ensure the integrity of the process, HCFA will identify prior to the validation inspection those accreditation or State requirements that vary from specific condition level requirements. These specific differences will be identified in the application and approval process. The results from both the accreditation or laboratory program survey and the validation survey are forwarded to HCFA by the responsible entities and evaluated by HCFA personnel only.

Comment: One commenter suggested that under "Validation Inspections", in the preamble of the proposed rule, laboratories should not only be selected on a random sample basis, but also on the basis of their size, volume, and complexity of testing. The commenter noted that from past selections, it seemed that small volume laboratories performing simple tests have usually been selected. The chance of finding major problems in these types of facilities is very low.

Response: Under the Social Security Act, validation inspections have historically been performed based on a representative sample methodology. A relatively large number of small volume laboratories occurring in a random sample would only occur if the universe consisted largely of these types of laboratories or if the accreditation organization or laboratory program had recently surveyed a large number of small volume laboratories. Our current sample methodology is to select from facilities surveyed by the accreditation agency within the past 60 days. We have, for clarification, also revised the regulation text to indicate that a representative (instead of "selective") sampling methodology will be used. The details of the sampling methodology will be provided in instructions to HCFA's regional offices when the validation program begins.

Comment: A few commenters indicated that the validation inspection process, deeming authority review and final determination should be applicable to accreditation programs, State licensing agencies and other HCFA agents.

Response: As stated above, approved accreditation organizations as well as approved State laboratory programs will be subject to formal validation reviews as provided at §§ 493.507 and 493.517, respectively. The "other HCFA agents" are not subject to this formal process because they are often highly specialized and very limited in the scope of their survey activities with respect to laboratories. It has, however, always been HCFA policy to require HCFA central office and/or regional office staff to evaluate the performance of these agents, including the State survey agency.

Section 493.509 Continuing Federal Oversight of an Accreditation Organization or Licensure Agency Requirements' Equivalency to HCFA Requirements

Comment: In the preamble of the proposed rule, we specifically invited comments regarding use of the 20 percent rate of disparity. We received 17 such comments as summarized below. (These provisions have now been relocated to § 493.511.)

- A major accreditation organization stated that it had no basis for challenging this criterion or any other criterion that may be imposed by the Department of Health and Human Services. It recommended that whatever criteria may be adopted be applied in an objective fashion by an unbiased entity.
- Two commenters were in favor of the 20 percent rate of disparity. One commenter stated, "Based on our own experience in laboratory accreditation, we think that a 20 percent disparity rate

is appropriate." The other commenter stated that if the validation inspections were truly standardized and controlled by HCFA agencies, the 20 percent disparity rate proposed in § 493.509(b)(i) is reasonable.

• Eleven commenters argued against the 20 percent rate of disparity. Listed below is a summary of the views of the commenters:

—Three commenters indicated that rate of disparity should be more stringent.

—One commenter preferred that no percentage figure be included in the final rule. The commenter recommended that HCFA provide a phase-in period for evaluation of accreditation organizations of at least 24 months since more than 90 percent of the laboratories falling under the CLIA regulations have been previously unregulated and will be inappropriately sanctioned. Further, the commenter held the opinion that such a 20 percent requirement may well limit the number of private accrediting organizations willing to apply for deeming authority and is counterproductive to the intent of CLIA.

—One commenter indicated that the reliability of findings depends on the sampling methodology, the size of the sample, and the statistical analysis of survey data. Therefore, in the commenter's view, selection of an arbitrary rate of disparity would be meaningless. The commenter did not believe the proposal provides enough information to allow assessment of whether a 20 percent degree of disparity would be statistically significant.

—One commenter suggested that HCFA, rather than measuring the disparity in condition level deficiencies, should evaluate the overall effectiveness of the organization at identifying poorly performing providers.

—Two commenters indicated that the rate of disparity is an untried concept and is too rigidly applied in this proposal.

—One commenter stated that the large degree of subjectivity and the ambiguities posed by different interpretations of the rule would create rates of disparity greater than or equal to the 20 percent proposed by HCFA.

—Two of the commenters suggested that the 20 percent rate of disparity was overly stringent. One said that the rate of disparity is unduly punitive and would likely result in the inability of most nonprofit accreditation organizations and State licensure agencies to acquire deemed status. The other commenter said to quantify acceptability at 80 percent is unproven and overly stringent.

Response: As indicated earlier in this rule, we have defined the term "equivalency" to mean that an accreditation organization's or State's requirements, as a whole, are equal to or more stringent than the corresponding condition level requirements, as a whole, established by HCFA. It is acceptable for an accreditation organization or a State to organize its requirements differently than the HCFA requirements or to have equivalent but not identical requirements as long as all condition level requirements are captured in the requirements of the accreditation organization or State laboratory program. For example, an accreditation organization or State may impose a less stringent standard than CLIA that is balanced or offset by a more stringent requirement elsewhere in the accreditation or State requirements pertaining to the same or related CLIA conditions. Each CLIA requirement will be reviewed for its equivalency with a corresponding requirement of the accreditation organization or State laboratory program. The comprehensive crosswalk developed and used in the approval process will permit HCFA to determine if differences in the deficiencies (i.e., failure to meet a requirement) or lack of deficiencies between validation inspections and accreditation or State inspection constitute equivalent results. In calculating the rate of disparity, HCFA will use CLIA condition level deficiencies where the accreditation organization or State laboratory program did not identify similar deficiencies. It is possible that the "comparable condition-level" requirements of the accreditation organization or the State laboratory program are not called "conditions." It could be that during the initial development of a crosswalk between the CLIA requirements and those of the accreditation organization or State, a determination was made that a particular condition level requirement is equivalent in terms of level and constituent lower level requirements to a requirement of the accreditation organization or State or to some combination of requirements, including those instances where less stringent requirements are balanced by more stringent requirements elsewhere. In that case, in calculating the rate of disparity, HCFA will only use those CLIA condition level deficiencies where the accreditation organization or State laboratory program did not identify deficiencies with its own requirements, when clearly noncompliance with the accreditation or State requirements resulted in the finding of noncompliance by HCFA. As indicated previously, HCFA will accommodate these distinctions in making validation conclusions. We believe that by using this approach the 20 percent rate of disparity becomes more understandable and predictable. The ultimate result of this approach is an objective comparison between requirements established by an accreditation organization or State laboratory program and those of HCFA and a determination as to whether or not accredited and licensed or approved laboratories are surveyed against equivalent requirements. We have tried to ensure against the possibility that the threshold rate of disparity may, with experience, need to be adjusted by revising the rate of disparity definition at § 493.2 (originally proposed in § 493.502) and adding the phrase "and it is reasonable to conclude that the deficiencies were present at the time of an accreditation or State laboratory program's survey". Additionally, where validation findings exhibit any disparity with respect to the findings of an accreditation organization or a State, we expect the accreditation organization or State to demonstrate an improvement in the equivalency of its findings over time. Therefore, in addition to the deeming authority review that must be implemented at the 20 percent threshold, we will also institute a deeming authority review whenever the validation inspection findings, irrespective of the rate of disparity, indicate widespread or systematic problems in an accreditation organization's processes that provide evidence that the organization's requirements are no longer equivalent to the CLIA requirements taken as a whole. In either instance, HCFA may impose a conditional approval for a probationary period not to exceed one year any time a deeming authority review is undertaken. We are moving the criteria that will or may trigger a validation review from proposed § 493.509(b) to § 493.511(a), which already partly addresses the issue.

We have revised the title of § 493.509 to show that the provision applies only to accreditation organizations. We have included a similar provision for States at § 493.519 of this rule.

Since approval of a State laboratory program will be granted for a six-year period, the results of the validation inspections will be used as a criterion in determining whether the approval of the State laboratory program can be

renewed, when an approved State laboratory program applies for such renewal. At the conclusion of the six year term, any approved organization or State laboratory program will have to reapply. The nature of the materials we will require as part of the reapplication submission will be based on a range of issues, including performance as indicated by the results of validation activities, analysis of data relating to deemed activity, changes in the accreditation or State program over the term of the approval and the scope of any changes made to the CLIA program or its requirements. In addition, we will also determine if the reapplication process should occur more frequently than every six years for that particular accreditation organization or State and inform the organization or State of the shorter approval period.

A State approval will also include a provision making the exemption biennially subject to automatic cancellation if the State fails to pay assessed fees. We believe this two-year renewable term will facilitate expedient termination of a State's approval when a technically sophisticated regulations program is compromised by inadequate financial backing. Moreover, the automatic cancellation process would serve to minimize the losses to the user-financed CLIA program, without embarrassing the State by having approval withdrawn for poor performance.

Comment: One commenter stated that the disparity might be single inspector-dependent and not typical of the remaining inspectors.

Response: A consensus among survey inspectors must be reached and the inspection must be reviewed by supervisory staff in the State survey agency before a provider or supplier is formally notified of deficiencies. The cited deficiencies are indicated on the inspection forms and should be considered representative of the inspection team, not a single individual.

Comment: The legislation requires that an accreditation organization notify HCFA 30 days in advance before a change in its standards so that HCFA may have an opportunity to review the changes. One commenter recommended that under comparability review, if an accreditation organization or State laboratory program makes any significant change in its personnel requirements, then the changed personnel requirements should be subject to public comment.

Response: We do not accept this recommendation. It is not feasible under a comparability review to solicit public comments each time any changes occur in an accreditation organization's or a State's requirements, personnel or otherwise. This process would be too cumbersome and would imply that personnel requirements should be considered more important than other requirements established by the accreditation organization or State laboratory program. However, should a decision be made that these changes result in a determination that the requirements are no longer equivalent, action would be taken as outlined in §§ 493.511 and 493.521 (which concerns probation and possible removal of deeming authority or approval of a State laboratory program). We seek public comment on the policies that we incorporate into regulations. After those regulations become final, we then execute those policies. The determination of comparability of personnel requirements is only one instance of the implementation of policy for which we are responsible.

Comment: One commenter recommended that HCFA personnel and the approved accreditation organization's personnel jointly examine the inspection findings and disparities before any adverse action against the laboratory is imposed.

Response: We do not accept the comment. If the results of the validation inspection warrant HCFA taking an adverse action against a laboratory, HCFA will do so. We will, however, notify the approved accreditation organization of our action. We believe this process assists in maintaining the objectivity and integrity of the program and is consistent with past practice for the accreditation program for hospitals. If necessary, for CLIA-exempt laboratories HCFA will seek action through the courts.

Comment: One commenter questioned the provision in proposed § 493.509(b)(2)(i) that requires HCFA to notify an organization that is not meeting our regulations requirements. The commenter stated that the term "requirements" is vague and should be deleted.

Response: We agree and have made the change in the regulations text.

Comment: One commenter recommended that the opportunity to explain or justify any findings or discrepancies noted during the validation review be mandatory rather than optional.

Response: We agree that the opportunity for an accreditation organization or State to explain or justify any findings or discrepancies noted during a comparability or validation review should be mandatory and we feel the regulation reflects this situation. However, we cannot force an accreditation organization or State laboratory program to exercise its rights.

Comment: Several commenters expressed concern that there is no appeal mechanism available for accreditation organizations to use when HCFA withdraws its approval from such organizations.

Response: We agree with the commenter that such procedures are necessary and we have amended Part 488 of the regulations to provide a reconsideration mechanism for the removal of deeming authority from accreditation organizations. We have also incorporated the same reconsideration procedure for States whose request for approval of a laboratory program has been denied, or States whose approval has been removed. We are adding this provision to the rule to help assure that accreditation organizations and States with approved laboratory programs have a fair opportunity to contest adverse HCFA decisions affecting their status under the CLIA program. This procedure encompasses the opportunity for an informal hearing before a hearing officer at which time the affected parties may submit evidence and argument either in writing or orally. In this way, affected parties may help shape the contents of the administrative record that will underlie the agency's final decision. The reconsideration procedure will be made available only after the effective date of HCFA's decision to deny, withdraw, or not renew, as appropriate, the entity's approval under CLIA. We considered other alternatives but concluded that by the time an organization or State faces withdrawal of its approved status, it will have had extensive and lengthy opportunities not just to be apprised of its deficiencies, but to correct them as well. Every effort will already have been made by HCFA to accommodate the entity's interests in retaining its approved status, such that an adverse action will be the culmination of steps that have led HCFA to believe that it cannot realistically expect the necessary corrective actions to be taken.

Additionally, the reconsideration process will include an opportunity for the Administrator to review the hearing officer's decision to either affirm, modify, or reverse that decision. If the Administrator does not choose to assert that review authority within 30 days of the hearing decision, the hearing officer's decision will constitute final administrative action. Once there is a

final agency decision on the matter, the results will be published in the Federal Register.

Section 493.511 Deeming Authority and Final Determination Review

Comment: One commenter disagreed that accreditation organizations or States should be placed on probation due to lack of comparability between requirements and problems of poor performance. This commenter stated that an alternative, a continuum of sanctions including probation, suspension, termination and various forms of civil monetary penalties, should be allowed to be continued up to a year.

Response: We have revised the regulations language in §§ 493.509(c) and 493.519(c) to reflect that reapplication for HCFA approval is required by accreditation organizations and State programs at least every six years and permits HCFA to compel an organization or State to submit reapplication materials at any time. We will request those materials when a comparability or validation review indicates that the organization or State is not meeting the requirements of Part 493, Subpart E. We have no authority under the statute to impose suspension, termination, or civil money penalties on the accreditation organization or State for lack of comparability between requirements or problems of poor performance. In the case of poor performance, a probationary period of up to a year will frequently be necessary to allow for correction of systemic performance problems and for HCFA to validate through surveys whether or not performance has improved.

Comment: One commenter indicated that under § 493.511(b), by which conditional approval is given for a probationary period of six months to adopt comparable requirements, some flexibility in this time period might be advisable, especially where a State or city laboratory program must go through a time consuming process in order to revise existing laws and regulations.

Response: We agree with this comment and have revised the regulation at § 493.511(b) to provide a probationary period of up to one year to adopt comparable requirements. As previously discussed, the statute does not explicitly authorize exemption from CLIA requirements based on city laws unless the State has expressly delegated laboratory licensure and oversight responsibility to the city, so that the city acts as the State's agent under State law.

Regulatory Impact

In the preamble of the proposed rule, under the section entitled "Executive Order 12291", we specifically requested comments regarding the extent to which new requirements imposed by this rule and the proposed rule, "Regulations Implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) (55 FR 20896, May 21, 1990), would affect pricing schemes of accreditation organizations. We received four such comments from six commenters. A summary of the comments are as follows:

Comment: One accreditation organization believed that its accreditation fee will have to at least double if it is approved as an accreditation organization by HCFA. This increase will be primarily a consequence of increased paperwork, additional computer programming, data processing, and increased staff to comply with the proposed unrealistic time guidelines, etc.

Response: We recognize that the accreditation fee that some accreditation organizations charge may be increased above current charges. However, until we can review applications from accreditation organizations and States against the new CLIA requirements that were published February 28, 1992 (57 FR 7002), we cannot determine whether or not an accreditation organization's or State laboratory program's requirements are comparable to ours. Until that determination can be made, we cannot determine how extensive the changes are that such organizations will have to make, nor how costly those procedural enhancements will be. In either case, the decision to seek approval of deeming authority or of a State laboratory program is voluntary on the part of the organization or State.

Comment: Two commenters believed that if several States received deeming authority, and each of these States require licensure of all laboratories doing business within those States, then the cost may exceed $100 million. Large interstate commerce laboratories would have to pay licensure fees in several States or stop receiving specimens from those States.

Response: We do not have the authority to dictate to a State the requirements a laboratory must meet in order to operate within that State's jurisdiction. Our concern is whether a laboratory meeting those State requirements can be exempted from meeting CLIA requirements. We do wish to point out to the commenter that, for CLIA purposes, interstate laboratories may receive specimens from many States, but a CLIA certificate is required only in those States where testing is actually performed.

Comment: One commenter agreed with the spirit of the CLIA proposed regulation but felt that several portions of the text, if implemented, would be expensive, cumbersome and counterproductive.

Response: We have performed an assessment of the projected costs and other impacts of this regulation to the best of our ability, given the scarcity of data. We have, in developing our proposal and this final regulation, attempted to remain cognizant of the impacts on all involved parties. However, our major objective is to implement the CLIA requirements and thereby ensure reliable test results and the health of the individuals served by laboratories.

We refer the reader to the Regulatory Impact Analysis contained in HSQ–176–FC, Regulations Implementing the Clinics Laboratory Improvement Amendments of 1988, published on February 28, 1992 (57 FR 7002), which addresses the impact of the entire CLIA program.

Comment: Two commenters stated that we should reimburse the accreditation organization for any costs incurred by the organization for the collection, processing, and transmission of the data to HCFA.

Response: We acknowledge that there may be additional costs incurred by the accreditation organization or State laboratory program for the collection, processing, and transmission of the data required by HCFA. We will limit our requests to essential data only. There are no constraints on accreditation organizations and laboratory programs to set their fee schedules to meet the costs of managing their programs. We published in the Federal Register on February 28, 1992 (57 FR 7188) a final rule stating that our fee for laboratories that participate by virtue of a certificate of accreditation would be considerably less than laboratories needing a full inspection.

Summary of Revisions

We are adopting the proposed rule as final after making the following revisions that were discussed in detail earlier in the preamble to this final rule.

- In § 493.2, we add a clarification to show that laboratories are not required to be accredited by a private nonprofit accreditation organization. However, they have no choice regarding State approval or licensure. We also transfer all proposed definitions from § 493.502

to § 493.2 and make a number of clarifying technical revisions. We have separated the definitions of "approved accreditation organization" and what we called "State licensure agency" and now refer to as "State laboratory program". We also distinguish between the State laboratory program and the State survey agency by including a definition of each. In response to comments, we have added a definition of "equivalency". We also show that the rate of disparity is based on sample validation inspections and a reasonable conclusion that deficiencies cited by HCFA were present at the time the accreditation organization or State surveyed the laboratory. We include a definition of "CLIA-exempt laboratory" (which revises what we proposed as "State-exempt") and have added a definition of "State" to indicate that under certain narrowly defined circumstances a local government could qualify for approval of its laboratory program. We clarify that "validation review period" is a one year period and that it follows the most recent surveys performed by the accreditation organization or State.

• We have removed all references to State licensure and State laboratory programs from proposed §§ 493.501 through 493.511 and placed provisions concerning State licensure agencies in §§ 493.513 through 493.521. (Changes to §§ 493.513 through 493.521 parallel those in §§ 493.501 through 493.511.)

The nomenclature changes in the above two bullets reflect the fact that some States may not license their laboratories but instead approve them for operation in some other way and that the laboratories, rather than the State, are exempt from CLIA requirements.

• In § 493.501(a)(1), we clarify that accredited laboratories must meet requirements equivalent to condition level requirements. (Throughout the final rule we change all references from "CLIA conditions" to "condition level requirements" for clarity.)

• In § 493.501 we add a paragraph (c) to set forth the application process.

• In § 493.501, we add a paragraph (d)(4) to show that accreditation organizations can be approved for a maximum period of six years.

• We clarify in paragraph (e) (redesignated from paragraph (b) in the proposed rule) that we publish a notice when we grant deeming authority to an accreditation organization, rather than when we determine that a laboratory is deemed to meet condition level requirements, and that the notice will specify the term of approval.

• In § 493.503(b)(2) we update cross references and in § 493.503(b)(3) we clarify that the laboratory must authorize its accreditation organization to submit to HCFA the PT results that constitute unsuccessful participation in the PT program, and a notification of the accreditation organization's adverse actions resulting from the PT failures within 30 days of the imposition of the adverse action (rather than the notice of the failure).

• We add a paragraph (4) to § 493.503(b) to show that on the basis of notification of adverse actions we may take an adverse action against a laboratory that fails to participate successfully in a PT program.

• We make clarifying revisions in § 493.504 to be consistent with other revisions.

• In § 493.506, we make several clarifying changes concerning PT results and the codes in which they are transmitted. We also show that an accreditation organization may request and be granted "deeming authority" for specific specialty or subspecialty areas. We revise the title to no longer limit the section's applicability to initial approval.

• In § 493.507(a), we change "selective" sample to "representative" sample.

• We have redesignated the proposed paragraph (e) at § 493.507 as paragraph (c)(2)(i)-(iii) and added a new paragraph (e) to reflect that accreditation survey results are disclosable, a provision proposed at § 493.507(b). However, for Medicare participating laboratories, they are disclosable only if they are related to an enforcement action taken by the Secretary. This revision is being made to conform with the language previously included in the preamble of the proposed rule (55 FR 33940), which we inadvertently neglected to include in the regulations text. Section 6019 of the Omnibus Budget Reconciliation Act of 1989 (OBRA '89) (Pub. L. 101–239), enacted December 19, 1989, amended section 1865(a) of the Social Security Act to allow the Secretary to disclose an accreditation survey and information related to it to the extent the survey and information are related to an enforcement action taken by the Secretary for Medicare participating laboratories. For laboratories that have a CLIA certificate but do not participate in Medicare, disclosure of surveys are governed by the provisions of the Freedom of Information Act. (5 U.S.C. 552)

• We are also adding a new paragraph (f) to provide for our onsite observation of accreditation organization operations.

• In §§ 493.509 and 493.519, we make several clarifying revisions for consistency and move the criteria for triggering a validation review from § 493.509 to § 493.511. We also add the reapplication procedures that are to be followed every six years or sooner if the approval or CLIA exemption is in jeopardy. We also add that our notice to the organization or State will indicate what reapplication materials we need and, in cases not involving routine reapplication, give a deadline for their submission.

• In § 493.511, we give accreditation organizations that fail to adopt requirements comparable to condition level requirements a probationary period of up to but not more than one year (rather than six months) to adopt comparable requirements. We also make some technical revisions. In new paragraph (i) we provide for our immediate withdrawal of our approval of deeming authority of an accreditation organization in situations involving immediate jeopardy.

• We remove our proposed deletion of §§ 493.1701(b)(4) and 493.1708 as they were already replaced, on February 28, 1992 (57 FR 7002).

• In §§ 493.511 and 493.521 and new subpart D in part 488 we give the accreditation organizations and States reconsideration rights.

• In § 493.513 we revise paragraph (a) to show that a laboratory in an approved State laboratory program is exempt from CLIA program requirements for a period not to exceed six years. We also revise paragraph (k) to add the term of approval to the public notice content.

• In § 493.521 we revise paragraph (g) to show that HCFA will not renew the approval of a State laboratory program if the State fails to pay the applicable fees to pay for validation costs.

Regulatory Impact Statement

A. Executive Order 12291

Executive Order 12291 (E.O. 12291) requires us to prepare and publish a final regulatory impact analysis for any proposed rule that meets one of the E.O. 12291 criteria for a "major rule"; that is, that will be likely to result in—

• An annual effect on the economy of $100 million or more;

• A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or

• Significant adverse effects on competition, employment, investment,

productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

In addition, we generally prepare a final regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), unless the Secretary certifies that a final regulation will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, we consider all accreditation organizations as small entities. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis for any final rule that may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital which is located outside a Metropolitan Statistical Area and has fewer than 50 beds.

This final rule revises the August 20, 1990 proposed rule with comment period, based on comments submitted by the public. Changes made as a result of comments received are summarized in the Comments and Responses section of this preamble. We do not believe that any of the changes incorporated into this final rule as a result of the comments would have any significant impact and we are therefore not preparing an analysis with respect to them.

Although we do not believe that the changes in this document will have a significant impact, we do acknowledge that there could be some impact on accredited laboratories and on laboratories in States with approved laboratory programs, especially with respect to use of accreditation or State exemption as a means of demonstrating compliance with CLIA requirements.

Inasmuch as these accredited or CLIA-exempt laboratories will be required to meet requirements that have equivalency with CLIA requirements, the impact on these laboratories will not differ substantially from the impact experienced by all laboratories as a result of the promulgation of the related final rules, HSQ-176-FC, Regulations Implementing the Clinical Laboratory Improvement Amendments of 1988 (57 FR 7002) and HSQ-179-F, Enforcement Procedures for Laboratories (57 FR 7218). The regulatory impact analysis that accompanies HSQ-176-FC explains the overall regulatory impact of all CLIA provisions, including those implemented under this rule.

Paperwork Burden

Section 493.506 of this rule contains information collection requirements that are subject to Office of Management and Budget (OMB) approval under the Paperwork Reduction Act of 1980. These collections require an accreditation organization or State laboratory program to agree to notify us of certain survey and PT results and certain actions and provide us with reports and other information as needed. Public reporting burden for these collections of information is estimated to be one hour per response for each organization and agency every two years.

A notice will be published in the **Federal Register** when approval is obtained.

List of Subjects

42 CFR Part 488

Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 493

Laboratories, Medicare, Medicaid, Health facilities, Reporting and recordkeeping requirements.

42 CFR Part 498

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

CHAPTER IV—HEALTH CARE FINANCING ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR chapter IV is amended as set forth below:

A. Part 488 is amended as follows:

PART 488—SURVEY AND CERTIFICATION PROCEDURES

1. The authority citation for part 488 is revised to read as follows:

Authority: Sec. 353 of the Public Health Service Act (42 U.S.C. 263a) and secs. 1102, 1814, 1861, 1865, 1866, 1871, 1880, 1881, 1883, 1913 of the Social Security Act (42 U.S.C. 1302, 1395f, 1395x, 1395bb, 1395cc, 1395hh, 1395qq, 1395rr and 1395tt).

2. Part 488 is amended by adding a new subpart D to read as follows:

Subpart D—Reconsideration of Adverse Determinations—Deeming Authority for Accreditation Organizations and CLIA Exemption of Laboratories Under State Programs

Sec.

488.201 Reconsideration.
488.203 Withdrawal of request for reconsideration.
488.205 Right to informal hearing.
488.207 Informal hearing procedures.
488.209 Hearing officer's findings.
488.211 Final reconsideration determination.

§ 488.201 Reconsideration.

(a) *Right to reconsideration.* (1) A national accreditation organization dissatisfied with a determination that its accreditation requirements do not provide (or do not continue to provide) reasonable assurance that the entities accredited by the accreditation organization meet the applicable CLIA requirements is entitled to a reconsideration as provided in this subpart.

(2) A State dissatisfied with a determination that the requirements it imposes on laboratories in that State and under the laws of that State do not provide (or do not continue to provide) reasonable assurance that laboratories licensed or approved by the State meet applicable CLIA requirements is entitled to a reconsideration as provided in this subpart.

(b) *Eligibility for reconsideration.* HCFA will reconsider any determination to deny, remove or not renew the approval of deeming authority to private accreditation organizations, or any determination to deny, remove or not renew the approval of a State laboratory program for the purpose of exempting the State's laboratories from CLIA requirements, if the accreditation organization or State files a written request for a reconsideration in accordance with paragraphs (c) and (d) of this section.

(c) *Manner and timing of request for reconsideration.* (1) A national accreditation organization or a State laboratory program described in paragraph (b), dissatisfied with a determination with respect to its deeming authority, or, in the case of a State, a determination with respect to the exemption of the laboratories in the State from CLIA requirements, may request a reconsideration of the determination by filing a request with HCFA either directly by its authorized officials or through its legal representative. The request must be filed within 60 days of the receipt of notice of an adverse determination or nonrenewal as provided in subpart A of part 488 or subpart E of part 493, as applicable.

(2) Reconsideration procedures are available after the effective date of the decision to deny, remove, or not renew the approval of an accreditation organization or State laboratory program.

(d) *Content of request.* The request for reconsideration must specify the findings or issues with which the accreditation organization or State disagrees and the reasons for the disagreement.

§ 488.203 Withdrawal of request for reconsideration.

A requestor may withdraw its request for reconsideration at any time before the issuance of a reconsideration determination.

§ 488.205 Right to informal hearing.

In response to a request for reconsideration, HCFA will provide the accreditation organization or the State laboratory program the opportunity for an informal hearing as described in § 488.207 that will—

(a) Be conducted by a hearing officer appointed by the Administrator of HCFA; and

(b) Provide the accreditation organization or State laboratory program the opportunity to present, in writing or in person, evidence or documentation to refute the determination to deny approval, or to withdraw or not renew deeming authority or the exemption of a State's laboratories from CLIA requirements.

§ 488.207 Informal hearing procedures.

(a) HCFA will provide written notice of the time and place of the informal hearing at least 10 days before the scheduled date.

(b) The informal reconsideration hearing will be conducted in accordance with the following procedures—

(1) The hearing is open to HCFA and the organization requesting the reconsideration, including—

(i) Authorized representatives;

(ii) Technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts); and

(iii) Legal counsel;

(2) The hearing is conducted by the hearing officer who receives testimony and documents related to the proposed action;

(3) Testimony and other evidence may be accepted by the hearing officer even though it would be inadmissable under the usual rules of court procedures;

(4) Either party may call witnesses from among those individuals specified in paragraph (b)(1) of this section; and

(5) The hearing officer does not have the authority to compel by subpoena the production of witnesses, papers, or other evidence.

§ 488.209 Hearing officer's findings.

(a) Within 30 days of the close of the hearing, the hearing officer will present the findings and recommendations to the accreditation organization or State laboratory program that requested the reconsideration.

(b) The written report of the hearing officer will include—

(1) Separate numbered findings of fact; and

(2) The legal conclusions of the hearing officer.

§ 488.211 Final reconsideration determination.

(a) The hearing officer's decision is final unless the Administrator, within 30 days of the hearing officer's decision, chooses to review that decision.

(b) The Administrator may accept, reject or modify the hearing officer's findings.

(c) Should the Administrator choose to review the hearing officer's decision, the Administrator will issue a final reconsideration determination to the accreditation organization or State laboratory program on the basis of the hearing officer's findings and recommendations and other relevant information.

(d) The reconsideration determination of the Administrator is final.

(e) A final reconsideration determination against an accreditation organization or State laboratory program will be published by HCFA in the **Federal Register.**

B. Part 493 is amended as follows:

PART 493—LABORATORY REQUIREMENTS

1. The authority citation for part 493 continues to read as follows:

Authority: Sec. 353 of the Public Health Service Act and secs. 1102, 1861(e), the sentence following 1861(s)(11), 1861(s)(12) and 1861(s)(13) of the Social Security Act (42 U.S.C. 263a, 1302, the sentence following sec. 1395x(s)(11), and sec. 1395x(s)(12) and (s)(13).)

2. The table of contents for part 493 is amended by adding a new subpart E to read as follows:

PART 493—LABORATORY REQUIREMENTS,

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

Sec.

493.501 General requirements for accredited laboratories.
493.503 Proficiency testing requirements of laboratories with deemed status.
493.504 Revocation of accreditation.
493.506 Federal review and approval of private, nonprofit accreditation organizations.
493.507 Validation inspections of laboratories with certificates of accreditation.
493.509 Continuing Federal oversight of private nonprofit accreditation organizations.
493.511 Removal of deeming authority and final determination review.
493.513 General requirements for CLIA-exempt laboratories.
493.515 Federal review of laboratory requirements of State laboratory programs.
493.517 Validation inspections of CLIA-exempt laboratories.
493.519 Continuing Federal oversight of an approved State laboratory program.
493.521 Removal of CLIA exemption and final determination review.

3. Section 493.2 is amended by adding definitions of "Approved accreditation organization for laboratories," "Approved State laboratory program," "CLIA-exempt laboratory", "Equivalency," "Rate of disparity," "State," "State licensure," "State survey agency," and "Substantial allegation of noncompliance" and "Validation review period", and by deleting the definition of "State-exempt laboratory" and by adding the definitions of "Accredited laboratory" and "HCFA agent" to read as follows:

§ 493.2 Definitions.

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Accredited laboratory means a laboratory that has voluntarily applied for and been accredited by a private, nonprofit accreditation organization approved by HCFA in accordance with this part;

Approved accreditation organization for laboratories means a private, nonprofit accreditation organization that has formally applied for and received HCFA's approval based on the organization's compliance with this part.

Approved State laboratory program means a licensure or other regulatory program for laboratories in a State, the requirements of which are imposed under State law, and the State laboratory program has received HCFA approval based on the State's compliance with this part.

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CLIA-exempt laboratory means a laboratory that has been licensed or approved by a State where HCFA has determined that the State has enacted laws relating to laboratory requirements that are equal to or more stringent than CLIA requirements and the State licensure program has been approved by

HCFA in accordance with subpart E of this part.

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Equivalency means that an accreditation organization's or a State laboratory program's requirements, taken as a whole, are equal to or more stringent than the CLIA requirements established by HCFA, taken as whole. It is acceptable for an accreditation organization's or State laboratory program's requirements to be organized differently or otherwise vary from the CLIA requirements, as long as (1) all of the requirements taken as a whole would provide at least the same protection as the CLIA requirements taken as a whole; and (2) a finding of noncompliance with respect to CLIA requirements taken as a whole would be matched by a finding of noncompliance with the accreditation or State requirements taken as a whole.

HCFA agent means an entity with which HCFA arranges to inspect laboratories and assess laboratory activities against CLIA requirements and may be a State survey agency, a private, nonprofit organization other than an approved accreditation organization, a component of HHS, or any other governmental component HCFA approves for this purpose. In those instances where all of the laboratories in a State are exempt from CLIA requirements, based on the approval of a State's exemption request, the State survey agency is not the HCFA agent.

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Rate of disparity means the percentage of sample validation inspections for a specific accreditation organization or State where HCFA, the State survey agency or other HCFA agent finds noncompliance with one or more condition level requirements but no comparable deficiencies were cited by the accreditation organization or the State, and it is reasonable to conclude that the deficiencies were present at the time of the most recent accreditation organization or State licensure inspection.

Example: Assume the State survey agency, HCFA or other HCFA agent performs 200 sample validation inspections for laboratories accredited by a single accreditation organization or licensed in an exempt State during a validation review period and finds that 60 of the 200 laboratories had one or more condition level requirements out of compliance. HCFA reviews the validation and accreditation organization's or State's inspections of the validated laboratories and determines that the State or accreditation organization found comparable deficiencies in 22 of the 60 laboratories and it is reasonable to conclude that deficiencies were present in the remaining 38 laboratories at the time of the accreditation organization's or State's inspection. Thirty-eight divided by 200 equals a 19 percent rate of disparity.

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State includes, for purposes of this part, each of the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands and a political subdivision of a State where the State, acting pursuant to State law, has expressly delegated powers to the political subdivision sufficient to authorize the political subdivision to act for the State in enforcing requirements equal to or more stringent than CLIA requirements.

State licensure means the issuance of a license to, or the approval of, a laboratory by a State laboratory program as meeting standards for licensing or approval established under State law.

State survey agency means the State health agency or other appropriate State or local agency that has an agreement under section 1864 of the Social Security Act and is used by HCFA to perform surveys and inspections.

Substantial allegation of noncompliance means a complaint from any of a variety of sources (including complaints submitted in person, by telephone, through written correspondence, or in newspaper or magazine articles) that, if substantiated, would have an impact on the health and safety of the general public or of individuals served by a laboratory and raises doubts as to a laboratory's compliance with any condition level requirement.

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Validation review period means the one year time period during which HCFA conducts validation inspections and evaluates the results of the most recent surveys performed by an accreditation organization or State laboratory program.

4. A new subpart E is added to read as follows:

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

§ 493.501 General requirements for accredited laboratories.

(a) *Deemed status.* HCFA may deem a laboratory to meet all the applicable CLIA program requirements of this Part if the laboratory is accredited by a private, nonprofit accreditation organization for laboratories that—

(1) Provides reasonable assurance to HCFA that it requires the laboratories it accredits to meet all of the requirements equivalent to the CLIA condition level requirements specified in this part and would, therefore, meet condition level requirements if those laboratories had not been granted deemed status and had been inspected against condition level requirements; and

(2) Meets the requirements of § 493.506 of this subpart.

(b) *Laboratory requirements.* To be deemed to meet the applicable CLIA program requirements, a laboratory accredited by a private, nonprofit accreditation organization must—

(1) Authorize its accreditation organization to release to HCFA all records and information required by HCFA;

(2) Permit inspections as required by these regulations;

(3) Obtain a certificate of accreditation as required by § 493.632 of this part; and

(4) Pay the applicable fees as required by §§ 493.638 and 493.645 of this part.

(c) *Application and reapplication process for accreditation organizations.* In applying or reapplying to HCFA for deeming authority, a private nonprofit accreditation organization must provide the following information to the Administrator of HCFA—

(1) The specialty(ies) or subspecialty(ies) for which the organization is requesting "deeming authority";

(2) A detailed comparison of individual accreditation requirements with the comparable condition level requirements; i.e., a crosswalk;

(3) A detailed description of the inspection process, including the frequency of inspections, copies of inspection forms, instructions, and guidelines, a description of the review and decision-making process of accreditation inspections and a description of the steps taken to monitor the correction of deficiencies;

(4) A description of the process for monitoring proficiency testing (PT) performance, including action to be taken in response to unsuccessful participation in an approved PT program;

(5) A description of the accreditation 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 system;

(6) Detailed information concerning the personnel who perform accreditation inspections, including but not limited to the size and composition of individual accreditation inspection teams, education and experience requirements

that those inspectors must meet and the content and frequency of the training provided to inspection personnel;

(7) Procedures to investigate and respond to complaints against accredited laboratories;

(8) A list of any currently accredited laboratories and the expiration date of each laboratory's accreditation;

(9) Procedures for making PT information available, including explanatory information required to interpret PT results, on a reasonable basis, upon request of any person;

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

(11) A proposed agreement between the accreditation organization and HCFA with respect to the notification requirements specified in § 493.506(b)(3) of this subpart; and

(12) Whether accreditation inspections are announced or unannounced.

(d) *Application review process.* Once HCFA receives an application for deeming authority from a private nonprofit accreditation organization—

(1) HCFA will determine if additional information is necessary to make a determination for approval of the accreditation organization's application for deeming authority and will so notify the organization and give it an opportunity to provide the additional information.

(2) HCFA may visit the organization's offices to verify representations made by the organization in its application, including, but not limited to, review of documents and interviews with the organization's staff.

(3) The accreditation organization will receive a formal notice from HCFA stating whether the request for deeming authority has been approved or denied and the rationale for any denial.

(4) HCFA may approve an accreditation organization for a period not to exceed six years.

(5) An accreditation organization may withdraw its application for approval of deeming authority at any time prior to the official notification specified in paragraph (d)(3) of this section.

(6) Except as provided in paragraph (d)(8) of this section, any accreditation organization whose request for approval of deeming authority is denied may request, within 60 days of the notification of the denial, that its original application be reconsidered.

(7) Except as provided in paragraph (d)(8) of this section, any accreditation organization whose request for approval of deeming authority has been denied may resubmit its application if the organization—

(i) Has revised its accreditation program to address the rationale for denial of its previous request;

(ii) Can demonstrate that it can provide reasonable assurance that its accredited facilities meet condition level requirements; and

(iii) Resubmits the application in its entirety.

(8) If an accreditation organization has requested, in accordance with part 488, subpart D of this chapter, a reconsideration of HCFA's determination that its request for deeming approval is denied, it may not submit a new application for deeming authority until a final reconsideration determination is issued.

(e) *Publication of names of approved accreditation organizations.* HCFA publishes a notice in the **Federal Register** when it grants deeming authority to an accreditation organization under paragraph (a) of this section. The notice—

(1) Names the accreditation organization;

(2) Describes the basis for granting deeming authority to the accreditation organization;

(3) Describes how the accreditation organization provides reasonable assurance to HCFA that laboratories accredited by the organization meet CLIA requirements equivalent to those specified in this part and would, therefore, meet CLIA requirements if those laboratories had not been granted deemed status, but had been inspected against condition level requirements; and

(4) Specifies a term of approval not to exceed six years.

§ 493.503 Proficiency testing requirements of laboratories with deemed status.

(a) *General.* A laboratory deemed to meet condition level requirements must meet the proficiency testing (PT) requirements of this part.

(b) *Release of PT results.* (1) A laboratory deemed to meet condition level requirements must 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 a 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.

(2) A laboratory that refuses to authorize the release of its PT results will no longer be deemed to meet the condition level requirements and will be subject to full review by HCFA, the State survey agency, or other HCFA agent in accordance with § 493.1777 of this chapter and may be subject to the suspension or revocation of its certificate of accreditation under § 493.1840 of this part.

(3) A laboratory with deemed status that has failed to achieve successful participation in an approved PT program must authorize its accreditation organization to release to HCFA its 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 this part. Such a laboratory must also 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 such actions.

(4) HCFA may, on the basis of the notification of adverse actions received from the accreditation organization, take an adverse action against a laboratory that fails to participate successfully in an approved PT program.

§ 493.504 Revocation of accreditation.

After a private, nonprofit accreditation organization withdraws or revokes its accreditation of a laboratory, the certificate of accreditation required by this part will continue in effect until the earlier of—

(a) 45 days after the laboratory receives notice of the withdrawal or revocation of the accreditation; or

(b) The effective date of any action taken by HCFA.

§ 493.506 Federal review and approval of private, nonprofit accreditation organizations.

(a) An accreditation organization may request and may be granted "deeming authority" for all specialties and subspecialties or for specific specialty or subspecialty areas. In the latter case, the accreditation organization will be accountable for the monitoring of compliance with all requirements equivalent to condition level requirements within the scope of the specialty or subspecialty.

(b) HCFA's review of a private, nonprofit accreditation organization includes, but is not necessarily limited to, an evaluation of the following—

(1) Whether the accreditation organization's requirements for laboratories are equal to or more

stringent than the condition level requirements for laboratories;

(2) The accreditation organization's inspection process to determine—

(i) The composition of the inspection team, qualifications of the inspectors, and the ability of the organization to provide continuing education and training to inspectors;

(ii) The comparability of the organization's full inspection and complaint inspection requirements to those of HCFA, including but not limited to inspection frequency, and the ability to investigate and respond to complaints against accredited laboratories;

(iii) The organization's procedures for monitoring laboratories found to be out of compliance with its requirements. (These monitoring procedures are to be used only when the accreditation organization identifies noncompliance. If noncompliance is identified through validation inspections, HCFA, the State survey agency, or other HCFA agent monitors corrections as authorized at § 493.507(b)(4) of this subpart);

(iv) The ability of the organization to provide HCFA with electronic data and reports, including the crosswalk specified in § 493.501(c)(2), in ASCII-comparable code that are necessary for effective validation and assessment of the organization's inspection process;

(v) The ability of the organization to provide HCFA with electronic data in ASCII-comparable 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;

(vi) The ability of the organization to provide HCFA with electronic data in ASCII-comparable code for all accredited laboratories, including the area of specialty or subspecialty;

(vii) The adequacy of numbers of staff and other resources; and

(viii) The organization's ability to provide adequate funding for performing required inspections; and

(3) The organization's agreement with HCFA that requires it to:

(i) Notify HCFA of any laboratory accredited by the organization that has had its accreditation withdrawn, revoked or limited by the accreditation organization denied, suspended, withdrawn or revoked or that has had any other adverse action taken against it by the accreditation organization within 30 days of the action taken;

(ii) Notify HCFA within 10 days of a deficiency identified in an accredited laboratory where the deficiency poses an immediate jeopardy to the laboratory's patients or a hazard to the general public;

(iii) Notify HCFA of all newly accredited laboratories (or laboratories whose areas of specialty or subspecialty are revised) within 30 days;

(iv) Notify each laboratory accredited by the organization within 10 days of HCFA's withdrawal of recognition of the organization's deeming authority;

(v) Provide HCFA with inspection schedules, as requested, for the purpose of conducting onsite validation inspections;

(vi) Provide HCFA, the State survey agency or other HCFA agent with any facility-specific data to include, but not be limited to, the following (upon request):

(A) PT results that constitute unsuccessful participation in an approved PT program; and

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

(vii) Provide HCFA written notification at least 30 days in advance of the effective date of any proposed changes in its requirements; and

(viii) Disclose any laboratory's PT results upon the reasonable request by any person.

§ 493.507 Validation inspections of laboratories with certificates of accreditation.

(a) *Basis for inspection.* HCFA, the State survey agency, or a HCFA agent may conduct an inspection of an accredited laboratory that has been issued a certificate of accreditation. The results of these inspections will be used to validate the accreditation organization's accreditation process. These inspections may be conducted on a representative sample basis or in response to substantial allegations of noncompliance.

(1) When conducted on a representative sample basis, the inspection is comprehensive, addressing all condition level requirements, or may be focused on a specific condition level requirement or requirements, and the number of laboratories sampled is sufficient to allow a reasonable estimate of the performance of each accreditation organization.

(2) When conducted in response to a substantial allegation of noncompliance, HCFA, the State survey agency or other HCFA agent inspects for any condition level requirement or requirements that HCFA determines to be related to the allegation. If HCFA, the State survey agency or other HCFA agent substantiates a deficiency and determines that the laboratory is out of compliance with any condition level requirement, HCFA, the State survey agency or other HCFA agent will conduct a full CLIA inspection.

(b) *Effect of selection for inspection.* A laboratory selected for inspection must:

(1) Authorize its accreditation organization to release to HCFA, the State survey agency or other HCFA agent, on a confidential basis, a copy of the results of the laboratory's most recent full, and any subsequent partial, accreditation inspection(s);

(2) Authorize the validation inspection to take place;

(3) Provide HCFA, the State survey agency, or other HCFA agent access to all facilities, equipment, materials, records and information that HCFA determines have a bearing on whether the laboratory is being operated in accordance with the requirements of this part, and permit HCFA, the State survey agency or other HCFA agent to copy any such material or require it to be submitted; and

(4) Authorize HCFA, the State survey agency or other HCFA agent to monitor the correction of any deficiencies found through the validation inspection.

(c) *Refusal to cooperate with the inspection.* (1) If a laboratory selected for inspection fails to comply with the requirements specified in paragraph (b) of this section it—

(i) Will be subject to full review by HCFA, the State survey agency or other 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) An accredited laboratory will be once again deemed to meet the condition level requirements by virtue of its accreditation when—

(i) It 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) It withdraws any prior refusal to allow a validation inspection; and

(iii) HCFA finds that the laboratory meets all the condition level requirements.

(d) *Consequences of a finding of noncompliance.* If a validation inspection results in a finding that the laboratory is out of compliance with one or more condition level requirements, the laboratory is subject to the same requirements and survey and enforcement processes applied to laboratories that are not accredited and that are found out of compliance following a State agency inspection under this part and to full review by

HCFA, the State survey agency or other HCFA agent in accordance with this part; i.e., the laboratory will be subject to the principal and alternative sanctions specified in § 493.1806 of this part.

(e) *Disclosure of accreditation and validation inspection results.* The accreditation inspection results are disclosable to the public only if they are related to an enforcement action taken by the Secretary. The results of all validation inspections conducted by HCFA, the State survey agency or other HCFA agents are disclosable.

(f) *Onsite observation of accreditation organization operations.* As part of the validation review process, HCFA may conduct an onsite inspection of the accreditation organization's operations and offices to verify the organization's representations and to assess the organization's compliance with its own policies and procedures. Such an onsite inspection may include, but is not limited to, the review of documents, the auditing of meetings concerning the accreditation process, the evaluation of accreditation inspection results or the accreditation decision-making process, and interviews with the organization's staff.

§ 493.509 Continuing Federal oversight of private, nonprofit accreditation organizations.

(a) *Comparability review.* In addition to reviewing the equivalency of specified accreditation requirements to the comparable condition level requirements when an accreditation organization initially applies to HCFA for "deeming authority", HCFA reviews the equivalency of requirements—

(1) When HCFA promulgates new condition level requirements;

(2) When HCFA identifies accreditation organizations whose requirements do not continue to be equal to or more stringent than condition level requirements;

(3) When an accreditation organization adopts new requirements;

(4) When an accreditation organization adopts changes to its inspection process as required by § 493.511(b); or

(5) Every six years or sooner if HCFA determines the organization requires an earlier review.

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

(c) *Reapplication procedures.* (1) Every six years, or sooner as determined by HCFA, an approved accreditation organization must reapply for continued approval of deeming authority. HCFA will notify the organization of the materials the organization must submit as part of the reapplication procedure.

(2) An accreditation organization that is not meeting the requirements of this subpart, as determined through a comparability or validation review, must furnish HCFA, upon request and at any time, with the reapplication materials HCFA requests. HCFA will establish a deadline by which the materials are to be submitted.

(d) *Notice.* HCFA provides written notice to the accreditation organization indicating that its approval may be in jeopardy if a comparability or validation review reveals that an accreditation organization is not meeting the requirements of this subpart and that a deeming authority review is being initiated. The notice contains the following information—

(1) A statement of the discrepancies that were found as well as other related documentation;

(2) An explanation of HCFA's review process on which the final determination will be based and a description of the possible actions as specified in § 493.511 that may be imposed by HCFA based on the findings from the comparability or validation review;

(3) A description of the procedures available if the accreditation organization desires an opportunity to explain or justify the findings made during the comparability or validation review; and

(4) The reapplication materials the organization must submit and the deadline for that submission.

§ 493.511 Removal of deeming authority and final determination review.

(a) *Deeming authority review.* (1) HCFA reviews, as appropriate, the criteria described in § 493.506 to reevaluate whether the accreditation organization continues to meet all these criteria. HCFA conducts a deeming authority review of an accreditation organization's program if the comparability or validation review produces findings as described at § 493.509(a) of this subpart.

(2) HCFA conducts, at its discretion, a deeming authority review of an accreditation organization's program if validation review findings, irrespective of the rate of disparity, indicate widespread or systematic problems in the organization's processes that provide evidence that the organization's requirements, taken as a whole, are no longer equivalent to CLIA requirements, taken as a whole.

(3) HCFA conducts a deeming authority review whenever validation inspection results over a one-year period indicate a rate of disparity of 20 percent or more between the findings of the accreditation organization and the findings of HCFA, State survey agencies, or other HCFA agents.

(b) Following the deeming authority review, if HCFA determines that the accreditation organization has failed to adopt requirements equal to or more stringent than CLIA requirements, HCFA may give the accreditation organization a conditional approval effective 30 days following the date of HCFA's determination of its deeming authority for a probationary period, not to exceed one year, to adopt comparable requirements.

(c) Following the deeming authority review, if HCFA determines that there are widespread systematic problems in the organization's inspection process, HCFA may give the accreditation organization conditional approval of its deeming authority during a probationary period not to exceed one year that is effective 30 days following the date of HCFA's determination.

(d) Within 60 days after the end of any probationary period, HCFA will make a final determination as to whether or not an accreditation organization continues to meet the criteria described at § 493.506 of this subpart and issues an appropriate notice (including reasons for the determination) to the accreditation organization. This determination is based on the evaluation of any of the following:

(1) The most recent validation inspection and review findings as described at § 493.509(b) of this subpart. In order for the accreditation organization to continue to have deeming authority, it must continue to meet the criteria in § 493.506 of this subpart;

(2) Facility-specific data and other related information;

(3) The accreditation organization's surveyors in terms of qualifications, ongoing education and training, composition of inspection team, etc.;

(4) The organization's inspection procedures; and

(5) The organization's accreditation requirements.

(e) HCFA may remove recognition of deeming authority effective 30 days from the date that it provides written notice to the accreditation organization that its deeming authority will be removed if the accreditation organization has not made improvements acceptable to HCFA during the probationary period.

(f) The existence of any validation review, deeming authority review, probationary status, or any other action by HCFA with respect to an accreditation organization does not affect or limit the conduct of any validation inspection of its accredited laboratories.

(g) HCFA will publish a notice in the **Federal Register** containing a justification of the basis for removing the deeming authority from an accreditation organization.

(h) After HCFA withdraws approval of an accreditation organization's deeming authority, the CLIA certificates of accreditation of all affected laboratories continue in effect for 60 days after the laboratory receives notification of the withdrawal of approval. HCFA may extend the period for an additional 60 days for a laboratory if it determines that the laboratory submitted an application for inspection to another approved accreditation organization or an application for a certificate or certificate of waiver to HCFA, the State agency or other HCFA agent before the initial 60 day period ends.

(i) If at any time HCFA determines that the continued approval of deeming authority of any accreditation organization poses an immediate jeopardy to the patients of the laboratories accredited by that organization, or such continued approval otherwise constitutes a significant hazard to the public health, HCFA may immediately withdraw the approval of deeming authority of that accreditation organization.

(j) Any accreditation organization that is dissatisfied with a determination to withdraw its deeming authority may request a reconsideration of that determination in accordance with subpart D of part 488.

§ 493.513 General requirements for CLIA-exempt laboratories.

(a) HCFA may exempt from CLIA program requirements, for a period not to exceed six years, all State-licensed or approved laboratories in a State if the State—

(1) Has in effect laws that provide for requirements equal to or more stringent than condition level requirements;

(2) Has an agency that licenses or approves laboratories that meet requirements equal to or more stringent than the CLIA condition level requirements specified in this part and would, therefore, meet condition level requirements if those laboratories had not been exempted from CLIA, but rather had been inspected for compliance with condition level requirements;

(3) Meets the requirements and is approved in accordance with § 493.515 of this subpart;

(4) Demonstrates that it has enforcement authority and administrative structures and resources adequate to enforce its laboratory requirements;

(5) Permits HCFA or HCFA agents to inspect laboratories in the State;

(6) Requires laboratories in the State to submit to inspections by HCFA or HCFA agents as a condition of licensure or approval;

(7) Agrees to pay the cost of the validation program administered by HCFA in that State as specified in §§ 493.645(b) and 493.646 of this part; and

(8) Takes appropriate enforcement action against laboratories found by HCFA or HCFA agents not to be in compliance with requirements equivalent to CLIA requirements.

(b) A laboratory in a State with an approved State laboratory program must—

(1) Authorize the laboratory program to release to HCFA or HCFA agent all records and information required by HCFA; and

(2) Permit inspection as required by these regulations.

(c) In applying to HCFA for exemption from the CLIA program, the State must provide the following information to HCFA—

(1) A detailed comparison of individual licensure or approval requirements with the comparable condition level requirements; i.e., a crosswalk;

(2) A detailed description of the inspection process including the frequency of inspections, copies of inspection forms, instructions and guidelines, a description of the review and decision-making process of licensure or approval inspections, whether inspections are announced or unannounced and a description of the steps taken to monitor the correction of deficiencies;

(3) A description of the State's enforcement authority, administrative structure and resources to enforce the State standards;

(4) A description of the process for monitoring proficiency testing (PT) performance, including action to be taken in response to unsuccessful participation in a HCFA-approved PT program;

(5) The State's procedures for responding to, and for the investigation of, complaints against licensed or approved laboratories;

(6) A list of all currently licensed or approved laboratories and the expiration date of each laboratory's current license or approval;

(7) Procedures under State confidentiality and disclosure requirements for the release of PT information, including explanatory information required to interpret PT results; and

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

(d) The State must also submit the following supporting documentation—

(1) A written presentation that demonstrates the agency's ability to furnish HCFA with electronic data in ASCII comparable code, including the crosswalk specified in paragraph (c)(1) of this section;

(2) A statement acknowledging that the State will notify HCFA through electronic data transmission of—

(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 any such action taken;

(ii) Changes in licensure (or approval) or inspection requirements; and

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

(e) If HCFA determines that additional information is necessary to make a determination for approval or denial of the application for exemption, HCFA will notify the State and afford it an opportunity to provide the additional information.

(f) HCFA may visit the State laboratory program offices to review the application of the State's policies and procedures and other information provided by the State. Such review includes, but is not limited to, examination of documents and interviews with staff.

(g) HCFA will furnish the State a formal notice stating whether the request for exemption has been approved or denied and the rationale for any denial.

(h) Except as provided in paragraph (m) of this section, any State whose application for approval for exemption, or for renewal of that approval, from CLIA has been denied may resubmit its request as soon as the State has taken the necessary action to address the rationale for any previous denial.

(i) A State may withdraw its request for exempt status at any time prior to the official notification specified in paragraph (g) of this section.

(j) Any State whose application for approval for exempt status is denied may request, within 60 days of the notification of the denial, that its original application or application for renewal be reconsidered in accordance with part 488, subpart D of this chapter.

(k) HCFA publishes a notice in the Federal Register when it grants exemption to a State under paragraph (a) of this section. The notice—

(1) Names the State;

(2) Describes the basis for granting the exemption to the State;

(3) Describes how the laboratory requirements of the State are equal to or more stringent than those specified in this part; and

(4) Specifies a term of approval not to exceed six years.

(l) A State that has received approval for the exemption of its laboratories from the CLIA program must reapply to HCFA every two years for renewal of its exemption status and renew its agreement to pay the cost of the HCFA administered validation program in that State.

(m) If a State has requested a reconsideration of HCFA's determination that its request for exemption, or for renewal of its exemption, of its laboratories from CLIA is denied, it may not resubmit its request until a final reconsideration determination is issued.

§ 493.515 Federal review of laboratory requirements of State laboratory programs.

(a) HCFA's review of a State laboratory program includes, but is not necessarily limited to, an evaluation of the following:

(1) Whether the State's requirements for laboratories are equal to or more stringent than the condition level requirements;

(2) The State's inspection process requirements to determine—

(i) The comparability of the full inspection and complaint inspection procedures to those of HCFA, including but not limited to inspection frequency and the ability to investigate and respond to complaints against licensed or approved laboratories;

(ii) The State's enforcement procedures for laboratories found to be out of compliance with its requirements;

(iii) The ability of the State to provide HCFA with electronic data and reports in ASCII-comparable code with the adverse or corrective actions resulting from PT results that constitute unsuccessful participation in PT programs and with other data HCFA determines are necessary for validation and assessment of the State's inspection process requirements;

(3) The State's agreement with HCFA to—

(i) Notify HCFA within 30 days of the action taken against any CLIA-exempt laboratory that has had its licensure or approval withdrawn or revoked or has been in any way sanctioned;

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

(iii) Notify each laboratory licensed by the State within 10 days of HCFA's withdrawal of the State's exemption;

(iv) Provide HCFA with written notification of any changes in its licensure (or approved) and inspection requirements;

(v) Disclose any laboratory's PT results in accordance with a State's confidentiality requirements;

(vi) Take the appropriate enforcement action against laboratories found by HCFA not to be in compliance with requirements comparable to condition level requirements and report such enforcement actions to HCFA;

(vii) Notify HCFA of all newly licensed laboratories, including the specialties and subspecialties, for which any laboratory performs testing within 30 days; and subspecialties, for which any laboratory performs testing within 30 days; and

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

§ 493.517 Validation inspections of CLIA-exempt laboratories.

(a) *Basis for inspection.* HCFA or a HCFA agent other than the State survey agency may conduct an inspection of any laboratory in a State with an approved laboratory program. The results of these inspections will be used to validate the appropriateness of the exemption of that State's licensed or approved laboratories from CLIA program requirements. These inspections may be conducted on a representative sample basis or in response to substantial allegations of noncompliance.

(1) When conducted on a representative sample basis, the inspection may be comprehensive, addressing all condition level requirements, or may be focused on a specific requirement or requirements. The number of laboratories sampled is sufficient to allow a reasonable estimate of the performance of the State.

(2) When conducted in response to a substantial allegation of noncompliance, HCFA or a HCFA agent inspects for any condition level requirement or requirements that HCFA determines to be related to the allegation. If HCFA substantiates a deficiency and determines that the laboratory is out of compliance with any condition level requirement, HCFA or other HCFA agent will conduct a full CLIA inspection.

(b) *Effect of selection for inspection.* A CLIA-exempt laboratory selected for a validation inspection must—

(1) Authorize the State to release to HCFA or a HCFA agent, on a confidential basis, a copy of the results of the laboratory's most recent full, and any subsequent partial, licensure or approval inspection(s);

(2) Authorize the validation inspection to take place; and

(3) Provide HCFA or a HCFA agent access to all facilities, equipment, materials, records and information that HCFA 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 any such materials or to require such copies to be submitted.

(c) *Refusal to cooperate with the inspection.* If a laboratory selected for a validation inspection fails to comply with the requirements specified in paragraph (b) of this section, HCFA will notify the State.

(d) *Consequences of a finding of noncompliance.* If a validation inspection results in a finding that the laboratory is out of compliance with one or more condition level requirements, HCFA will direct the State to take the appropriate enforcement action(s).

(e) *Disclosure of State and validation inspection results.* The disclosure of State inspection results will be the responsibility of the approved State laboratory program, in accordance with State law. The results of all validation inspections conducted by HCFA or other HCFA agents are disclosable.

(f) *Onsite observation of State laboratory program operations.* As part of the validation review process, HCFA may conduct an onsite inspection of a State's laboratory program offices and operations to verify 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 HCFA agents. Such an onsite inspection may include, but is not limited to, the review of documents, auditing meetings concerning the licensure or approval process, the evaluation of State inspection results and the licensure or

approval decision-making process, and interviews with State employees.

§ 493.519 Continuing Federal oversight of an approved State laboratory program.

(a) *Comparability review.* In addition to reviewing the equivalency of specified licensure or approval requirements to the comparable condition level requirements when a State initially applies to HCFA for exemption of its licensed or approved laboratories from condition level requirements, HCFA reviews the equivalency of requirements when—

(1) HCFA promulgates new condition level requirements;

(2) HCFA identifies a State whose requirements do not continue to be equal to or more stringent than condition level requirements;

(3) A State laboratory program adopts new requirements;

(4) A State laboratory program adopts changes to its inspection process requirements as required by § 493.521(b); or

(5) Every six years or sooner if HCFA determines the State laboratory requires an earlier review.

(b) *Validation review.* Following the end of a validation review period, HCFA evaluates the validation inspection results for each approved State laboratory program.

(c) *Reapplication procedures.* (1) Every six years, or sooner as determined by HCFA, an approved State laboratory program must reapply for continued approval of CLIA exemption. HCFA will notify the State of the materials the State must submit as part of the reapplication procedure.

(2) A State that is not meeting the requirements of this subpart as determined through a comparability or validation review must furnish HCFA, upon request and at any time, with the reapplication materials HCFA requests. HCFA will establish a deadline by which the materials are to be submitted.

(d) *Notice.* HCFA provides written notice to the State, 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. The notice contains the following information—

(1) A statement of the discrepancies that were found, as well as other related documentation;

(2) An explanation of HCFA's review process on which the final determination will be based and a description of the possible actions as specified in § 493.521 that may be imposed by HCFA based on the findings from the validation or comparability review;

(3) A description of the procedures available if the State desires an opportunity to explain or justify the findings made during the comparability or validation review; and

(4) The reapplication materials the State laboratory program must submit and the deadline for the submission of those materials.

§ 493.521 Removal of CLIA exemption and final determination review.

(a)(1) HCFA conducts a review of a State's laboratory program if the comparability review produces findings as described at § 493.519(a), of this subpart. HCFA reviews, as appropriate, the criteria described in § 493.515 to reevaluate whether the laboratory program continues to meet all these criteria.

(2) HCFA conducts, at its discretion, an exemption review of an approved State laboratory program if validation review findings, irrespective of the rate of disparity, indicate widespread or systematic problems in the State's licensure or approval processes that provide evidence that the State's requirements, taken as a whole, are no longer equivalent to CLIA requirements, taken as a whole.

(3) HCFA conducts a review of an approved State laboratory program whenever validation inspection results over a two-year period indicate a rate of disparity of 20 percent or more between the findings of the State and the findings of HCFA or other HCFA agents.

(b) Following the review, if HCFA determines that the State has failed to adopt requirements equal to or more stringent than CLIA requirements, HCFA may give the State, within 30 days of its determination, a conditional approval of its exempt status for a probationary period not to exceed one year to afford the State the opportunity to adopt equal or more stringent requirements.

(c) Following the review, if HCFA determines that there are widespread or systematic problems in the State's inspection process, HCFA may give the State conditional approval of the exemption of its licensed or approved laboratories during a probationary period not to exceed one year that is effective 30 days. following the date of the determination;

(d) Within 60 days after the end of any probationary period, HCFA makes a final determination as to whether or not a State continues to meet the criteria described at § 493.515 of this subpart and issues an appropriate notice (including reasons for the determination) to the State. This determination is based on the evaluation of any of the following—

(1) The most recent validation inspection(s) and review findings. In order for the State to continue to be exempt, it must meet the criteria in § 493.519 of this subpart;

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

(3) Inspection procedures;

(4) Licensure or approval requirements.

(e) HCFA may remove its approval of a State laboratory program effective 30 days from the date that it provides written notice to the State of this proposed action if the State has not made improvements acceptable to HCFA during the probationary period.

(f) The existence of any validation review, probationary status, or any other action by HCFA does not affect or limit the conducting of any validation inspection.

(g) HCFA will cancel the approval of a State laboratory program if the State fails to pay the applicable fees as specified in §§ 493.645 and 493.646.

(h) If HCFA determines at any time that the continued approval of a State laboratory program poses an immediate jeopardy to the patients of the laboratories in that State, or such continued approval otherwise constitutes a significant hazard to the public health, HCFA may immediately withdraw the approval of that State laboratory program.

(i) HCFA will publish a notice in the **Federal Register** containing a justification of the basis for removing its approval of the State laboratory program.

(j) After HCFA withdraws approval of a State laboratory program, the exempt status of licensed or approved laboratories in the State continues in effect for 60 days after the laboratory receives notification from the State of the withdrawal of HCFA's approval of the program. HCFA may extend this period for an additional 60 days for a laboratory if it determines that the laboratory submitted an application for accreditation to an approved accreditation organization or an application to HCFA for a certificate or certificate of waiver before the initial 60 day period ends.

(k) HCFA may withdraw a State laboratory program's approval if the State refuses to take enforcement action against a laboratory in that State where HCFA determined it to be necessary. Laboratories that are in a State where

program approval has been removed are subject to the same requirements and survey and enforcement processes applied to laboratories that are not exempt from meeting CLIA requirements.

(l) Any State that is dissatisfied with a determination to remove the approval of its laboratory program may request a reconsideration of that determination in accordance with part 488, subpart D of this chapter.

C. Part 498 is amended as follows:

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM

1. The authority citation continues to read as follows:

Authority: Secs. 205(a), 1102, 1869(c), 1871, and 1872 of the Social Security Act (42 U.S.C. 405(a), 1302, 1395ff(c), 1395hh and 1395ii), unless otherwise noted.

2. Section 498.3 is amended by adding new paragraphs (d) (11) and (12) to read as follows:

§ 498.3 Scope and applicability.

* * * * *

(d) *Administrative actions that are not initial determinations.*

* * * * *

(11) The determination that the accreditation requirements of a national accreditation organization do not provide (or do not continue to provide) reasonable assurance that the entities accredited by the accreditation organization meet the applicable long-term care requirements, conditions for coverage, conditions of certification, conditions of participation, or CLIA condition level requirements.

(12) The determination that requirements imposed on a State's laboratories under the laws of that State do not provide (or do not continue to provide) reasonable assurance that laboratories licensed or approved by the State meet applicable CLIA requirements.

Dated: April 4, 1992.

J. Michael Hudson,

Acting Administrator, Health Care Financing Administration.

Approved: April 24, 1992.

Louis W. Sullivan,

Secretary.

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