assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small business, small not-for-profit enterprises and government entities with jurisdiction over populations of less than 50,000.

As discussed in section III.C. below, findings of failure to submit required SIP revisions do not by themselves create any new requirements. Therefore, I certify that today's action does not have a significant impact on small entities.

*C. Unfunded Mandates Act*

Under sections 202, 203, and 205 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act'') signed into law on March 22, 1995, EPA must undertake various actions in association with proposed or final rules that include a Federal mandate that may result in estimated costs of $100 million or more to the private sector, or to State, local, or tribal governments in the aggregate.

In addition, under the Unfunded Mandates Act, before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, EPA must have developed, under section 203, a small government agency plan.

EPA has determined that today's action is not a Federal mandate. The CAA provision discussed in this notice requires states to submit SIPs. This notice merely provides findings that Arizona has not met that requirement. This notice does not, by itself, require any particular action by any State, local, or tribal government, or by the private sector.

For the same reasons, EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments.

*D. Submission to Congress and the General Accounting Office*

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. However, section 808 provides that any rule for which the issuing agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rule) that notice and public procedure thereon are impracticable, unnecessary or contrary to the public interest, shall take effect at such time as the agency promulgating the rule determines. 5 U.S.C. 808(2). As stated previously, EPA has made such a good cause finding, including the reasons therefor, and established an effective date of April 27, 1998. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

*E. Paperwork Reduction Act*

This rule does not contain any information collection requirements which require OMB approval under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

*F. Judicial Review*

Under CAA Section 307(b)(1), a petition to review today's action may be filed in the Court of Appeals for the appropriate circuit by July 13, 1998. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. See section 307(b)(2) of the Act.

**List of Subjects in 40 CFR Part 52**

Environmental protection, Air pollution control, Carbon monoxide, Intergovernmental relations.

**Authority:** 42 U.S.C. 7401 *et seq.*

Dated: April 27, 1998.

**Felicia Marcus,**

*Regional Administrator, Region IX.*

[FR Doc. 98–12853 Filed 5–13–98; 8:45 am]

**BILLING CODE 6560–50–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

### Centers for Disease Control and Prevention

### 42 CFR Part 493

**[HCFA–2239–F]**

**RIN 0938–AH82**

## CLIA Program; Simplifying CLIA Regulations Relating to Accreditation, Exemption of Laboratories Under a State Licensure Program, Proficiency Testing, and Inspection

**AGENCY:** Health Care Financing Administration (HCFA), and Centers for Disease Control and Prevention (CDC), HHS.

**ACTION:** Final rule.

**SUMMARY:** This final rule responds to selected comments received on a final rule with a comment period implementing the Clinical Laboratory Improvement Amendments of 1988, which was published in the **Federal Register** on February 28, 1992, in the areas of proficiency testing and inspections for clinical laboratories. In responding to these comments, we accommodate, when possible, the Administration's regulatory reform initiative by reducing duplicative material, emphasizing outcome-oriented results, and simplifying regulations. In that regard, we also are streamlining our regulations in the areas of State exemption, and granting deemed status to laboratories accredited by an approved accreditation organization.

**EFFECTIVE DATE:** These regulations are effective on June 15, 1998.

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**FOR FURTHER INFORMATION CONTACT:** Judy Yost, (410) 786–3531.

**SUPPLEMENTARY INFORMATION:**

## I. Background

On February 28, 1992, we published in the **Federal Register**, at 57 FR 7002, final regulations with an opportunity for public comment, ''Regulations Implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA),'' that set forth requirements for laboratories that are subject to CLIA. CLIA requirements apply to any laboratory that examines human specimens for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. The regulations at 42 CFR part 493 establish uniform requirements for all laboratories regardless of location, size, or type. A laboratory must meet these Federal requirements, or a laboratory may meet the requirements if it is either accredited by a private, nonprofit accreditation organization approved by HCFA, and holds a valid CLIA certificate, or it is located in a State that HCFA has granted an exemption from CLIA requirements because the State has in effect laws that provide for requirements equal to or more stringent than CLIA requirements.

On July 31, 1992, we published in the **Federal Register**, at 57 FR 33992, a final rule that established the criteria used to approve accreditation organizations and State licensure programs. These regulations are found in subpart E of part 493 and are based on statutory requirements in section 353 (e) and (p) of the Public Health Service Act.

## II. Provisions of the Final Regulations

These regulations respond to public comments received on the February 28, 1992 rule concerning the inspection of laboratories and the regulatory use of proficiency testing. In responding to the concerns of the commenters, we accommodate, whenever possible, the Administration's regulatory reform commitment by:

(1) Eliminating duplicative material and reorganizing regulations concerning accreditation by a private, nonprofit accreditation organization and exemption from CLIA requirements under an approved State licensure program (subpart E of part 493); (2) emphasizing education in proficiency testing to improve laboratory performance (subpart H of part 493); and (3) focusing on an outcome-oriented approach in laboratory inspections (subpart Q of part 493).

### *A. Accreditation of a Laboratory by a Private, Nonprofit Accreditation Organization or Exemption From CLIA Requirements Under an Approved State Laboratory Program (Subpart E)*

Based on the requirements in section 353(e) and (p) of the Public Health Service Act and regulations in part 493, subpart E, HCFA has approved six accreditation organizations. They are: American Association of Blood Banks, American Osteopathic Association, American Society for Histocompatability and Immunogenetics, College of American Pathologists, Commission on Office Laboratory Accreditation, and Joint Commission on Accreditation of Healthcare Organizations. We have also approved three State licensure programs for CLIA exemption of licensed laboratories within the State: Washington, New York, and Oregon.

The existing regulations in subpart E contain duplicative information, which we are eliminating by restructuring subpart E and consolidating requirements. The revised subpart better reflects the process involved and better organizes the information required from organizations and States to obtain HCFA approval. This restructuring does not change the current requirements, but only redesignates them into a more customer-oriented document, making them easier for users to understand. In this process, we use new section numbers, but retain all the requirements in subpart E.

### *B. Participation in Proficiency Testing for Laboratories Performing Tests of Moderate Complexity (Including the Subcategory of Provider-performed Microscopy), High Complexity, or Any Combination of These Tests (Subpart H)*

Proficiency testing (PT) is the testing of laboratory samples, the values of which are unknown to the laboratory, to assess the accuracy of the laboratory's results. PT serves as a test performance indicator, as well as provides invaluable feedback. Under the CLIA regulations, laboratories test PT samples three times a year for the tests the laboratory performs, which are listed in subpart I of part 493. Samples for these three testing events are provided and graded by HCFA-approved PT programs. A laboratory's performance is described as satisfactory performance, unsatisfactory performance, or unsuccessful performance. Satisfactory performance occurs when a laboratory attains a passing score for all analytes, subspecialties, or specialties. Unsatisfactory performance occurs when a laboratory fails to attain the minimum satisfactory score for an analyte, subspecialty, or specialty for a testing event. Unsuccessful performance occurs when a laboratory fails to attain the minimum satisfactory score for an analyte, subspecialty, or specialty for two consecutive or two of three consecutive testing events.

#### *Comments Concerning Regulatory Use of PT*

In response to the concerns of commenters received on the final rule published February 28, 1992, we are emphasizing our existing policy that uses PT as an outcome indicator of laboratory performance and for educational purposes. We found that the commenters' recommendations were consistent with our regulatory reform initiative.

*Comment:* Many commenters recommended that we use PT performance more for educational purposes than for punitive actions. Commenters stated that PT is an excellent mechanism for assisting laboratories to identify and solve problems, evaluate personnel, and improve test performance; however, while PT is a valuable educational tool, it has limitations that should preclude it from use as the sole indicator for regulatory intervention.

*Response:* We agree with the commenters. We allow a laboratory to undertake education or training, or both, to correct initial unsuccessful PT performance for each laboratory specialty in which it performs PT. An educational focus for an initial occurrence of unsuccessful PT affords the laboratory further opportunity to undertake training of its personnel, or to obtain technical assistance, or both, to identify, correct, and prevent the problems that led to PT failures. We are revising subpart H to clarify and emphasize HCFA's educational approach. This approach will not release the laboratory from its responsibility to perform patient testing accurately and reliably. It is, however,

less punitive than some laboratories' initial perception of the PT actions we would impose, and provides an incentive, as well as a mechanism for laboratories to improve their performance.

The enforcement provisions in § 493.1838 give a laboratory the opportunity to train personnel or to obtain technical assistance, or both, when the laboratory has performed PT unsuccessfully. We are adding a new paragraph (c) to § 493.803, which sets forth the educational emphasis of PT, to respond to comments received on PT requirements. These regulatory additions unify commenters' recommendations with the Administration's Reinventing Government initiative by focusing on education as a correction to the problem, as opposed to punitive measures.

*Comment:* Commenters recommended that HCFA use PT performance as an index of performance or a screening tool to identify potential problems. Commenters also suggested that we impose stricter sanctions (that is, that we remove from a laboratory's certificate the laboratory's authorization to test a specific analyte) when a laboratory demonstrates an unwillingness or inability to correct the problems that caused the failure.

*Response:* We agree with the commenters. We have also established some exceptions at § 493.803(c) that encompass the commenters' suggestions. We would take more assertive actions when there is an immediate jeopardy to patient health and safety, when a laboratory demonstrates an inability or unwillingness to provide evidence that it has taken steps to correct its PT problem(s), or if it has a history of noncompliance with CLIA requirements other than proficiency testing (for example, a laboratory that has had condition level deficiencies in quality control).

**C. Inspection—Subpart Q**

We are revising part 493 subpart Q, Inspections, in response to commenters' concerns. We are also reconstructing this subpart into a more concise format, using succinct, easier to understand language. Additionally, we are redirecting the HCFA inspection process to focus more on outcomes, rather than a solely process-oriented review of a laboratory. These actions also follow the Administration's Reinventing Government initiative in that the onsite survey is less process dependent.

1. Alternate Quality Assessment Survey

*Comment:* We received comments requesting that we inspect laboratories onsite every 2 years, but provide a ''paper inspection'' that the laboratory would complete between biennial onsite inspections.

*Response:* We believe that it would be a prudent use of our resources, and a sensible means of allowing greater flexibility than the program currently provides, to have an inspection scheme that gears itself to the variations we see in laboratory compliance. For those laboratories that we believe pose potential risks to public health and safety, judging from their compliance history, we continue to believe that regular onsite inspections present the most viable course of assuring ourselves that these laboratories maintain compliance with CLIA requirements. On the other hand, for those laboratories that have a sustained record of maintaining compliance, the need to have a constantly recurring onsite presence is not as compelling.

We believe that the statute specifically authorizes our focussed use of limited inspection resources. Specifically, section 353(g)(2) of the Public Health Service Act calls for inspections to be performed on a biennial basis, ''or with such other frequency as the Secretary determines to be necessary to assure compliance'' with CLIA standards. We believe that the use of the Alternate Quality Assurance Survey allows us to be in a position to inspect onsite with less frequency than we have before, while still assuring that those laboratories that require the closest supervision will continue to receive it. This approach would further the statutory mandate that we have a schedule for inspections that enables us to ensure facility compliance with program requirements.

With input from our partners in the State survey agencies and our regional office surveyors, we will review and evaluate information, such as the type and number of deficiencies (if any) cited at the last onsite inspection, proficiency testing performance, and complaints lodged against the laboratory. We consider information of this type in determining whether a laboratory may be a candidate for this self-inspection (the Alternate Quality Assessment Survey). We believe that a self-inspection process will motivate laboratories to improve their performance. It is also an example of the Reinventing Government initiative put into practice.

A laboratory may receive the Alternate Quality Assessment Survey in lieu of an onsite inspection. Based on a review of the completed Alternate Quality Assessment Survey form and information submitted by the laboratory, should we conclude that, for any reason, the laboratory is not performing in a manner expected by the statute and regulations, we will follow the Alternate Quality Assessment Survey with an onsite inspection to verify that the laboratory is in compliance with CLIA requirements. A laboratory will not receive the Alternate Quality Assessment Survey for two consecutive certification cycles.

We will monitor and evaluate the effectiveness of the Alternate Quality Assessment Survey process through verification inspections of approximately 5 percent of the laboratories receiving the self-survey questionnaire. We will adjust the self assessment process, as indicated.

2. Outcome-oriented Survey Process

*Comment:* Among the commenters' recommendations were indications that our February 28, 1992 regulations implementing the CLIA requirements may not be applicable to all functions of all laboratories. We were reminded that certain standards might not be required for every type of testing performed; for example, the requirements for specimen preparation and storage of specimens would not directly apply to most point-of-care testing and, typically, have minimum impact on the quality of testing in this setting. Although HCFA surveyors have not held laboratories to requirements that are not applicable to a particular laboratory's testing activities, there was a concern from the commenters that the surveyors would interrupt direct patient care and spend an inordinate amount of time performing a line-by-line comparison of regulations that would not apply to the type of testing performed by the entity.

*Response:* In an effort to be responsive to those concerns, we are enhancing our inspection or survey process by focusing on outcomes. The outcome-oriented survey is the onsite inspection mechanism that is used for all laboratories. Onsite inspections are performed for: initial surveys for newly regulated laboratories; validation inspections of accredited or CLIA-exempt laboratories, laboratories that do not qualify for the Alternate Quality Assessment Survey; and for alternate cycles for those laboratories completing the Alternate Quality Assessment Survey. The emphasis of the survey is on the quality of the laboratory's performance and is based on a review of the laboratory's oversight and monitoring of its preanalytical,

analytical, and postanalytical testing processes using the quality assurance requirements in the regulations. Surveyors will review laboratory performance from the perspective of the effect on patient care rather than a line-by-line comparison for regulatory compliance. While we will look at outcomes as indicators of compliance, should we identify noncompliance with requirements set forth in the CLIA rules, we will cite deficiencies and, if necessary, impose sanctions. Our improvements to the survey mechanism are also in line with the Administration's Reinventing Government initiative by focusing on outcomes, as opposed to process.

In summary, on commenters' recommendations, we are providing to laboratories an onsite survey process that is less process dependent and more outcome-oriented, as well as a self-evaluative assessment (the Alternate Quality Assessment Survey), to motivate laboratories toward self-monitoring of their overall performance.

3. Specific Comments and Responses on Issues Concerning Inspection of Laboratories

We received 114 comments concerning subpart Q, Inspections. Many of the commenters raised identical or closely related issues, and we combined them, when appropriate.

*Comment:* We received numerous comments regarding announced versus unannounced inspections. Some commenters believed that only a physician office laboratory should have announced inspections, especially when direct patient care is provided. They believed that it would be a waste of the inspector's time if, at the time of the inspection, the laboratory was closed, the director unavailable, or the laboratory was not conducting testing. Other commenters believed that the option for announced inspections should be provided to all laboratories. These commenters believed that, even if given advance notice of an inspection, a laboratory would still not be able to ''falsify'' documentation or other data that would not be readily identified by a competent inspector. Another group of commenters stated that follow-up inspections should be unannounced. One commenter believed that we should set standards limiting agency discretion to conduct unannounced inspections. Still another commenter believed that ''warrants'' should be required when the laboratory owner does not give advance consent for his or her laboratory to be inspected.

*Response:* We agree with commenters who recommended announced inspections for all laboratories. We have instituted a policy of announced inspections for all initial and recertification inspections, which allows a laboratory the latitude to include multiple members of the staff in the inspection process for the educational value. Announced, routine inspections are more efficient, in that the laboratory can make previous testing records more accessible before the inspection, and these inspections are also less intrusive when the laboratory is a health care facility providing direct patient care.

We are revising subpart Q by eliminating the modifiers ''announced and unannounced'' and keeping only the unqualified term ''inspections.'' This is in accordance with section 353(g)(1) of the Public Health Service Act, which clearly provides for either announced or unannounced inspections. This provision applies to all laboratories, in keeping with the site-neutral intent of the CLIA statute. However, we are maintaining our policy that all complaint and follow-up inspections are unannounced and are conducted during routine hours of operation. Because these inspections are most probably for cause, laboratories are evaluated during normal operating conditions so that an appropriate assessment can be made.

We disagree with the commenter who believed that we should develop standards limiting agency discretion to conduct unannounced inspections. The law allows the Secretary to determine when announced or unannounced inspections should be conducted and does not call for standards to be developed limiting this provision. We believe that the survey procedures and instructions contained in the HCFA State Operations Manual (HCFA Pub. 7) adequately outline situations in which an announced or unannounced inspection should be conducted.

We disagree with the commenter who suggested that we require a ''warrant'' when the laboratory owner does not give advance consent for the laboratory to be inspected. The law provides us with the authority to enter a laboratory for the purpose of conducting an inspection. If an owner, director, or any employee of the laboratory refuses our reasonable request for permission to inspect the laboratory and its operations, the laboratory may be subject to revocation of its CLIA certificate, as provided in section 353(i)(1)(E) of the Public Health Service Act and § 493.1840 of the regulations.

*Comment:* A few commenters said the word ''will'' should be changed to ''may'' in the following context: ''HHS will conduct announced or unannounced surveys'' at § 493.1776(a) (now found at § 493.1775(b)).

*Response:* We agree with the commenters. However, as previously explained, we are removing the specific words ''announced'' and ''unannounced,'' and the pertinent portion of § 493.1775(b) now reads, '' * * * HCFA or a HCFA agent may conduct an inspection at any time during the laboratory's hours of operation * * *'' to be consistent with the rest of the subpart.

*Comment:* One commenter believed that CLIA requires yearly inspections, while other commenters recommended that we conduct inspections every other year onsite with a paper inspection in alternate years.

*Response:* Section 353(g)(1) of the Public Health Service Act requires inspections on a biennial basis or with such other frequency that the Secretary determines necessary to ensure compliance with the CLIA requirements. We conduct complaint inspections, as necessary, after we determine that the complaint alleges a violation of CLIA requirements. We agree with the commenters' recommendation for onsite inspections to be alternated with a self-evaluative survey. We have developed a self-assessment form, the Alternate Quality Assessment Survey, to be used in alternate cycles for laboratories with a history of compliance because there is less need to have a constantly recurring presence in those laboratories.

*Comment:* Some commenters suggested that inspections be conducted by professional organizations. There was concern that surveyors would not be knowledgeable about specialty testing or regulatory requirements, and might inappropriately apply requirements. Another group of commenters believed that cytology inspections should be conducted by a qualified pathologist and cytotechnologist.

*Response:* Inspections for laboratories holding certificates of compliance are performed by HCFA regional office laboratory consultants or State survey agency personnel, or both, and stress an outcome-oriented focus. In addition to mandatory participation at a HCFA-sponsored laboratory surveyor training program and one-on-one training with an experienced surveyor, we also provide written guidelines to assist surveyors in evaluating laboratory compliance with Federal regulations. This training provides the surveyor with comprehensive, detailed information regarding the regulations, outcome-oriented survey process, and surveyor

guidelines, all of which complement their technical background. Training is also provided at the State and Federal regional levels on an on-going basis. Moreover, we have a contract in place with an organization of cytology professionals, which provides specialized reviews of selected cytology laboratories. The individuals who participate in these reviews are qualified as general supervisors and technical supervisors in cytology. This contract has been in effect since 1989.

HCFA also has approved six professional organizations as accrediting bodies under CLIA. These organizations sought deeming authority for their programs, which were equal to, or more stringent than, the CLIA requirements taken as a whole. A laboratory may, therefore, choose to apply for a certificate of accreditation; in which case, a HCFA-approved accreditation organization would serve as its inspecting agency for CLIA.

*Comment:* One organization believed that it is inappropriate for a surveyor to interview an employee during an inspection, and if a disgruntled employee makes false or specious comments against his or her employer, it may impugn the reputation of the laboratory director.

*Response:* We disagree. Any interviews conducted during the course of an inspection are to assist the surveyor in gathering information for the determination of the laboratory's compliance with the applicable requirements under part 493. Any pertinent information received during an inspection is verified, and determination of a facility's compliance is based on all elements of the inspection process, not just individual interviews.

*Comment:* Another group of commenters was concerned that patient records will be reviewed during the course of the inspection and believed that patient privacy may be compromised.

*Response:* We understand the commenters' concerns; however, laboratory surveyors are health care professionals who are familiar with the need for patient privacy. Confidentiality of patient and laboratory information is also reinforced during surveyor training sessions. Laboratory surveyors appreciate and respect patient confidentiality. Therefore, we do not believe patient privacy would be compromised.

*Comment:* A few commenters believed that we should only conduct inspections for cause. One commenter believed that complaints should be better defined. Another commenter believed that complaints should be verified before a complaint inspection is conducted.

*Response:* Section 353(g)(2) of the Public Health Service Act requires that we conduct inspections biennially or with such frequency as the Secretary determines is necessary. For those laboratories with a history of compliance, there is less need to have a constantly recurring onsite presence, and we have developed a self-evaluative survey, the Alternate Quality Assessment Survey, to be used in alternate cycles. We believe the use of the Alternate Quality Assessment Survey allows us to be in a position to inspect onsite with less frequency than we have before, while still ensuring that those laboratories that require the closest supervision will continue to receive it.

A complaint is an allegation against a laboratory by any individual for any perceived or real violation of the CLIA requirements. For example, there may be a complaint that a laboratory is operating without a certificate or that a laboratory is performing testing outside of the certificate it holds. Inspectors are instructed to determine if the complaint involves CLIA requirements or regulations under the jurisdiction of another agency. If the complaint involves a violation of State or other Federal law that is under the jurisdiction of another agency (for example, the Occupational Safety and Health Administration), we refer the complaint to the appropriate State or agency for investigation. If the complaint is an alleged violation of the CLIA requirements, we may conduct an unannounced onsite inspection focusing on the alleged violations.

*Comment:* A commenter wanted the phrase ''including allegations that individuals other than physicians are performing microscopic exams'' added at § 493.1776(a)(2). Another group of commenters believed that we should conduct unannounced inspections to substantiate which individuals are performing testing.

*Response:* When a complaint alleges that an individual performing tests is not qualified, we investigate the laboratory's compliance with the CLIA personnel qualification requirements. It is our policy to conduct unannounced complaint inspections. To clarify this policy we are moving § 493.1776(a)(2) to § 493.1775(b) and also referencing this in § 493.1773(f).

*Comment:* Some commenters objected to ''onsite proficiency testing'' as part of the inspection process as being inappropriate based on the complications involved in testing PT samples and suggested that we delete § 493.1777(b)(1).

*Response:* We disagree with the commenters. Section 493.1777(b)(1), now § 493.1773(b)(1), provides the surveyor with the authority to require a laboratory to perform testing, which may include analysis of PT samples from a HCFA-approved PT program, as part of the inspection. We are aware of the complications referred to by the commenters. Although the option of requiring a laboratory to perform testing on PT samples exists, it is not routinely employed by surveyors. If it were employed, it would be structured to address complications expressed by the commenters.

*Comment:* One commenter believed that we should require onsite (proficiency) testing during routine inspections for laboratories holding a certificate of waiver.

*Response:* Section 353(d)(2)(C) of the Public Health Service Act specifically exempts laboratories performing only waived tests from routine inspections and all quality standards including PT. We, therefore, may not require this testing or routinely inspect waived testing.

*Comment:* A few commenters suggested that we add the following language to § 493.1775, ''States may coordinate the Medicare/Medicaid compliance surveys for skilled nursing facilities, nursing facilities, and intermediate care facilities for the mentally retarded with CLIA compliance activities.''

*Response:* We encourage coordination of inspections under the Medicare, Medicaid, and CLIA programs. Due to separate laws and funding, resources, expertise, and availability, we can do no more than encourage inspectors from different programs to coordinate inspections to reduce the burden on facilities. Thus, we are making no change to the regulations.

*Comment:* Commenters also suggested that we change § 493.1775(d) to read: ''* * *payments for laboratory services to the laboratory or * * * '' to ensure that a suspension of Medicare payments for laboratory services by a provider could not result in the suspension of payments for any non-laboratory services.

*Response:* We are moving this requirement from § 493.1775(d) to § 493.1773(g). As stated above, CLIA and Medicare/Medicaid are separate programs. Actions we take under the CLIA program may result in a laboratory being unable to perform certain tests. We notify the Medicare and Medicaid programs, as appropriate, of any action we take to suspend, limit or revoke the

CLIA certificate, which may have an impact on the facility's overall participation in Medicare/Medicaid.

*Comment:* One commenter suggested that we change § 493.1780(b)(4)(ii) to ensure that inspection reports from accreditation bodies are readily available to inspectors.

*Response:* The current regulations require that an accrediting organization submit pertinent information to HCFA, which includes inspection reports from the accreditation organization's surveys. We find that performing validation inspections without prior knowledge of the organization's findings offers a more unbiased approach for our surveyors than performing inspections with prior knowledge. Therefore, inspection reports from accreditation organizations are not normally made available to surveyors before they perform validation inspections. However, these reports are used in the comparability review of the organization's inspection.

*Comment:* Some commenters urged us to approve the College of American Pathologists as an accrediting organization, so that laboratories that are accredited by this organization will meet CLIA requirements.

*Response:* HCFA approved the College of American Pathologists as an accreditation organization (see notice published February 9, 1995 in the **Federal Register** at 60 FR 7774). Five other organizations have also been approved as accreditation organizations: American Association of Blood Banks; American Osteopathic Association; American Society for Histocompatibility and Immunogenetics; Commission on Office Laboratory Accreditation; and Joint Commission on Accreditation of Health Care Organizations.

*Comment:* Several commenters indicated that it is possible for mobile laboratories providing services in more than one State to operate under one certificate. They questioned which State would have the responsibility to inspect the laboratories.

*Response:* When a mobile laboratory provides service in more than one State under one certificate, the State in which the laboratory's home base is located has the responsibility to ascertain compliance with the regulations. This may involve contacting other State survey agencies and coordinating survey activity or scheduling the survey to coincide with testing performed in the State in which the home base is located.

*Comment:* Another commenter suggested that we inspect a mobile laboratory when it reaches a specific mileage limit.

*Response:* Section 353(g)(2) of the Public Health Service Act requires that we conduct inspections on a biennial basis or with such other frequency as the Secretary determines to be necessary to assure compliance with CLIA requirements and standards. While there is latitude in determining frequency of inspection, we believe the assurance of accurate testing is independent of mileage traveled. Therefore, we will continue to inspect mobile laboratories with the same frequency as other types of laboratories.

**Conforming Changes**

To avoid the continued use of an overly long term in the text of the regulations, we are adding a definition for the term, ''State licensure program,'' which means a State laboratory licensure or approval program.

**III. Waiver of Proposed Rulemaking**

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite prior public comment on proposed rules. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

With regard to all elements of this regulation except one, we are responding to comments we received in previous rulemaking documents and, in response to earlier rules. Accordingly, a final rule is justified. The one exception concerns the rewritten subpart E. But here, since we are making no substantive changes, but merely condensing and reorganizing content, we believe that it is unnecessary and not in the public interest to delay the effectiveness of this clarification, as would happen were we to issue a proposed rule.

Therefore, we find good cause to waive the notice of proposed rulemaking and to issue this final rule.

**IV. Redesignation Table**

The following table is a guide to readers in identifying the source of requirements in the final rule.

| Existing section | New section |
|---|---|
| 493.501(a) introductory text | 493.551(a) |
| 493.501(a)(1) | 493.551(a)(1) |
| 493.501(a)(2) | 493.551(a)(2) |
| 493.501(b) introductory text | 493.551(b) |
| 493.501(b)(1) | 493.551(a)(3) |
| 493.501(b)(2) | 493.551(a)(3) |
| 493.501(b)(3) | 493.551(b)(1) |
| 493.501(b)(4) | 493.551(b)(2) |
| 493.501(c) introductory text | 493.553(a) |
| 493.501(c)(1) | 493.557(a)(1) |
| 493.501(c)(2) | 493.553(a)(1) |
| 493.501(c)(3) | 493.553(a)(2) (i)–(iv) & (vi) |
| 493.501(c)(4) | 493.553(a)(3) |
| 493.501(c)(5) | 493.557(a)(2) |
| 493.501(c)(6) | 493.557(a)(3) (i)–(iii) |
| 493.501(c)(7) | 493.553(a)(4) |
| 493.501(c)(8) | 493.553(a)(5) |
| 493.501(c)(9) | 493.553(a)(6) |
| 493.501(c)(10) | 493.557(a)(4) |
| 493.501(c)(11) | 493.557(a)(5) |
| 493.501(c)(12) | 493.553(a)(2)(v) |
| 493.501(d) introductory text | 493.553(b) |
| 493.501(d)(1) | 493.553(b)(1) |
| 493.501(d)(2) | 493.553(b)(2) |

| Existing section | New section |
|---|---|
| 493.501(d)(3) | 493.553(b)(3) |
| 493.501(d)(4) | 493.553(c) |
| 493.501(d)(5) | 493.553(d) |
| 493.501(d)(6) | 493.561(a)(1) |
| 493.501(d)(7) | 493.561(b) (1)–(3) |
| 493.501(d)(8) | 493.561(a)(2) |
| 493.501(e) introductory text | 493.559(a) |
| 493.501(e)(1) | 493.559(b)(1) |
| 493.501(e)(2) | 493.559(b)(4) |
| 493.501(e)(3) | 493.559(b)(2)(ii) |
| 493.501(e)(4) | 493.559(b)(5) |
| 493.503(a) | 493.551(b)(3) |
| 493.503(b)(1) | 493.551(b)(4) |
| 493.503(b)(2) | 493.551(b)(4) |
| 493.503(b)(3) | 493.551(b)(5)–(6) |
| 493.503(b)(4) | 493.551(b)(6) |
| 493.504 | 493.551(c) |
| 493.506(a) | 493.559(b)(2)(i) & 493.557(a)(1) |
| 493.506(b)(1) | 493.555(a) |
| 493.506(b)(2)(i) | 493.557(a)(3) (i)–(iii) |
| 493.506(b)(2)(ii) | 493.555(b) |
| 493.506(b)(2)(iii) | 493.557(a)(6) |
| 493.506(b)(2)(iv) | 493.557(a)(7) |
| 493.506(b)(2)(v) | 493.557(a)(8) |
| 493.506(b)(2)(vi) | 493.557(a)(9) |
| 493.506(b)(2)(vii) | 493.557(a)(10) |
| 493.506(b)(2)(viii) | 493.557(a)(11) |
| 493.506(b)(3)(i) | 493.555(c)(1) |
| 493.506(b)(3)(ii) | 493.555(c)(2) |
| 493.506(b)(3)(iii) | 493.555(c)(3)(i) |
| 493.506(b)(3)(iv) | 493.555(c)(4) |
| 493.506(b)(3)(v) | 493.555(c)(5) |
| 493.506(b)(3)(vi) | 493.557(b)(12)(i)–(ii) |
| 493.506(b)(3)(vii) | 493.557(b)(13) |
| 493.506(b)(3)(viii) | 493.557(b)(14) |
| 493.507(a) introductory text | 493.563(a)(1) |
| 493.507(a)(1) | 493.563(b) |
| 493.507(a)(2) | 493.563(c) |
| 493.507(b) | 493.565 |
| 493.507(c) | 493.567 |
| 493.507(d) | 493.569 |
| 493.507(e) | 493.571 |
| 493.507(f) | 493.563(e) + (d) |
| 493.509(a) | 493.573(a) |
| 493.509(b) | 493.573(b) |
| 493.509(c) | 493.573(c) |
| 493.509(d) | 493.573(d) |
| 493.511(a)(1) | 493.575(a)(1) |
| 493.511(a)(2) | 493.575(a)(3) |
| 493.511(a)(3) | 493.575(a)(4) & (a)(4)(i) |
| 493.511(b) | 493.575(b)(1) |
| 493.511(c) | 493.575(b)(2) |
| 493.511(d) introductory text | 493.575(c) |
| 493.511(d)(1) | 493.575(c)(1) |
| 493.511(d)(2) | 493.575(c)(2) |
| 493.511(d)(3)–(4) | 493.575(c)(3) |
| 493.511(d)(5) | 493.575(c)(4) |
| 493.511(e) | 493.575(d) |
| 493.511(f) | 493.575(e) |
| 493.511(g) | 493.575(f) |
| 493.511(h) | 493.575(g)(1) & (g)(3) |
| 493.511(i) | 493.575(h)(1) |
| 493.511(j) | 493.575(k) |
| 493.513(a) introductory text | 493.553(c) & 493.551(a) |
| 493.513(a)(1)–(2) | 493.551(a)(1) |
| 493.513(a)(3) | 493.551(a)(2) |
| 493.513(a)(4) | 493.557(b)(1) |
| 493.513(a)(5) | 493.557(b)(2) |
| 493.513(a)(6) | 493.557(b)(3) |
| 493.513(a)(7) | 493.557(b)(4) |
| 493.513(a)(8) | 493.557(b)(5) |
| 493.513(b)(1)–(2) | 493.551(a)(3) |
| 493.513(c) introductory text | 493.553(a) |
| 493.513(c)(1) | 493.553(a)(1) |

| Existing section | New section |
|---|---|
| 493.513(c)(2) | 493.553(a)(2)(i)–(vi) |
| 493.513(c)(3) | 493.557(b)(1) |
| 493.513(c)(4) | 493.553(a)(3) |
| 493.513(c)(5) | 493.553(a)(4) |
| 493.513(c)(6) | 493.553(a)(5) |
| 493.513(c)(7) | 493.553(a)(6) |
| 493.513(c)(8) | 493.553(b)(6) |
| 493.513(d)(1) | 493.557(b)(7) |
| 493.513(d)(2) | 493.557(b)(8)(i)–(iii) |
| 493.513(e) | 493.553(b)(1) |
| 493.513(f) | 493.553(b)(2) |
| 493.513(g) | 493.553(b)(3) |
| 493.513(h) | 493.561(c) |
| 493.513(i) | 493.553(d) |
| 493.513(j) | 493.561(a)(1) |
| 493.513(k) | 493.559(a) |
| 493.513(k)(1) | 493.559(b)(1) |
| 493.513(k)(2) | 493.559(b)(4) |
| 493.513(k)(3) | 493.559(b)(3) |
| 493.513(k)(4) | 493.559(b)(5) |
| 493.513(l) | 493.557(b)(14) |
| 493.513(m) | 493.561(a)(2) |
| 493.515 (a)(1) | 493.555(a) |
| 493.515(a) | 493.555 introductory text |
| 493.515(a)(2) | 493.555(b) |
| 493.515(a)(2)(ii) | 493.557(b)(9) |
| 493.515(a)(2)(iii) | 493.557(b)(10) |
| 493.515(a)(3) introductory text | 493.555(c) introductory text |
| 493.515(a)(3)(i) | 493.555(c)(1) |
| 493.515(a)(3)(ii) | 493.555(c)(2) |
| 493.515(a)(3)(iii) | 493.555(c)(4) |
| 493.515(a)(3)(iv) | 493.557(b)(11) |
| 493.515(a)(3)(v) | 493.557(b)(12) |
| 493.515(a)(3)(vi) | 493.557(b)(13) |
| 493.515(a)(3)(vii) | 493.555(c)(3)(ii) |
| 493.515(a)(3)(viii) | 493.555(c)(5) |
| 493.517(a) | 493.563(a)(2)(i)–(ii) |
| 493.517(a)(1) | 493.563(b)(1)(2) |
| 493.517(a)(2) | 493.563(c)(1)–(2) |
| 493.517(b)(1) | 493.565(a) |
| 493.517(b)(2) | 493.565(b) |
| 493.517(b)(3) | 493.565(c) |
| 493.517(c) | 493.567(b) |
| 493.517(d) | 493.569(b) |
| 493.517(e) | 493.571(b) and (c) |
| 493.517(f) | 493.563(f) |
| 493.519(a) | 493.573(a) |
| 493.519(b) | 493.573(b) |
| 493.519(c)(1) | 493.573(c)(1) |
| 493.519(c)(2) | 493.573(c)(2) |
| 493.519(d) introductory text | 493.573(d)(1)(ii) |
| 493.519(d)(1)–(4) | 493.573(d)(2)(i)–(iv) |
| 493.521(a)(1) | 493.575(a)(2) |
| 493.521(a)(2) | 493.575(a)(3) |
| 493.521(a)(3) | 493.575(a)(4) & (4)(ii) |
| 493.521(b) | 493.575(b)(1) |
| 493.521(c) | 493.575(b)(2) |
| 493.521(d) | 493.575(c) |
| 493.521(e) | 493.575(d) |
| 493.521(f) | 493.575(e) |
| 493.521(g) | 493.575(i) |
| 493.521(h) | 493.575(h) |
| 493.521(i) | 493.575(f) |
| 493.521(j) | 493.575(g)(2)–(3) |
| 493.521(k) | 493.575(j)(1)–(2) |
| 493.521(l) | 493.575(k) |
| 493.1775(a) | 493.1773(a); 493.1775(a) |
| 493.1775(b)(1) | 493.1773(b)(2) |
| 493.1775(b)(2) | 493.1773(b)(4) |
| 493.1775(b)(3) | 493.1773(b)(3) |
| 493.1775(b)(4)(1)–(ii) | 493.1773(f); 493.1775(b)(1)–(4) |
| 493.1775(b)(4)(iii)–(iv) | 493.1775(a) |
| 493.1775(b)(5) | 493.1773(b)(5) |
| 493.1775(c) | 493.1773(d) |

| Existing section | New section |
|---|---|
| 493.1775(d) | 493.1773(g) |
| 493.1776(a) introductory text | 493.1773(a); 493.1775(a) & (b) |
| 493.1776(a)(1)–(4) | 493.1773(f); 493.1775(a) |
| 493.1776(a)(4) (uncoded text) | deleted; redundant |
| 493.1776(b)(1) | 493.1773(b)(2) |
| 493.1776(b)(2) | 493.1773(b)(4) |
| 493.1776(b)(3) | 493.1773(b)(3) |
| 493.1776(b)(4) | 493.1773(f); 493.1775(b)(1)–(4) |
| 493.1776(b)(5) | 493.1773(b)(5) |
| 493.1776(c) | 493.1773(d) |
| 493.1776(d) | 493.1773(g) |
| 493.1777 introductory text | 493.1773(a), (f); 493.1777(a)–(c) |
| 493.1777(a) | 493.1777(a)–(b) |
| 493.1777(b) | 493.1773(b) |
| 493.1777(c) | 493.1773(c) |
| 493.1777(d) | deleted; redundant |
| 493.1777(e) | 493.1773(d) |
| 493.1777(f) | 493.1773(e) |
| 493.1777(g) | 493.1773(g) |
| 493.1780(a) | 493.1773(a); 493.1780(a) |
| 493.1780(b) | 493.1773(a), (f); 493.1780(b) |
| 493.1780(c) | 493.1773(b) |
| 493.1780(d) | 493.1773(c) |
| 493.1780(e) | deleted; redundant |
| 493.1780(f) | 493.1773(d) |
| 493.1780(g) | 493.1773(g); 493.1780(c) |

## V. Regulatory Impact Statement

### *A. General*

Consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), we prepare a regulatory flexibility analysis unless we certify that a rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, all clinical laboratories are considered to be small entities. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule 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 that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

### *B. Provisions of the Final Regulations*

This rule has been drafted in response to comments pertaining to proficiency testing and the CLIA inspection process. As our responses to commenters' concerns were developed, it became apparent that we were also fulfilling the Administration's regulatory reform initiative. This initiative directs us to revise regulations that are outdated or otherwise in need of reform. We have, therefore, also included subpart E of part 493 in this rule.

*Subpart E*

Subpart E of part 493 provides for the accreditation of a laboratory by an accreditation organization, and the exemption of laboratories within a particular State from CLIA requirements when the accreditation organization or State applies requirements that are equal to, or more stringent than, the CLIA requirements taken as a whole. Subpart E contains requirements for State licensure programs, accreditation organizations, laboratories seeking deemed status by virtue of accreditation by a HCFA-approved accreditation organization, and laboratories that operate within a State that HCFA has determined maintains requirements that are equal to or more stringent than the CLIA requirements. We are revising subpart E by removing duplicative information. We are reorganizing subpart E to distinguish accreditation organization and State licensure program responsibilities from those of laboratories. We are combining common requirements for accreditation organizations and State licensure programs. These actions will accommodate the Administration's regulatory reform initiative. We are making no substantive changes to the content or the intent. Therefore, we are not imposing additional burden. The relief established by reorganizing and combining like requirements is not quantifiable, but it should aid in the submission of materials for approvals and reapprovals.

*Subpart H*

The changes we are making in § 493.803(c) reflect HCFA's policy of an educational focus for proficiency testing. We are clarifying existing enforcement options in response to comments received concerning PT sanctions. In this rule, subpart H provides that, if a laboratory is initially unsuccessful in PT, it must obtain technical assistance, or undertake training of personnel, or both, rather than having HCFA impose principal or alternative sanctions. This affords the laboratory an additional opportunity to correct the problem that caused the PT failure, encouraging quality testing in a more positive manner. We believe that a laboratory should have ample opportunity to investigate the reason for its initial failure, to obtain the necessary technical assistance or training, or both, to correct the problems that caused the failure and implement a plan of action, which should prevent reoccurrence. This requirement also exists in subpart R, Enforcement Procedures. Principal and alternative sanctions may apply if the laboratory refuses to correct its problems, has repeated compliance problems, or immediate jeopardy exists. While this educational approach has always been a viable option, based on comments received on previous rulemaking, we believe that it is important to clarify that this option exists and will be exercised. We are revising the regulation accordingly.

We are not imposing any additional burden with this clarification; we are

only identifying which of our enforcement actions or options we implement in a particular circumstance.

*Subpart Q*

We are eliminating redundant information by restructuring and organizing all generic requirements for an onsite inspection into one section of the regulations. In addition we have implemented the commenter-recommended laboratory self-inspection process (the Alternate Quality Assessment Survey). Although an onsite inspection may not be performed, the survey agency personnel must still review and evaluate the self-inspection responses submitted by the laboratory and take any necessary action. While travel and onsite time is eliminated for inspections of these laboratories, the laboratory surveyors, however, may realize little or no reduction in the time spent on the overall process. We expect laboratories that perform the Alternate Quality Assessment Survey to benefit from the educational aspects realized by performing this self evaluative survey and minimized disruption to their activities.

Our onsite survey process, which is outcome-oriented, concentrates on a review of each laboratory's specific testing activities and its impact on patient health and safety. We are unable to predict the long term effects because they are dependent upon each individual laboratory's compliance and testing activities. Although it is difficult to quantify the financial impact due to the variability from laboratory to laboratory, we expect that our collective efforts to streamline and clarify the regulations may reduce the laboratory costs associated with CLIA in many cases, without diminishing quality.

*C. Conclusion*

For these reasons, we have determined, and the Secretary certifies, that this regulation does not result in a significant impact on a substantial number of small entities and does not have a significant effect on the operations of a substantial number of small rural hospitals. Therefore, we are not preparing analyses for either the RFA or section 1102(b) of the Act.

*D. OMB Review*

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

*E. Collection of Information Requirements*

This final rule contains information collections that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995. The title, description, and respondent description of the information collection requirements are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Section 493.803 and subpart Q (newly revised §§ 493.1771 through 493.1780 previously numbered §§ 493.1775 through 493.1780) are currently approved under OMB approval number 0938–0612 with an expiration date of April 30, 2001. Subpart E (newly revised sections §§ 493.551, 493.553, 493.555, 493.557, 493.559, and 493.561, which were previously contained in §§ 493.501, 493.506, 493.513 and 493.515) is currently approved under OMB approval number 0938–0686 with an expiration of April 30, 1999.

Section 493.803 contains the requirement that a laboratory must successfully participate in a PT program approved by HCFA for the specialties, subspecialties, and analytes listed in the regulation, if these tests are performed by the laboratory. The burden associated with this requirement is the testing of PT specimens and recording the results.

Subpart Q sets forth conditions and standards for inspection of laboratories. The burden associated with inspections of laboratories, or alternative mechanisms to determine compliance, consists of retrieving records and documentation necessary for the inspector to ascertain compliance, participating in entrance and exit conferences for onsite inspections, responding to a statement of deficiencies that may result from an inspection, and documenting any corrective action.

Subpart E sets forth the requirements and process for a private, nonprofit accreditation organization voluntarily seeking approval under the CLIA program and a State licensure program voluntarily seeking exemption for its laboratories within the State from the CLIA program. The burden associated with these sections is the compilation of specific information that must be submitted for evaluation as well as the requirements for providing ongoing information.

**Description of Respondents**

Respondents for § 493.803 and subpart Q, §§ 493.1771 through 493.1780 fall in the categories of: small businesses or organizations, businesses or other for-profit, non-profit institutions, State and local governments, and Federal agencies.

Respondents for subpart E, §§ 493.551, 493.553, 493.555, 493.557, 493.559, and 493.561 are private nonprofit accreditation organizations and State licensure programs.

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

| CFR section | Annual number of respondents | Annual frequency | Average burden per response in hours | Annual burden in hours |
|---|---|---|---|---|
| Subpart E 493.551 through 493.561 | 11 | varies, as needed | 192 | 2112 |
| Subpart H 493.803 | 63,600 | 3 events | 1 | 190,800 |
| Subpart Q 493.1771 through 493.1780 | 36,918 | biennial | 4 | 4,618 |

Persons interested in commenting on these currently approved information collections should send comments to the following address: Health Care Financing Administration, Office of Information Services, Information Technology Investment Management Group, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland, 21244–1850. Attn: HCFA–2239–F.

**List of Subjects in 42 CFR Part 493**

Grant programs-health, Health facilities, Laboratories, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR chapter IV is amended as follows:

## PART 493—LABORATORY REQUIREMENTS

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

**Authority:** Sec. 353 of the Public Health Service Act, secs. 1102, 1861(e), the sentence following sections 1861(s)(11) through 1861(s)(16) of the Social Security Act (42 U.S.C. 263a, 1302, 1395x(e), the sentence following 1395x(s)(11) through 1395x(s)(16)).

## Subpart A—General Provisions

### § 493.2 [Amended]

2. Section 493.2 is amended by adding in alphabetical order the following definition of *State licensure program:*

* * * * *

*State licensure program* means a State laboratory licensure or approval program.

* * * * *

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

### §§ 493.501 through 493.521 [Removed]

3. Sections 493.501 through 493.521 are removed.

4. In subpart E, new §§ 493.551, 493.553, 493.555, 493.557, 493.559, 493.561, 493.563, 493.565, 493.567, 493.569, 493.571, 493.573, and 493.575 are added to read as follows:

Sec.



### § 493.551 General requirements for laboratories.

(a) *Applicability*. HCFA may deem a laboratory to meet all applicable CLIA program requirements through accreditation by a private nonprofit accreditation program (that is, grant deemed status), or may exempt from CLIA program requirements all State licensed or approved laboratories in a State that has a State licensure program established by law, if the following conditions are met:

(1) The requirements of the accreditation organization or State licensure program are equal to, or more stringent than, the CLIA condition-level requirements specified in this part, and the laboratory would meet the condition-level requirements if it were inspected against these requirements.

(2) The accreditation program or the State licensure program meets the requirements of this subpart and is approved by HCFA.

(3) The laboratory authorizes the approved accreditation organization or State licensure program to release to HCFA all records and information required and permits inspections as outlined in this part.

(b) *Meeting CLIA requirements by accreditation*. A laboratory seeking to meet CLIA requirements through accreditation by an approved accreditation organization must do the following:

(1) Obtain a certificate of accreditation as required in subpart D of this part.

(2) Pay the applicable fees as required in subpart F of this part.

(3) Meet the proficiency testing (PT) requirements in subpart H of this part.

(4) Authorize its PT organization to furnish to its accreditation organization the results of the laboratory's participation in an approved PT program for the purpose of monitoring the laboratory's PT and for making the annual PT results, along with explanatory information required to interpret the PT results, available on a reasonable basis, upon request of any person. A laboratory that refuses to authorize release of its PT results is no longer deemed to meet the condition-level requirements and is subject to a full review by HCFA, in accordance with subpart Q of this part, and may be subject to the suspension or revocation of its certificate of accreditation under § 493.1840.

(5) Authorize its accreditation organization to release to HCFA or a HCFA agent the laboratory's 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 § 493.2 of this part, when the laboratory has failed to achieve successful participation in an approved PT program.

(6) Authorize its accreditation organization to release to HCFA a notification of the actions taken by the organization as a result of the unsuccessful participation in a PT program within 30 days of the initiation of the action. Based on this notification, HCFA may take an adverse action against a laboratory that fails to participate successfully in an approved PT program.

(c) *Withdrawal of laboratory accreditation*. After an accreditation organization has withdrawn or revoked its accreditation of a laboratory, the laboratory retains its certificate of accreditation for 45 days after the laboratory receives notice of the withdrawal or revocation of the accreditation, or the effective date of any action taken by HCFA, whichever is earlier.

### § 493.553 Approval process (application and reapplication) for accreditation organizations and State licensure programs.

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

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

(2) A detailed description of the inspection process, including the following:

(i) Frequency of inspections.

(ii) Copies of inspection forms.

(iii) Instructions and guidelines.

(iv) A description of the review and decision-making process of inspections.

(v) A statement concerning whether inspections are announced or unannounced.

(vi) A description of the steps taken to monitor the correction of deficiencies.

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

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

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

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

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

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

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

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

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

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

**§ 493.555 Federal review of laboratory requirements.**

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

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

(b) The organization's or State's inspection process to determine the comparability of the full inspection and complaint inspection procedures and requirements to those of HCFA, including, but not limited to, inspection frequency and the ability to investigate and respond to complaints against its laboratories.

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

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

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

(ii) In any way been sanctioned; or

(iii) Had any adverse action taken against it.

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

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

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

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

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

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

**§ 493.557 Additional submission requirements.**

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

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

(2) A description of the organization's data management and analysis system with respect to its inspection and accreditation decisions, including the kinds of routine reports and tables generated by the systems.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(8) Submit a statement acknowledging that the State will notify HCFA through electronic transmission of the following:

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

(ii) Changes in licensure or inspection requirements.

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) For an accreditation organization:

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

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

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

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

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

### § 493.561 Denial of application or reapplication.

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

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

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

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

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

(3) It resubmits the application in its entirety.

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

### § 493.563 Validation inspections—Basis and focus.

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

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

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

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

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

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

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

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

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

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

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

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

(1) A review of documents.

(2) An audit of meetings concerning the accreditation process.

(3) Evaluation of accreditation inspection results and the accreditation decision-making process.

(4) Interviews with the accreditation organization's staff.

(f) *Onsite inspection of a State licensure program.* An onsite inspection of a State licensure program office may include, but is not limited to, the following:

(1) A review of documents.

(2) An audit of meetings concerning the licensure or approval process.

(3) Evaluation of State inspection results and the licensure or approval decision-making process.

(4) Interviews with State employees.

**§ 493.565 Selection for validation inspection—laboratory responsibilities.**

A laboratory selected for a validation inspection must do the following:

(a) Authorize its accreditation organization or State licensure program, as applicable, to release to HCFA or a HCFA agent, on a confidential basis, a copy of the laboratory's most recent full, and any subsequent partial inspection.

(b) Authorize HCFA or a HCFA agent to conduct a validation inspection.

(c) Provide HCFA or a HCFA agent with access to all facilities, equipment, materials, records, and information that HCFA or a HCFA agent determines have a bearing on whether the laboratory is being operated in accordance with the requirements of this part, and permit HCFA or a HCFA agent to copy material or require the laboratory to submit material.

(d) If the laboratory possesses a valid certificate of accreditation, authorize HCFA or a HCFA agent to monitor the correction of any deficiencies found through the validation inspection.

**§ 493.567 Refusal to cooperate with validation inspection.**

(a) *Laboratory with a certificate of accreditation.* (1) A laboratory with a certificate of accreditation that refuses to cooperate with a validation inspection by failing to comply with the requirements in § 493.565—

(i) Is subject to full review by HCFA or a HCFA agent, in accordance with this part; and

(ii) May be subject to suspension, revocation, or limitation of its certificate of accreditation under this part.

(2) A laboratory with a certificate of accreditation is again deemed to meet the condition-level requirements by virtue of its accreditation when the following conditions exist:

(i) The laboratory withdraws any prior refusal to authorize its accreditation organization to release a copy of the laboratory's current accreditation inspection, PT results, or notification of any adverse actions resulting from PT failure.

(ii) The laboratory withdraws any prior refusal to allow a validation inspection.

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

(b) *CLIA-exempt laboratory.* If a CLIA-exempt laboratory fails to comply with the requirements specified in § 493.565, HCFA notifies the State of the laboratory's failure to meet the requirements.

**§ 493.569 Consequences of a finding of noncompliance as a result of a validation inspection.**

(a) *Laboratory with a certificate of accreditation.* If a validation inspection results in a finding that the accredited laboratory is out of compliance with one or more condition-level requirements, the laboratory is subject to—

(1) The same requirements and survey and enforcement processes applied to laboratories that are not accredited and that are found out of compliance following an inspection under this part; and

(2) Full review by HCFA, in accordance with this part; that is, the laboratory is subject to the principal and alternative sanctions in § 493.1806.

(b) *CLIA-exempt laboratory.* If a validation inspection results in a finding that a CLIA-exempt laboratory is out of compliance with one or more condition-level requirements, HCFA directs the State to take appropriate enforcement action.

**§ 493.571 Disclosure of accreditation, State and HCFA validation inspection results.**

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

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

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

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

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

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

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

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

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

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

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

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

(2) An accreditation organization or State licensure program that does not meet the requirements of this subpart, as determined through a comparability or

validation review, must furnish HCFA, upon request, with the reapplication materials HCFA requests. HCFA establishes a deadline by which the materials must be submitted.

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

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

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

(2) The notice contains the following information:

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

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

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

(iv) The reapplication materials that the accreditation organization or State licensure program must submit and the deadline for that submission.

**§ 493.575 Removal of deeming authority or CLIA exemption and final determination review.**

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

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

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

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

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

(i) One year for accreditation organizations.

(ii) Two years for State licensure programs.

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

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

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

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

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

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

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

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

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

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

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

(g) *Withdrawal of approval-effect on laboratory status*—(1) *Accredited laboratory.* After HCFA withdraws approval of an accreditation organization's deeming authority, the certificate of accreditation of each affected laboratory continues in effect for 60 days after it receives notification of the withdrawal of approval.

(2) *CLIA-exempt laboratory.* After HCFA withdraws approval of a State licensure program, the exempt status of each licensed or approved laboratory in the State continues in effect for 60 days after a laboratory receives notification from the State of the withdrawal of HCFA's approval of the program.

(3) *Extension.* After HCFA withdraws approval of an accreditation organization or State licensure program, HCFA may extend the 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 for the appropriate certificate to HCFA or a HCFA agent before the initial 60-day period ends.

(h) *Immediate jeopardy to patients.* (1) If at any time HCFA determines that the continued approval of deeming authority of any accreditation organization poses immediate jeopardy to the patients of the laboratories accredited by the organization, or continued approval otherwise constitutes a significant hazard to the public health, HCFA may immediately withdraw the approval of deeming authority for that accreditation organization.

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

(i) *Failure to pay fees.* HCFA withdraws the approval of a State licensure program if the State fails to pay the applicable fees, as specified in §§ 493.645(a) and 493.646(b).

(j) *State refusal to take enforcement action.* (1) HCFA may withdraw approval of a State licensure program if the State refuses to take enforcement action against a laboratory in that State when HCFA determines it to be necessary.

(2) A laboratory that is in a State in which HCFA has withdrawn program approval is subject to the same requirements and survey and enforcement processes that are applied to a laboratory that is not exempt from CLIA requirements.

(k) *Request for reconsideration.* Any accreditation organization or State that is dissatisfied with a determination to withdraw approval of its deeming authority or remove approval of its State licensure program, as applicable, may request that HCFA reconsider the determination, in accordance with subpart D of part 488.

## Subpart H—Participation in Proficiency Testing for Laboratories Performing Tests of Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests

5. In § 493.803, paragraph (b) is revised and a new paragraph (c) is added to read as follows:

### § 493.803 Condition: Successful participation.

* * * * *

(b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, HCFA imposes sanctions, as specified in subpart R of this part.

(c) If a laboratory fails to perform successfully in a HCFA-approved proficiency testing program, for the initial unsuccessful performance, HCFA may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists:

(1) There is immediate jeopardy to patient health and safety.

(2) The laboratory fails to provide HCFA or a HCFA agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance.

(3) The laboratory has a poor compliance history.

## Subpart Q—Inspection

6. In subpart Q, new §§ 493.1771 and 493.1773 are added to read as follows:

### § 493.1771 Condition: Inspection requirements applicable to all CLIA-certified and CLIA-exempt laboratories.

(a) Each laboratory issued a CLIA certificate must meet the requirements in § 493.1773 and the specific requirements for its certificate type, as specified in §§ 493.1775 through 493.1780.

(b) All CLIA-exempt laboratories must comply with the inspection requirements in §§ 493.1773 and 493.1780, when applicable.

### § 493.1773 Standard: Basic inspection requirements for all laboratories issued a CLIA certificate and CLIA-exempt laboratories.

(a) A laboratory issued a certificate must permit HCFA or a HCFA agent to conduct an inspection to assess the laboratory's compliance with the requirements of this part. A CLIA-exempt laboratory and a laboratory that requests, or is issued a certificate of accreditation, must permit HCFA or a HCFA agent to conduct validation and complaint inspections.

(b) General requirements: As part of the inspection process, HCFA or a HCFA agent may require the laboratory to do the following:

(1) Test samples, including proficiency testing samples, or perform procedures.

(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part.

(3) Permit laboratory personnel to be observed performing all phases of the total testing process (preanalytic, analytic, and postanalytic).

(4) Permit HCFA or a HCFA agent access to all areas encompassed under the certificate including, but not limited to, the following:

(i) Specimen procurement and processing areas.

(ii) Storage facilities for specimens, reagents, supplies, records, and reports.

(iii) Testing and reporting areas.

(5) Provide HCFA or a HCFA agent with copies or exact duplicates of all records and data it requires.

(c) Accessible records and data: A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection.

(d) Requirement to provide information and data: A laboratory must provide, upon request, all information and data needed by HCFA or a HCFA agent to make a determination of the laboratory's compliance with the applicable requirements of this part.

(e) Reinspection: HCFA or a HCFA agent may reinspect a laboratory at any time to evaluate the ability of the laboratory to provide accurate and reliable test results.

(f) Complaint inspection: HCFA or a HCFA agent may conduct an inspection when there are complaints alleging noncompliance with any of the requirements of this part.

(g) Failure to permit an inspection or reinspection: Failure to permit HCFA or a HCFA agent to conduct an inspection or reinspection results in the suspension or cancellation of the laboratory's participation in Medicare and Medicaid for payment, and suspension or limitation of, or action to revoke the laboratory's CLIA certificate, in accordance with subpart R of this part.

7. Section 493.1775 is revised to read as follows:

### § 493.1775 Standard: Inspection of laboratories issued a certificate of waiver or a certificate for provider-performed microscopy procedures.

(a) A laboratory that has been issued a certificate of waiver or a certificate for provider-performed microscopy procedures is not subject to biennial inspections.

(b) If necessary, HCFA or a HCFA agent may conduct an inspection of a laboratory issued a certificate of waiver or a certificate for provider-performed microscopy procedures at any time during the laboratory's hours of operation to do the following:

(1) Determine if the laboratory is operated and testing is performed in a manner that does not constitute an imminent and serious risk to public health.

(2) Evaluate a complaint from the public.

(3) Determine whether the laboratory is performing tests beyond the scope of the certificate held by the laboratory.

(4) Collect information regarding the appropriateness of tests specified as waived tests or provider-performed microscopy procedures.

(c) The laboratory must comply with the basic inspection requirements of § 493.1773.

**§ 493.1776 [Removed]**

8. Section 493.1776 is removed.

9. Section 493.1777 is revised to read as follows:

**§ 493.1777 Standard: Inspection of laboratories that have requested or have been issued a certificate of compliance.**

(a) *Initial inspection.* (1) A laboratory issued a registration certificate must permit an initial inspection to assess the laboratory's compliance with the requirements of this part before HCFA issues a certificate of compliance.

(2) The inspection may occur at any time during the laboratory's hours of operation.

(b) *Subsequent inspections.* (1) HCFA or a HCFA agent may conduct subsequent inspections on a biennial basis or with such other frequency as HCFA determines to be necessary to ensure compliance with the requirements of this part.

(2) HCFA bases the nature of subsequent inspections on the laboratory's compliance history.

(c) *Provider-performed microscopy procedures.* The inspection sample for review may include testing in the subcategory of provider-performed microscopy procedures.

(d) *Compliance with basic inspection requirements.* The laboratory must comply with the basic inspection requirements of § 493.1773.

10. Section 493.1780 is revised to read as follows:

**§ 493.1780 Standard: Inspection of CLIA-exempt laboratories or laboratories requesting or issued a certificate of accreditation.**

(a) *Validation inspection.* HCFA or a HCFA agent may conduct a validation inspection of any accredited or CLIA-exempt laboratory at any time during its hours of operation.

(b) *Complaint inspection.* HCFA or a HCFA agent may conduct a complaint inspection of a CLIA-exempt laboratory or a laboratory requesting or issued a certificate of accreditation at any time during its hours of operation upon receiving a complaint applicable to the requirements of this part.

(c) *Noncompliance determination.* If a validation or complaint inspection results in a finding that the laboratory is not in compliance with one or more condition-level requirements, the following actions occur:

(1) A laboratory issued a certificate of accreditation is subject to a full review by HCFA, in accordance with subpart E of this part and § 488.11 of this chapter.

(2) A CLIA-exempt laboratory is subject to appropriate enforcement actions under the approved State licensure program.

(d) *Compliance with basic inspection requirements.* CLIA-exempt laboratories and laboratories requesting or issued a certificate of accreditation must comply with the basic inspection requirements in § 493.1773.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program, Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: October 13, 1997.

**Nancy-Ann Min DeParle,**

*Deputy Administrator, Health Care Financing Administration.*

Dated: September 18, 1997.

**David Satcher,**

*Director, Centers for Disease Control and Prevention.*

Approved: February 2, 1998.

**Donna E. Shalala,**

*Secretary.*

[FR Doc. 98–12752 Filed 5–13–98; 8:45 am]

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## DEPARTMENT OF JUSTICE

## 48 CFR Part 2802 and 2846

**[Justice Acquisition Circular 98–1]**

## Amendment to the Justice Acquisition Regulations (JAR Regarding: Definitions

**AGENCY:** Justice Management Division, Justice.

**ACTION:** Final rule, correction.

**SUMMARY:** This document contains corrections to the final regulations (Justice Acquisition Regulations) that were published Thursday, April 2, 1998 (63 FR 16118–16136). The regulations related to the reissuance of the JAR to implement regulatory changes resulting from the Federal Acquisition Reform Act, the Federal Acquisition Streamlining Act and the recommendations of the National Performance Review.

**EFFECTIVE DATE:** May 14, 1998.

**FOR FURTHER INFORMATION CONTACT:** Janis Sposato, Procurement Executive, Justice Management Division (202) 514–3103.

**SUPPLEMENTARY INFORMATION:**

### A. Background

The final regulations that are the subject of these corrections superseded the 1985 version of the JAR and all amendments (Justice Acquisition Circulars 85–1 through 97–1) issued prior to the date of publication of that final rule.

### B. Regulatory Flexibility Act

The Department of Justice certifies that this final rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, because the amendment sets forth only corrections to internal departmental procedures.

### C. Paperwork Reduction Act

The final rule imposes no new information collection requirements that require approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980 (Pub. L. 96–511). All information collection requirements have been submitted to OMB. In those cases where an OMB control number has been assigned, the control number is included in the regulation.

### List of Subjects in 48 CFR Parts 2802 and 2846

Government procurement.

**Stephen R. Colgate,**

*Assistant Attorney General for Administration.*

Accordingly, 48 CFR parts 2802 and 2846 are corrected by making the following correcting amendments.

1. The authority citation for 48 CFR Parts 2802 and 2846 continues to read as follows:

**Authority:** 28 U.S.C. 510; 40 U.S.C. 486(c); 28 CFR 0.75(j) and 28 CFR 0.76(j).

## PART 2802—DEFINITIONS OF WORDS AND TERMS—[CORRECTED]

2. On page 16121, in the middle of the first column, the citation set forth as Subpart 2.1—Definitions in the table of contents of part 2802 and in the accompanying text which immediately follows, is corrected to read as follows:

### Subpart 2802.1—Definitions

## PART 2802—QUALITY ASSURANCE—[CORRECTED]

3. On page 16134, in the lower third of the third column, under Part 2846, a paragraph number and title (2846.610, General) are added as set forth below, to the table of contents and the text that appears directly under Subpart 2846.6—Material Inspection and Receiving reports.