

inspections to determine the "appropriateness" of tests, rather than their "addition, deletion or continued inclusion".

- In § 493.602 we clarify Federal validation survey activity to include accredited laboratories and change "State-exempt" to "CLIA exempt" to agree with references that were changed in previous regulations.

- In §§ 493.638, 493.639, and 493.645(c), we revise the text so that it more accurately reflects what costs fees do and do not cover; for example, they do cover the cost of categorizing tests.

- In the title of § 493.645 and paragraph (a) we are changing the word "licensure" to "laboratory" and, in paragraph (a), "State-exempt" to "CLIA-exempt" to conform to changes made in previous regulations.

IV. Waiver of Delay in Effective Date

We find good cause to waive the usual 30-day delay in effective date for most of the revisions. Those persons who become qualified under the revised regulations are no less qualified now than they will be in 30 days. Hence, it serves no purpose to delay our regulations. Other revisions are very technical in nature and to delay their effective date is also unnecessary. Also, under the provisions of the current regulations, revisions of the list of PPM tests may be done outside of a rulemaking process through publication of a **Federal Register** notice that does not require a 30 day delay. As indicated earlier, we also will consider comments received on the addition of three new PPM procedures. Therefore, we find good cause to waive the delay in effective date of this rule.

V. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, if we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Collection of Information Requirements

The portions of §§ 493.7, 493.35, 493.39, 493.43, 493.53, 493.55, and 493.57 of this document that have been revised contain information collection and recordkeeping requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980

(44 U.S.C. 3501 *et seq.*). These reporting and recordkeeping requirements are not effective until a notice of OMB's approval is published in the **Federal Register**. The information collection requirements concern the performance of recordkeeping. The respondents who will provide the information include any entity performing laboratory testing used for assessment, diagnostic or treatment purposes. Public reporting burden for this collection of information is estimated to be 61 hours per laboratory per year.

Organizations and individuals desiring to submit comments on the information collection and recordkeeping requirements should direct them to the OMB official whose name appears in the **ADDRESSES** section of this preamble.

VII. Regulatory Impact Statement

Background

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

Also, section 1102(b) of the Act requires the Secretary 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. This 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.

General

This rule modifies CLIA regulations published February 28, 1992 and January 19, 1993. There are approximately 157,000 entities enrolled under CLIA that may be affected by the provisions of this rule. The significance of the effect will vary depending on the volume and complexity of tests performed; whether the entity employs midlevel practitioners to perform provider-performed microscopy (PPM) procedures; and whether employees meet the personnel requirements contained in the February 28, 1992 regulations. While we cannot estimate the number of entities that may make changes in their laboratory testing

practices as a result of this rule, we believe the modifications to the CLIA program will benefit the affected entities in several ways. This rule will help to ease implementation of the CLIA program at no loss to public health and safety by offering alternative qualification standards for laboratory employees who would be adversely affected by the original personnel requirements. It also increases patient access to laboratory services, especially in rural and underserved areas, by expanding the list of personnel qualified to conduct certain laboratory tests. In addition, it reduces the regulatory burden for laboratories by enabling them to provide an expanded menu of tests under a PPM certificate without incurring the costs associated with obtaining a certificate of compliance.

Categorization of Tests

Expanding the list of PPM procedures may affect a laboratory's choice of certificate. Laboratories with certificates for PPM are not subject to costs associated with the routine inspections required under a certificate of compliance. Therefore, laboratories holding a certificate of compliance that change to a certificate for PPM will have a decrease in compliance costs and the number of inspections. Certificate of waiver laboratories choosing to expand their test menu to include PPM procedures and obtain a certificate of PPM will have increased certificate fees, as well as additional costs inherent in meeting applicable requirements, such as personnel and proficiency testing. The current biennial fee for a certificate of waiver is \$100, as compared to \$150 for a certificate for PPM. Although the cost of obtaining a certificate for PPM is more than for a certificate of waiver, it is less than the cost associated with a certificate of compliance.

Provider-Performed Microscopy Procedures

All providers performing microscopy examinations in conjunction with patient evaluations may be affected by the expansion of the subcategory of microscopy procedures to include midlevel health care practitioners and dentists. Many midlevel practitioners routinely perform patient examinations and associated laboratory testing, and in some States, are authorized to practice independently. Because there is such a wide variety of settings in which these services are offered, we cannot quantify the percentage of tests done by each type of health professional. However, there are no data to indicate that the quality of their tests results is not at least equivalent to the tests performed