Supporting Statement for the Clinical Laboratory Improvement Act Program;
Granting and Withdrawal of Deeming Authority to Private Nonprofit
Accreditation Organizations and of CLIA Exemption Under State Laboratory
Programs and Supporting Regulations in 42 CFR Part 493, Subpart E (493.551 - 493.557)

A. Background

This information was published originally as HSQ181F in 1992, subsequently consolidated and renumbered as part of HCFA-2239F published May 14, 1998. The Clinical Laboratory Improvement Amendments of 1988 (CLIA) established a new section 353 of the Public Health Service Act (PHSA) to replace the existing section 353. The new section 353 requires the Department of Health and Human Services (HHS) to establish certification requirements, with certain exceptions, for any laboratory that performs testing on human specimens. Laboratories must meet performance requirements based on test complexity in order to be certified by HHS. CLIA also provides for the recognition of private accreditation organizations and State licensure programs whose standards are determined to be equal to or more stringent than the HHS requirements.

Final regulations were published February 28, 1992, at 42 CFR 493 which implemented the certificate, laboratory standards and inspection requirement sections of CLIA. There have been several subsequent rules that have modified these regulations.

On July 31, 1992, final regulations implementing the provisions of 353 PHSA concerning the recognition of private accreditation organizations and State licensure programs for CLIA purposes were published as Subpart E of part 493. These regulations establish that we may approve a private, nonprofit organization as an accreditation organization for clinical laboratories under the CLIA program if the organization's requirements for its accredited laboratories are equal to or more stringent than the applicable CLIA program requirements of part 493. These regulations also provide for the CLIA exemption of laboratories in a State that applies licensure requirements that are equal to or more stringent than those of CLIA.

On May 14, 1998, as part of the Reinventing Government Initiative, revisions to Subpart E were published as part of other CLIA final rulemaking. The revisions to Subpart E eliminate duplicative information by restructuring and consolidating requirements for accreditation organizations and State licensure programs seeking approval under CLIA The revised Subpart better reflects the information required and process involved in obtaining approval. This restructuring does not change the 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 for Subpart E.

B. Justification

1. Need and Legal Basis

The information required is necessary to determine whether a private accreditation organization/State licensure program standards and accreditation /licensure process is at least equal to or more stringent than those of CLIA. If an accreditation organization is approved, laboratories it accredits are "deemed" to meet the CLIA requirements based on this accreditation. Similarly, if a State licensure program is determined to have requirements that are equal to or more stringent than those of CLIA, its laboratories are considered to be exempt from CLIA certification and requirements. Legislative authority for this regulation is found in Section 353 of the PHSA.

2. Information Users

The information collected will be used by HHS to determine comparability/equivalency of the accreditation organization standards and policies or State licensure program standards and policies to those of the CLIA program, to ensure the continued comparability/equivalency of the standards and to fulfill certain statutory reporting requirements.

3. Use of Information Technology

As part of the approval process we ascertain the ability of the organization or State licensure program to provide CMS with electronic data and reports. This ensures an efficient use of both the organization's/States resources as well as CMS. However, if this requirement cannot be specifically met, we are willing to accept alternative methods/means the organization/State licensure program may present in order to achieve the same goal.

4. Duplication of Efforts

These requirements do not duplicate any current information collection. They contain the information necessary to ascertain comparability of other standards to the standards established in the CLIA regulations.

5. Small Businesses

These requirements affect accreditation organizations or State licensure programs and do not directly impact small businesses.

6. Less Frequent Collection

If this information is not collected, we are unable to monitor continued comparability of licensure or accreditation standards to those of CLIA. We also would not be able to determine the reimbursement eligibility for the accredited or CLIA exempt laboratories. This information is necessary to fulfill the statutory and regulatory provisions to approve organizations and State licensure programs and monitor the performance of laboratory accreditation/State licensure programs.

7. Special Circumstances

In order to keep CMS apprised of accreditation activity there is certain information they must provide us within specific timeframes established in the regulation. For example they must notify CMS within 10 days of finding a deficiency in an accredited laboratory which poses an immediate jeopardy to patients; they must notify us within 30 days of newly accredited laboratories. These and the other activities outlined in the regulation are necessary for coordination of survey activity, timely and appropriate Medicare and Medicaid reimbursement, and effective administration of the CLIA program.

8. Federal Register/Outside Consultation

A 60-day Federal Register notice was published on January 18, 2008, attached.

Notice of these information collection requirements was published in the proposed rule, August 20, 1990 at 55 FR 33943. We received comments on the proposed rule and addressed concerns raised through publication of the final rule July 31, 1992 at 57 FR 34012. Also, the Public Health Service held several work sessions in Atlanta with technical experts in order to assist in developing a practical and effective regulation. These individual consultants were not part of any advisory committee and no group consensus was sought at any of the sessions.

In addition, the Clinical Laboratory Improvement Advisory Committee (CLIAC) generally hold meetings on a quarterly basis, to discuss CLIA related issues.

9. Payment/Gifts to Respondents

There is no payment or gift made to the respondents. The laboratories accredited by approved organizations submit fees to the CLIA program for certificates of accreditation. A State that is granted an exemption submits payment to the CLIA program for the laboratories it licenses.

10. Confidentiality

We do not pledge confidentiality. When an accreditation organization is approved or an

exemption granted to a State licensure program, a notice is published in the Federal Register. This notice describes the basis for the approval or exemption, including a description of how the requirements are equivalent.

11. Sensitive Questions

There are no questions of a sensitive nature contained in this collection of information.

12. Burden Estimate (Hours & Wages)

The hour burden associated with this Paperwork Reduction Act package is as follows:

SECTIONS 493.551, 493.553, 493,555 and 493.557

These sections contain the requirements and process for an accreditation organization voluntarily seeking approval under the CLIA program, as well as a State licensure program seeking exemption of its laboratories from the CLIA program.

These sections outline the requirements the organization or State must meet, including the specific information which must be submitted so that a comparison between their requirements and survey process and those of CLIA may be performed.

These sections also contain criteria used to determine comparability of the requirements as well as the notification requirements the accreditation organization or State must follow concerning laboratories it has approved. These include: laboratories which are newly accredited/licensed, laboratories that have had their accreditation withdrawn/license revoked, and laboratory inspection schedules.

Accreditation Organizations

Laboratory accreditation organizations existed prior to the implementation of CLIA. Submission of an application for recognition of the accreditation program for CLIA purposes is voluntary. The burden associated with these sections is estimated to be 96 hours per organization initially to accumulate information and develop a crosswalk; and approximately 4 hours per month subsequent to approval to supply required information on status of its laboratories.

Since organizations will generally be approved for at least a two-year period, the annual burden for initial application is 96 hours/2 years for an average of 48 hours per year. Subsequent requests for approval (reapproval) should be less since the initial development of the crosswalk will have been completed.

Submitting required information on an ongoing basis is estimated to require 4 hours per month or 48 hours annually.

TOTAL ESTIMATED ANNUAL BURDEN

4 X 12 = 48 hours per each approved organization

TOTAL BURDEN (Based on 6 approved organizations)

6 X 48 hours = 288 hours

COST BURDEN for 493.551/493.557

$30/hr (average salary) X 288 hours = $8,640

State Licensure Programs

State licensure of laboratories existed prior to the implementation of CLIA. Submission of an application for recognition of a State licensure program for CLIA exemption is voluntary on the part of the State. The burden associated with these sections is estimated to be 96 hours per State licensure program initially to accumulate information and develop a crosswalk; and approximately 4 hours per month subsequent to approval to supply required information on status of its laboratories.

Since State licensure programs will generally be approved for at least a two year period the annual burden for initial application is 96 hours/2 years for an average of 48 hours per year. Subsequent requests for approval (re-approval) should be less since the initial development of the crosswalk will have been completed.

Submitting required information on an ongoing basis is estimated to require 4 hours per month or 48 hours annually.

TOTAL ESTIMATED ANNUAL BURDEN

4 X 12 = 48 hours per each State licensure approved program.

TOTAL BURDEN (Based on 2 Approved State Licensure Programs)

2 X 48 = 96 Hours

COST BURDEN for 493.551/493.557

$30/hr (average salary) X 96 hours = $2,880

ESTIMATED TOTAL ANNUAL BURDEN OF 493.551, 493.553, 493.555 and 493.557

288 hours + 96 Hours = 384 HOURS

TOTAL COST ANNUAL BURDEN

The cost burden associated is approximately $11,520*

*Using an average rate of $30/hr X 384 hours

Note , since we are restricted from obtaining fees directly from laboratories in those States which are approved as "CLIA-exempt," the costs associated with evaluating the State licensure program are collected directly from the State. The specific cost is based on the State's proportionate share of general overhead costs for the ratio of the number of laboratories in the State to the total number of laboratories nationally. This would be in addition to the cost reflected above.

13. Capital Costs

There are no capital startup costs or costs for purchasing services.

14. Cost to Federal Government

Congress legislated the CLIA program to be self-funding; therefore, administration of the program and the development of requirements are to be funded through the collection of user fees. Costs associated with the certification of laboratories which are accredited by approved organizations, including the approval of accreditation organizations, are included in the fees associated with obtaining a certificate of accreditation. Since we are restricted from obtaining fees directly from laboratories in those States which are approved as "CLIA-exempt", the costs associated with evaluating the State licensure program are collected directly from the State. The specific cost is based on the State's proportionate share of general overhead costs for the ratio of the number of laboratories in the State to the total number of laboratories nationally.

15. Changes to Burden

There area no program changes. There is a burden reduction based on new calculations.

16. Publication/Tabulation Dates

There are no plans to publish the information collected under this submission. However, when an accreditation organization is approved or an exemption granted to a State licensure program, a notice is published in the Federal Register. This notice describes the basis for the approval or exemption, including a description of how the requirements are equivalent.

17. Expiration Date

These information collection requirements do not lend themselves to an expiration date.

18. Certification Statement

This is not applicable to this information collection.

C. Statistical Methods

There are no statistical methods.