Supporting Statement
Granting and Withdrawal of Deeming Authority to Private Nonprofit Accreditation Organizations and CLIA Exemption Under State Laboratory Programs (CMS-R-185)

A. Background

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) established a new section 353 of the Public Health Service Act (PHSA) which 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 on February 28, 1992, at 42 CFR part 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, 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.

We are revising the ICR by adding amending collection requirements for 493.553-557. The proposed rule, CMS-3326-P, was published on July 26, 2022 (87 FR 44896). These require laboratories to revise and update policies and procedures applicable to new or amended requirements. There is no collection instrument.

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

In order to attain deemed status under CLIA, the acreditation organization's (AO)/State licensure program submission package must contain specific information, including a copy of the AO/State licensure program's standards for laboratories, a detailed comparison of those standards to the comparable condition-level CLIA requirements, the AO/State licensure program's laboratory inspection protocol, a description of its process for monitoring their laboratories' proficiency testing (PT) performance, and other operational details of the program. CMS approval may not exceed 6 years. The reapproval process is every 6 years, or sooner if CMS determines an earlier review is required.

The information collected will be used by HHS to determine comparability/equivalency of the accreditation organization's or State licensure program's 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. It will be used to evaluate 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 HHS, including, but not limited to, inspection frequency and the ability to investigate and respond to complaints against its laboratories.

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

The approval process (application and reapplication) for accreditation organizations and State licensure programs require certain information to be provided within specific timeframes established in the regulation (Sections 493.551, 493.553, 493.555 and 493.557). The reapplication/reapproval process may be performed more frequently than every 6 years. Also, CMS determines if additional information is necessary to make a determination for approval or denial of the application and notifies the accreditation organization or State to afford it an opportunity to provide the additional information.

Less frequent collection of information will impact our ability to monitor the accreditation organizations' or State licensure programs' continued comparability of licensure or accreditation standards to those of CLIA. We also would not be able to determine in a timely manner, 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

The proposed rule, CMS-3326-P, was published on July 26, 2022 (87 FR 44896).

The 60-day Federal Register notice published XXXXXX.

The 30-day Federal Register notice published XXXXXX.
The following information was requested from the Accreditation Organizations and Exempt States to update the hour burden and cost burden information:

1) Number of hours (per year) to accumulate information and develop a crosswalk (to determine comparability/equivalency of the Accreditation Organization standards and policies or State licensure program standards and policies to those of the CLIA program);
(2) Number of hours (per mo/yr) to submit required information on an ongoing basis (to ensure the continued comparability/equivalency of the standards);
(3) Cost Burden (per yr) (average salary/hr) x # of hours (per yr) from #1 above.

9. Payment/Gifts to Respondents

There is no payment or gift made to the respondents.

10. Confidentiality

We do not pledge confidentiality.

11. Sensitive Questions

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

12. Burden Estimate (Hours & Wages)

The time and cost estimates are based on values provided by each accreditation organization and exempt State. Specifically, as part of their data submission, each entity submits information regarding the number number of hours per year the entity took to accumulate information and develop a crosswalk; the number of hours required to submit information on an ongoing basis; and the cost burden per year. The calculation based on this data are illustrated in table at the end of this section. Section 1 of the table lists the aforementioned data submitted by the accreditation organizations and exempt States. Section 2 of the table lists the calculations for both time and cost. The left side of Section 2 pertains to the accreditation organizations. The right side of Section 2 pertains to the exempt States.

The burden estimates associated with this information collection request are 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

Submission of an application for recognition of the accreditation program for CLIA purposes is voluntary. The estimated annual burden associated with these sections is 232 hours, which is the calculated mean time require by AOs to accumulate information and develop a crosswalk. Since organizations are generally approved for a six-year period, the annual burden for application is 232 hours divided by 6 years for an average of 39 hours per year. Submitting required information on an ongoing basis is estimated to require 42 hours per month or 504 hours annually. The total burden per organization is 543 hours per year (39 hours per year for the application, and 504 hours per year for submitting required information on an ongoing basis).

State Licensure Programs

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 24 hours per State licensure program to accumulate information and develop a crosswalk; and approximately 25 hours per month subsequent to approval to supply required information on status of its laboratories. Since State licensure programs are generally approved for a six-year period, the annual burden for application is 48 hours/6 years for an average of 8 hours per year. Submitting required information on an ongoing basis is estimated to require 25 hours per month or 300 hours annually.

Name of Accreditation Organization/Exempt State >>>	A2LA	AABB	ACHC	ASHI	CAP	COLA	NY	TJC	WA
Section 1 - Collected Data									
(1) Number of hours (per year) for organization to accumulate information and develop a crosswalk (comparison between your requirements and survey process and those of CLIA).	**120**	**160**	**180**	**30**	**150**	**729**	**240**	**550**	**48**
(2) Number of hours (per mo/yr) to submit required information on an ongoing basis.	**3**	**20**	**18**	**5**	**75**	**90**	**20**	**100**	**30**
(3) Cost Burden (per yr) (average salary/hr) x # of hours (per yr); from #1 above	**3000**	**7,360**	**13,500**	**1,500**	**8,881.50**	**42,058**	**14,000**	**27,326**	**10,000**

Section 2 Calculations

(1) **CROSSWALK -** Number of hours (per year) to accumulate information and develop a crosswalk (comparison between AO/ES requirements and survey process and those of CLIA requirements)

AO (please see above data)
Mean = ((A2LA+AABB+ACHC+CAP+TJC)** ÷ 5)
Mean = 232 hrs.
Crosswalk Burden = (232 hrs. ÷ 6yr.) = 39 hrs./yr.
(High and Low outliers removed/not included)
Note: Develop Crosswalk every 6 years; in general, approval is for 6 years

ES (please see above data)
Mean = ((NY+ WA)) ÷ 2)
Mean = 288 hrs
Crosswalk Burden = (288 hrs. ÷ 6 yr.) = 48 hrs./yr.

(2) **ONGOING BASIS - Number of hours (per mo/yr)** to submit required information on an ongoing basis. ****(High and Low outliers removed/not included)**

AO
Mean = ((A2LA+AABB+ACHC +CAP+TJC)** ÷ 5)
Mean = 42 hrs./mo.

ES
Mean = ((NY+ WA) ÷ 2)
Mean = 25 hrs./mo.

Mean = 42 hrs./mo) x (12 mo./yr.)
Mean = 504 hrs./year

Mean = 25 hrs./mo.) x (12 mo./yr.)
Mean = 300 hrs/yr.

Total AO = 39 hours per year (application) + 504 hours per year (submitting required information ongoing) = 543 hours (annual) per each approved organization.

Total ES = 48 hours per year (application) + 300 hours per year (submitting required information ongoing) = 348 hours (annual) per each State licensure approved program.

(3) COST BURDEN PER YEAR - (average salary/hr.) x # of hours (per yr.)

AO			
COLA	819	=	$51/hr.
CAP	225	=	$39/hr.
TJC	650	=	$42/hr.
ASHI	35	=	$43/hr.
ACHC	198	=	$68/hr.
AABB	180	=	$41/hr.
A2LA	123	=	$24/hr.

ES		
NY	260 =	$54/hr.
WA	78 =	$128 hr.

ES Cost = $91 hr + $91 hr=$182 hr x 696 = $126,672 (annual cost burden)
= $182-/hr x 696 = $126,672**
(2 exempt states x 348 hours per state =696 hours per year)
**Including 100% of the hour wage to account for fringe and overhead

AO Cost = 46/hr + 46/hr = $92
= $92/hr* (average salary) x 4,648 hours = $427, 616 (annual)
(7 organizations x 664 hours = 4,648 total hours per year)
*Including 100% of the hour wage to account for fringe and overhead

Sections 493.551-557: Accreditation Organization and Exempt State Costs to Update Policies and Procedure

As outlined in the proposed rule, CMS-3326-P [87 FR 44896], seven approved accrediting organizations and two exempt States would have to review their policies and procedures, provide updates and submit the changes to CMS for approval (9 organizations/exempt States x 10 or 15 hours). We assume a one-time cost of 10 to 15 hours to identify the applicable legal obligations and to develop the policies and procedures needed to reflect the new requirements for personnel and histocompatibility. A management level employee (11-9111) would perform this task at an hourly wage of $57.61 per hour as published by the 2021 Bureau of Labor Statistics. The wage rate would be $115.22 to include overhead and fringe benefits. The total cost would range from $10,370 to $15,555 (9 x 10- or 15 hours x $115.22).

Summary of All Costs for Collection of Information CMS-3326-F

Information Collection Requests*	Burden Hours Increase/Decrease (+/-)*	Cost (+/-)*
Accreditation Organization and Exempt State Costs to Update Policies and Procedure	+15	$17,283
TOTAL	**+15**	**$17,283**

*All costs reflected in this table are one-time only costs. There are no ongoing costs.

13. Capital Costs

There are no capital costs.

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. Five full-time employees (FTE) in the Division of Clinical Laboratory Improvement and Quality (DCLIQ) will review and evaluate the data. The FTEs are GS-13, so the cost to the federal government will range from $53.85 per hour to $70.00 per hour. It will take approximately 10 hours for a total cost of $2,693 to $3,500 (hourly wage ($53.85 or 70.00 X 5 X 10).

15. Changes to Burden

The previous burden hours were 5344. The burden hours have increased from 5,344 to 5,359.
It is important to note that the current burden hours and cost values were obtained from the accreditation organizations and exempt States based on their experience. The accreditation organizations and exempt States email the data to CMS as part of the information collection request process. Based on the data received, CMS updates the information collection request accordingly. As part of the update process, we have also updated the cost values to include the use of 100% of the hourly wage to account for fringe and overhead.

The revised requirement for the AO/ESs to update their policies and procedures is a one-time cost, and is not recurring. It will be a one-time increase of 15 burden hours.

16. Publication/Tabulation Dates

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. *The list of approved Accreditation Organizations and Exempt States can be viewed via the CMS CLIA website at* www.cms.gov/CLIA/; information is available at Accreditation Organizations/Exempt States

17. Expiration Date

The current list and contact information of the approved Accreditation Organizations and Exempt States are available on the CMS CLIA website. The expiration date is also posted on the website at https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Accreditation_Organizations_and_Exempt_States.

18. Certification Statement

There are no exceptions to the certification statement.