

Supporting Statement – Part A

CLIA Proficiency Testing (PT) (CMS-10690)

A. Background

This is an extension package. The purpose of this package is to request Office of Management and Budget (OMB) approval for the information collection request (ICR) for proficiency testing (PT) and reapproval of PT programs. The ICR includes laboratories filling in PT submission forms for microbiology PT and document collection for a PT program if it needs to reapply for approval using the initial approval process.

On October 31, 1988, Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (Pub. L. 100-578) (CLIA '88), codified at 42 U.S.C. 263a, to ensure the accuracy and reliability of testing in all laboratories, including, but not limited to, those that participate in Medicare and Medicaid, that test human specimens for purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment, or the assessment of health, of human beings. The Secretary established the initial regulations implementing CLIA on February 28, 1992 at 42 CFR part 493 (57 FR 7002). Among other things, those regulations required laboratories conducting moderate or high complexity testing to enroll in an approved PT program for each specialty, subspecialty, and analyte or test for which the laboratory is certified under CLIA. PT evaluates a laboratory's performance by testing of unknown samples just as it would test patient samples. A Health and Human Services (HHS)-approved PT program sends unknown samples to a laboratory for analysis. After testing, the laboratory reports its results to the PT program. The program grades the results using the CLIA grading criteria and provides the laboratory with its scores. PT is crucial to maintaining the quality of laboratory testing because it independently verifies the accuracy and reliability of laboratory testing, including the competency of testing personnel. PT referral was further addressed by enactment of the Taking Essential Steps for Testing Act of 2012 (Pub. L. 112-202, December 4, 2012) (TEST Act) and our implementing regulations (79 FR 25435 and 79 FR 27105). As of July 2025, there were 307,193 CLIA-certified laboratories, of which 33,990 Certificate of Compliance (CoC) and Certificate of Accreditation (CoA) laboratories were required to enroll in an HHS-approved PT program and comply with the PT regulations.

Testing has evolved significantly since 1992, and technology is now more accurate and precise than the methods in use at the time the PT regulations became effective for all laboratories in 1994. In addition, many tests for analytes for which PT was not initially required are now in routine clinical use. For example, tests for cardiac markers, such as troponins, and hemoglobin A1c test commonly used to monitor glycemic control in persons

with diabetes, were not routinely performed prior to 1992. Recognizing these changes, we finalized revisions to our existing PT regulations in the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Proficiency Testing Regulations Related to Analytes and Acceptable Performance (CMS 3355-F) which published July 11, 2022 (87 FR 41194). Each PT program supplies laboratories with its forms required for enrolling in microbiology PT; and reapplication for approval has no standardized forms required.

The original CLIA regulation PRA Supporting Statement for CLIA (0938-0612) did not include the collection requirements for microbiology PT provisions or PT programs included in this final rule. We determined during the proposed rule phase that this ICR would be needed to cover the additional information collections. We plan to include these two information collections when the PRA package OMB Control number: 0938-0612 is due for renewal.

B. Justification

1. Need and Legal Basis

The information required is necessary to determine an entity's compliance with the Congressionally-mandated program with respect to the regulation of laboratory testing (CLIA). In addition, laboratories participating in the Medicare program must comply with CLIA requirements as required by section 6141 of OBRA 89. Medicaid, under the authority of section 1902(a)(9)(C) of the Social Security Act, pays for services furnished only by laboratories that meet Medicare (CLIA) requirements.

Legislative authority for these requirements and the supporting regulations is found in Section 353 of the Public Health Service Act. This ICR reflects a series of records required to be maintained by laboratories and PT programs participating in the CLIA program and are based upon the publication of the final PT rule, CMS-3355-F.

Clarification for Reporting of Microbiology Organism Identification: The CLIA regulations outline the requirements related to participation and successful performance for laboratories performing nonwaived testing. Laboratories are required to test these samples in the same manner as it tests patient samples as well as detect and identify organisms to highest level performed on patient specimens. PT programs determine the organisms that should be reported as part of the laboratory's identification. It is the laboratory's responsibility to select the appropriate PT module that covers its testing services and to complete the enrollment form. In order to accurately score a laboratory's participation, the PT programs must be able to grade the responses from the laboratories. This requires the laboratory to submit the appropriate PT form to the PT program when enrolling in microbiology PT. The PT submission form is developed and supplied to the laboratories by the PT programs and is not a CMS form. After the laboratory reports its results to the PT program, the program grades the

results using the CLIA grading criteria and provides the laboratory with its scores.

PT Program Reapproval: The cICR from PT program reapproval is necessary to allow CMS, if widespread or systemic problems are encountered during the annual reapproval process, to have the option of requiring a PT program to reapply using the process for initial approval. The regulations require PT programs to meet specific criteria listed by specialty, subspecialty, and analyte, or test. The PT programs are also required to provide HHS with additional information and data upon request and submit such information necessary for HHS to conduct an annual evaluation to determine whether the PT program continues to meet the applicable requirements. Should CMS encounter this situation, we would need to collect information to ensure the PT program meets CLIA requirements.

2. Information Users

Laboratories are currently required to report PT results for microbiology organism identification to the highest level that they report results on patient specimens. We are clarifying that this is required when reporting microbiology PT results to PT programs. The information that the laboratory submits to the PT program will be used by the PT program to determine successful participation in PT.

As part of the PT program reapproval process CMS ascertains the ability of the program to meet the applicable sections of subpart I. CMS will use the information from the PT programs to determine if a PT program continues to meet the requirements found in subpart I of the CLIA regulations.

3. Use of Information Technology

The laboratory transmits results to the PT programs via either electronic or hard copy submission. This mechanism to provide these results is determined by the PT program and is outside the scope of CMS' authority. However, we believe that all eight of the current PT programs have mechanism for electronic submission of results. As a result, we believe the ability for the PT programs to track this data already exists in their software; however, they may need to make minor modifications to their software in order to provide CMS with an audit trail of laboratory PT submission information. There is no addition to the work product the PT programs would need to produce for CMS, just the mode of transmission of the documents.

As part of the reapproval process, we ascertain the ability of the PT program to provide CMS with electronic documents. This ensures an efficient use of both the program's resources as well as CMS. However, if this requirement cannot be specifically met, we are willing to accept alternative methods/means the PT 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 compliance with requirements established in the CLIA regulations.

5. Small Businesses

We believe the majority of clinical laboratories qualify as small businesses. As such, we would not be incurring undue burden as all laboratories, regardless of small business status, would be required to collect this information, if applicable. Although the effect of collecting this information may minimally increase laboratory burden hours and costs, implementation of these changes in a final rule will increase the confidence of laboratory professionals and the end-users of test results, including physicians and other healthcare providers, patients, and the public, in the reliability and accuracy of test results. We do not expect this minimal burden to affect the operation of current or new laboratories.

6. Less Frequent Collection

If this information is not collected except during the annual reapproval process, we are unable to monitor continued compliance of PT programs to CLIA requirements. This collection of information would only occur if CMS identifies that a PT program has widespread or systemic problems during the reapproval process.

7. Special Circumstances

There are no special circumstances.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published XXXXXXXXXXXX.

9. Payments/Gifts to Respondents

There is no payment or gift made to the respondents.

10. Confidentiality

Confidentiality will be maintained to the extent provided by law. We pledge confidentiality of patient-specific data in accordance with the Privacy Act of 1974 (5 U.S.C. 552a).

11. Sensitive Questions

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

12. Burden Estimates (Hours & Wages)

Clarification for Reporting of Microbiology Organism Identification

We estimate the number of laboratories who are not currently reporting microbiology organisms to the highest level that they report results on patient specimens to be about 10 percent of 13,265 laboratories with a specialty in microbiology, which is 1,327. We estimate it would take 20 minutes for a laboratory to fill this information on the PT submission form. The PT submission form is developed and supplied to the laboratories by the PT programs and is not a CMS form. Each laboratory would report this information 3 times a year which would take approximately 1 hour in total. The total annual burden is 1,327 hours (1,327 laboratories X 1 hour). A Clinical Laboratory Technologists/Technicians (29-2010) would perform this task at an hourly wage of \$29.75 as published in 2024 by the Bureau of Labor Statistics (<https://data.bls.gov/oes/#/industry/000000>). The wage rate would be \$59.50 to include overhead and fringe benefits. The total cost would be \$78,957 (1,327 hours X \$59.50).

PT Program Reapproval

If a PT program would need to reapply for approval using the initial approval process, we would estimate that the cost would be 10 hours for document collection. The total burden is 80 hours (8 PT programs X 10 hours). However, this would not be an annual burden, rather it would only occur as outlined above, and we believe that this would only occur rarely. An Office/Administrative Support Worker (43-9000) would perform this task at an hourly wage of \$22.09 as published in 2024 by the Bureau of Labor Statistics (<https://data.bls.gov/oes/#/industry/000000>). The wage rate would be \$44.18 to include overhead and fringe benefits. The total cost would be \$3,534 (80 hours X \$44.18).

Information Collection Requests	Burden Hours Increase/Decrease (+/-)*	Cost (+/-)*
A. Clarification for Reporting of Microbiology Organism Identification	+1,327	+ 78,957
B. PT Program Reapproval	+80	+3,534
TOTAL	+1,407	+82,491

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

Congress intended for the CLIA program to be self-funding, and laboratories are assessed user fees to fund the operation of the program. Three full-time employees (FTE) in the Division of Clinical Laboratory Quality and Improvement (DCLIQ) will oversee the revised requirements. The FTEs are GS-13, so the cost to the federal government will be \$75.11 per hour. It will take approximately 1 hour annually. The annual cost to the Federal Government is \$451 (\$150.22 (per hour salary including overhead) x 3 FTEs x 1 hour)).

15. Changes to Burden

After publication and implementation of the final rule, burden hour estimates increased due to an error in calculating the affected laboratories and increased wages. The calculation was incorrect in the original submission. Ten percent of 34,113 is 3,411, not 341 as stated in the original submission. 34,113 is the total of all nonwaived laboratories. The current number of nonwaived laboratories with the specialty of microbiology is 13,265, with 10% being 1,327. In addition, there are only 8 approved proficiency testing programs instead of 9, reducing the hours from 90 to 80. Overall, there was an increase in the number of burden hours from 431 to 1,407. Changes in burden are also the result of an average increase in hourly wages for office/administrative support workers and clinical laboratory technologists/technicians from \$18.41 to \$22.09 and from \$26.92 to \$29.75, respectively. The cost increased from \$21,673 to \$82,491.

16. Publication/Tabulation Dates

There are no plans to publish the information collected under this submission.

17. Expiration Date

The expiration date will be displayed on the CLIA website found at https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Proficiency_Testing_Providers.html.

18. Certification Statement

There are no exceptions to the certification statement.

