Supporting Statement – Part A

CLIA Proficiency Testing (PT) (CMS-10690)

A. Background

The purpose of this package is to request Office of Management and Budget (OMB) approval for the collection of information requirements for proficiency testing (PT) and reapproval of PT programs.

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 proficiency testing (PT) program for each specialty, subspecialty, and analyte or test for which the laboratory is certified under CLIA. 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 January 2017, there were 246,143 CLIA-certified laboratories, of which 36,777 Certificate of Compliance and Certificate of Accreditation laboratories were required to enroll in a Health and Human Services (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 are proposing revisions to our existing PT regulations in this proposed rule.

B. Justification

1. Need and Legal Basis

Subpart H (42 C.F.R. §§493.801 through 493.865) of 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 42 C.F.R. §493.801(b)). In addition, subpart H describes the requirement for successful performance. Microbiology can be found in §§493.821 through

493.831. In order to accurately score a laboratory's participation, the PT programs must be able to grade the responses from the laboratories. Scoring of samples for microbiology can be found at §§493.801(b), 493.911(b), 493.913(b), 493.915(b), 493.917(b), and 493.919(b).

The need and legal basis related to PT program reapproval is necessary to allow CMS, if widespread or systemic problems are encountered during the annual reapproval process, the option of requiring a PT program to reapply using the process for initial approval. 42 C.F.R. §493.901(c) requires PT programs to meet specific criteria listed by specialty, subspecialty, and analyte, or test. §493.903(c) requires PT programs 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.

The need and legal basis related to PT programs to having a mechanism to track changes related to electronic submission of PT results is necessary so that CMS is able to determine when laboratories submit PT results to the PT program. For PT referral investigations and determinations, an audit trail that includes all instances of reported results would aid in determining if a laboratory compared PT results obtained from another laboratory and changed their previously submitted results. 42 CFR 493.901 and 493.903 requires PT programs to meet specific administrative responsibilities, including the requirement to provide CMS with requested data.

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 nine 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

PT Program Reapproval

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.

Submission of PT Data by Laboratories

Minor modifications to the PT programs' software would be a one-time cost when the requirement is implemented.

7. Special Circumstances

There are no special circumstances.

8. Federal Register/Outside Consultation

This information collection request is associated with 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).

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 collection of information.

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 34,113 laboratories which is 341 laboratories. 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. The total annual burden is 341hours (341 laboratories X 1 hour). A Clinical Laboratory Technologists/Technicians (29-2010) would perform this task at an hourly wage of $26.92 as published in 2020 by the Bureau of Labor Statistics (https://www.bls.gov/oes/2020/may/oes_nat.htm). The wage rate would be $53.84 to include overhead and fringe benefits. The total cost would be $18,359 (341 hours X $53.84).

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 90 hours (9 PT programs X 10 hour). 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 $18.41 as published in 2020 by the Bureau of Labor Statistics

(https://www.bls.gov/oes/2020/may/oes_nat.htm). The wage rate would be $36.82 to include overhead and fringe benefits. The total cost would be $3,314 (90 hours X $36.82).

Submission of PT Data by Laboratories

This requirement was not finalized.

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 are included in the fees associated with obtaining a CLIA certificate. 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

In the proposed rule we calculated that, on average, the impact would be between $721 and $3,218 per laboratory, with laboratories having fewer analytes bearing a smaller burden. In the final rule, the estimated cost for remains relatively unchanged, and will be between $695 and $2,511. The burden hours decreased from 593 to 431. The burden cost decreased from $36,577 to $21,673. This is due to not finalizing a proposed provision requiring the submission of PT data by laboratories to limit the participants' online submission of PT data to one submission or that a method be provided to track changes made to electronically reported results. Feedback from commenters indicated that this would be a significant burden, and CMS agreed.

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.