



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10690]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain . Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA web site by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term “collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* CLIA Proficiency Testing (PT); *Use:* 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 (OMB control number: 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 under OMB control number: 0938-0612 is due for renewal.

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. *Form Number:* CMS-10690 (OMB control number: 0938-1357); *Frequency:* Yearly; *Affected Public:* Private sector - Not-for-profit organizations; *Number of Respondents:* 1,335; *Total Annual Responses:* 1,335 *Total Annual Hours:* 1,407. (For policy questions regarding this collection contact Penny Keller at 410-786-2035.)

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Director,

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Office of Strategic Operations and Regulatory Affairs.