purposes. This information is vital to the certification process. In this revision, changes were made to the form to facilitate its completion and data entry. We anticipate that the changes will not increase the time to complete the form. *Form Number:* CMS–116 (OMB control number: 0938–0581); *Frequency:* Biennially and Occasionally; *Affected Public:* Private Sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 50,236; *Total Annual Responses:* 50,236; *Total Annual Hours:* 50,236. (For policy questions regarding this collection contact Cheryl Murphy at *Cheryl.Murphy@cms.hhs.gov*.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10065/10066 and CMS–10690]

Agency Information Collection Activities: Proposed Collection; 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 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates 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 must be received by November 12, 2025.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. Electronically. You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. By *regular mail.* You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier: ____,/OMB Control Number: ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

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 website 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 N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10065/10066 Hospital Notices: IM/DND

CMS–10690 CLIA Proficiency Testing (PT)

Under the 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 requires federal agencies to publish a 60-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.

Information Collections

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Hospital Notices: IM/DND; *Use:* This information collection applies to beneficiaries in Original Medicare and enrollees in Medicare health plans. The purpose of the IM is to inform beneficiaries and enrollees of their rights as hospital inpatients and how to request a discharge appeal by a Quality Improvement Organization (QIO) and how to file a request. Consistent with 42 CFR 405.1205 for Original Medicare and 422.620 for Medicare health plans, hospitals must provide the initial IM within 2 calendar days of admission. A follow-up copy of the signed IM is given no more than 2 calendar days before discharge. The follow-up copy is not required if the first IM is provided within 2 calendar days of discharge. *Form Number:* CMS–10065/10066 (OMB control number: 0938–1019); *Frequency:* Yearly; *Affected Public:* Private Sector, Business or other for profits, Not for profit institutions; *Number of Respondents:* 25,397,156; *Total Annual Responses:* 25,397,156; *Total Annual Hours:* 4,313,823. (For policy questions regarding this collection contact: Katherine Hosna at 410–786–4993 or *KatherineHosna@cms.hhs.gov*).

2. *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.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts,Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–3031]

Alternative Tools: Assessing Drug Manufacturing Facilities Identified in Pending Applications; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Alternative Tools: Assessing Drug Manufacturing Facilities Identified in Pending Applications.'' This guidance provides information to applicants on how FDA intends to use alternative tools to assess drug manufacturing facilities identified in a marketing application (*i.e.,* a new drug application (NDA), an abbreviated new drug application (ANDA), a biologics license application (BLA), or a supplement to any of these types of applications). As part of the negotiations relating to the reauthorization of the Prescription Drug User Fee Act (PDUFA) and the Biosimilar User Fee Act (BsUFA), as described in ''PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027'' (PDUFA VII commitment letter) and ''Biosimilar Biological Product Reauthorization Performance Goals and Procedures for Fiscal Years 2023 Through 2027'' (BsUFA III commitment letter), FDA agreed to issue guidance on the use of alternative tools to assess manufacturing facilities named in pending applications and to incorporate best practices from the use of such tools during the Coronavirus Disease 2019 (COVID–19) pandemic. This guidance finalizes the draft guidance of the same title issued on September 22, 2023.

DATES: The announcement of the guidance is published in the **Federal Register** on September 12, 2025.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows: