

related to erroneous test results in order to be certified by HHS.

This information collection reflects a series of records required to be maintained by laboratories participating in the CLIA program and are based upon the publication of a final quality assessment rule on January 24, 2003, and the publication of the final fee, histocompatibility, personnel, and alternative sanction rule on December 28, 2023 (88 FR 89976). Included in the revisions were amendments to the histocompatibility and personnel regulations under CLIA to address obsolete regulations and update the regulations to incorporate technological changes, and that are reflected in this extension package.

The previous iteration was a revision of the information collection. Based on notice of final rulemaking, CMS-3326-F (88 FR 89976) published on December 28, 2023, we revised the ICR by adding additional sections.

The final rule addressed recommendations provided by the Centers for Disease Control and Prevention (CDC)'s Clinical Laboratory Improvement Advisory Committee (CLIAC). CMS and CDC incorporated changes in the rulemaking to remove specific regulations already covered in the general requirements and laboratory director responsibilities. The additional requirements included sections 493.1278, 493.1359, 493.1405-1411; 493.1423, 493.1443-1445, 493.1461-1463; 493.1483; 493.1489-1491. These sections included histocompatibility (493.1278) and personnel (493.1359, 493.1405-1411; 493.1423, 493.1443-1445, 493.1461-1463; 493.1483; 493.1489-1491) which required laboratories to revise and update policies and procedures applicable to new or amended requirements. *Form Number:* CMS-R-26 (OMB Control Number: 0938-0612); *Frequency:* Monthly, occasionally; *Affected Public:* Business or other for-profits and Not-for-profit institutions, State, Local or Tribal Governments, and the Federal government; *Number of Respondents:* 49,626; *Total Annual Responses:* 88,259,802; *Total Annual Hours:* 14,514,802. (For policy questions regarding this collection contact Penny Keller at 410-786-2035).

3. *Type of Information Collection Request:* Extension of currently approved collection; *Title of Information Collection:* Granting and Withdrawal of Deeming Authority to Private Nonprofit Accreditation Organizations and CLIA Exemption Under State Laboratory Programs; *Use:* This is an extension package. 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 eliminated 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 did not change the requirements, but only redesignated them into a more customer-oriented document, making them easier for users to understand. In this process we used new section numbers, but retained all the requirements for Subpart E.

The last iteration required accreditation organizations and State licensure programs to revise and update policies and procedures applicable to new or amended requirements in the final rule, CMS-3326-F, to remain compliant with the regulations at 493.553-557. The accreditation

organizations or State licensure programs are required to meet or exceed the CLIA regulations. The final rule, CMS-3326-F, was published on December 28, 2023 (88 FR 89976). *Form Number:* CMS-R-185 (OMB control number: 0938-0686); *Frequency:* Occasionally; *Affected Public:* Private Sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 9; *Total Annual Responses:* 9; *Total Annual Hours:* 5,359. (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

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10185]

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 August 3, 2026.

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 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 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.

Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Part C and D Reporting Requirements; *Use:* Section 1857(e)(1) and Section 1860D–12(b)(3)(D) of the Social Security Act (the Act) provides broad authority for the Secretary to add terms to the contracts with Medicare Advantage Organizations (MAOs) and Part D sponsors, including terms that require the sponsor to provide the Secretary with information as the Secretary may find necessary and appropriate.

Pursuant to our statutory authority, the Centers for Medicare & Medicaid Services (CMS) codified these information collection requirements for MAOs in regulation at 42 CFR 422.516 and for Part D sponsors in regulation at 42 CFR 423.514.

The data collected through the reporting requirements for MAOs and Part D sponsors are used by CMS and other stakeholders for oversight, monitoring, compliance, and performance evaluation. CMS staff use the data to monitor and hold organizations accountable, while academic researchers and governmental entities such as the Government Accountability Office (GAO) and the Office of Inspector General (OIG) have inquired about this information collection. Reported data may be used for CMS performance metrics such as the Medicare Part C and D Star Ratings and Display Measures, and analyzed for program oversight to ensure the availability, accessibility, and acceptability of sponsors’ services. *Form Number:* CMS–10185 (OMB control number: 0938–0992); *Frequency:* Yearly; *Affected Public:* Business or other for-profits; *Number of Respondents:* 758; *Total Annual Responses:* 35,196; *Total Annual Hours:* 96,938. (For policy questions regarding this collection contact Bindu Aryal at 410–786–6987 or bindu.aryal@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

Administration for Children and Families

[Office of Management and Budget #: 0970–0033]

Submission for Office of Management and Budget Review; Office of Refugee Resettlement Annual Survey of Refugees

AGENCY: Office of Refugee Resettlement, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families (ACF) within the U.S. Department of Health and Human Services seeks an extension to the existing data collection for the Annual

Survey of Refugees (ASR) (Office of Management and Budget #: 0970–0033; Expiration Date: October 30, 2026) through 2027. The ASR is a yearly sample survey of refugee households entering the U.S. in the previous 5 fiscal years (FYs). There are no changes currently requested to the form, but ACF intends to submit a revision request in 2027 for future annual requests.

DATES: *Comments due* August 3, 2026.

ADDRESSES: The public may view and comment on this information collection request at: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202606-0970-026. You can also obtain copies of the proposed collection of information by emailing infocollection@acf.hhs.gov. Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: Data from the ASR are used to meet the Office of Refugee Resettlement’s (ORR) Congressional reporting requirements, as set forth in the Refugee Act of 1980, section 413(a) of the Immigration and Nationality Act. ORR makes survey findings available to the public and uses findings for the purposes of program planning, policymaking, and budgeting. There are no changes to the survey. Information collection materials will be translated into 20 languages. ACF acknowledges that English is the official language and authoritative version of all federal information and will note this on the translated material.

This request is for an extension to allow ORR to complete the 2025 ASR and to field the 2026 ASR. Changes to the 2025 ASR, which is currently in process, at this time would be problematic for data quality and cost efficiencies. Maintaining the current survey safeguards compliance with congressional requirements, preserves the validity of the data, and avoids operational disruptions that could undermine the completion and credibility of the 2025 ASR. There are ongoing efforts to test the feasibility of an online survey and based on the findings of these tests, revisions will be proposed to the ASR that are expected to reduce burden. While those efforts are completed and integrated for future years, ORR proposes to use the current version of the ASR for 2025 and 2026. A revision request will be submitted in 2027 to implement changes.

Respondents: The ASR secures a nationally representative sample of refugee households arriving in the United States in the previous 5 FYs.