



## Centers for Medicare & Medicaid Services

[Document Identifier: CMS-R-26, CMS-R-185, CMS-116, CMS-2746 and CMS-10261]

### 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](http://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:* Revision of a currently approved collection; *Title of Information Collection:* Clinical Laboratory Improvement Amendments (CLIA) Regulations; *Use:* The information 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.

This is a revision of the information collection. Based on the notice of proposed rulemaking, published in the *Federal Register* on July 26, 2022 (87 FR 44896), we are revising

the information collection request by adding sections. The additional requirements include sections 493.1278, 493.1359, 493.1405-1411; 493.1423, 493.1443-1445, 493.1461-1463; 493.1483; 493.1489-1491. These sections include histocompatibility (493.1278) and personnel (493.1359, 493.1405-1411; 493.1423, 493.1443-1445, 493.1461-1463; 493.1483; 493.1489-1491) require 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 Jelani Sanaa at 410-786-1139).

2. *Type of Information Collection Request*: Revision 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*: The information required is necessary to determine whether a private accreditation organization/State licensure program standards and accreditation /licensure process is at least equal to or more stringent than those of the Clinical Laboratory Improvement Amendments of 1988 (CLIA). If an accreditation organization is approved, the laboratories that it accredits are “deemed” to meet the CLIA requirements based on this accreditation. Similarly, if a State licensure program is determined to have requirements that are equal to or more stringent than those of CLIA, its laboratories are considered to be exempt from CLIA certification and requirements. The information collected will be used by HHS to: determine comparability/equivalency of the accreditation organization standards and policies or State licensure program standards and policies to those of the CLIA program; to ensure the continued comparability/equivalency of the standards; and to fulfill certain statutory reporting requirements.

We are revising the information collection request by adding and amending collection requirements for 493.553-557. The proposed rule published in the *Federal Register* on July 26, 2022 (87 FR 44896). These require laboratories to revise and update policies and procedures applicable to new or amended requirements. *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 Arlene Lopez at 410-786-6782.)

3. *Type of Information Collection Request*: Revision of a currently approved collection; *Title of Information Collection*: Clinical Laboratory Improvement Amendments (CLIA) Application Form and Supporting Regulations; *Use*: Section 353 (b) of the Public Health Service Act specifies that the laboratory must submit an application in such form and manner as the Secretary shall prescribe that describes the characteristics of the laboratory and examinations and procedures performed by the laboratory. The application must be completed by entities performing laboratory's testing specimens for diagnostic or treatment purposes. This information is vital to the certification process. In this revision, the majority of changes were minor changes to the form and accompanying instructions to facilitate the completion and data entry of the form. 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*: 64,598; *Total Annual Responses*: 64,598; *Total Annual Hours*: 64,598. (For policy questions regarding this collection contact Kimberly Weaver at 410-786-3366.)

4. *Type of Information Collection Request*: Reinstatement of a previously approved collection; *Title of Information Collection*: End Stage Renal Disease Death Notification; *Use*: The ESRD Death Notification form (CMS-2746) is completed by all Medicare-approved ESRD

facilities upon death of an ESRD patient. Its primary purpose is to collect fact of death and cause of death of ESRD patients. The ESRD Program Management and Medical Information System (PMMIS) has the responsibility of collecting, maintaining, and disseminating, on a national basis, uniform data pertaining to ESRD patients and their treatment of care. All renal facilities approved to participate in the ESRD program are required by Pub. L. 95-292 to supply data to this system.

Federal regulations require that the ESRD Networks examine the mortality rates of every Medicare-approved facility within its area of responsibility. CMS-2746 provides the necessary data to assist the ESRD Networks in making decisions that result in improved patient care and in cost-effective distribution of ESRD resources. The data is used by the ESRD Networks to verify facility deaths and to monitor facility performance. The form is also used by health care planning agencies and researchers to determine survival rates by diagnoses. This request is to revise the form to better align with the common verbiage used on standardized forms, by other Federal agencies, including the Census Bureau. *Form Number:* CMS-2746 (OMB control number: 0938-0448); *Frequency:* Yearly; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents:* 7,726; *Total Annual Responses:* 101,491; *Total Annual Hours:* 50,746. (For policy questions regarding this collection contact Christina Goatee at 410-786-6689.)

5. *Type of Information Collection Request:* Revision of currently approved collection; *Title of Information Collection:* Part C Medicare Advantage Reporting Requirements; *Use:* The Centers for Medicare and Medicaid Services (CMS) established reporting requirements for Medicare Advantage Organizations (MAOs) under the authority described in 42 CFR 422.516(a). Each MAO must have an effective procedure to develop, compile, evaluate, and report to CMS, its enrollees, and the public at the times and in the manner that CMS requires.

These Part C Reporting Requirements will provide key data to CMS on the utilization and cost of these benefits that has not been available since the removal of benefit utilization

requirements in 2011. This proposed collection will also build upon the previous collection-by-asking for information regarding all unique supplemental benefits categories. These categories match the current Plan Benefit Package (PBP) which is submitted annually by plans.

Additionally, the proposed collection will request information to be split out by the authority under which each plan offers the benefits (mandatory, optional, mandatory-SSBCI, mandatory-Uniformity Flexibility). *Form Number:* CMS-10261 (OMB control number: 0938-1054); *Frequency:* Annually; *Affected Public:* Business or other for-profits; *Number of Respondents:* 743; *Total Annual Responses:* 6,687; *Total Annual Hours:* 187,979. (For policy questions regarding this collection contact Lucia Patrone at (410) 786-8621).

Dated: September 20, 2023.

**William N. Parham, III,**

*Director,*

*Paperwork Reduction Staff,*

*Office of Strategic Operations and Regulatory Affairs.*

**4120-01-U-P**

[FR Doc. 2023-20739 Filed: 9/22/2023 8:45 am; Publication Date: 9/25/2023]