

CMS-116 Clinical Laboratory Improvement Amendments (CLIA) Application Form and Supporting Regulations

CMS-2746 End Stage Renal Disease Death Notification

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 Collection

1. *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.)

2. *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 Public Law 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.)

Dated: July 11, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10847]

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

Correction

In notice document 2023-14176 beginning on page 42722 in the issue of Monday, July 3, 2023, make the following correction:

On page 42722, in the third column, in the third line of the **DATES** section, “August 2, 2023” should read “July 31, 2023”.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for Office of Management and Budget Review; Guidance for Tribal Temporary Assistance for Needy Families Program (Office of Management and Budget #0970-0157)

AGENCY: Office of Family Assistance; Administration for Children and Families; Department of Health and Human Services.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF) is requesting a 3-year extension of the form ACF-123: Guidance for the Tribal Temporary Assistance for Needy Families (TANF) Program (Office of Management and Budget (OMB) #0970-0157, expiration date: August 31, 2023). There are minor clarifying changes requested to the guidance.

DATES: *Comments due within 30 days of publication.* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

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