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.

[FR Doc. 2023–14985 Filed 7–13–23; 8:45 am]

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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''.

[FR Doc. C1–2023–14176 Filed 7–13–23; 8:45 am]

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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

for Public Comments'' or by using the search function.

SUPPLEMENTARY INFORMATION:

Description: 42 U.S.C. 612 (Section 412 of the Social Security Act) requires each Indian tribe that elects to administer and operate a TANF program to submit a TANF Tribal Plan. This request includes the renewal of the guidance for completing the initial Tribal TANF Plan. The TANF Tribal Plan is a mandatory statement submitted to the Secretary of the United States Department of Health and Human Services (HHS) by the Indian tribe, which consists of an outline of how the Indian tribe's TANF program will be administered and operated. It is used by the Secretary to determine whether the plan is approvable and to determine that the Indian tribe is eligible to receive a TANF assistance grant. It is also made available to the public. The renewal includes minor edits, such as updating hyperlinks and correcting typographical errors. Additionally, the list of requirements has been reformatted so that it is easier to read and use.

Respondents: Indian tribes applying to operate a TANF program and to renew their Tribal Family Assistance Plan.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Guidance for the TANF Program	75	1	68	5,100	1,700

Estimated Total Annual Burden Hours: 1,700.

Authority: 42 U.S.C. 612.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–15001 Filed 7–13–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2680]

Pediatric Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) announces a forthcoming public advisory committee meeting of the Pediatric Advisory Committee (the Committee). The general function of the Committee is to provide advice and recommendations to the Agency on pediatric regulatory issues. At least one portion of the meeting will be closed to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held virtually on September 19, 2023, from 9 a.m. to 5:30 p.m. Eastern Time and September 20, 2023, from 9 a.m. to 1 p.m. Eastern Time.

ADDRESSES: All meeting participants will be joining this advisory committee via an online teleconferencing platform. All meeting participants will be heard, viewed, captioned, and recorded for this advisory committee meeting via an online teleconferencing and/or video conferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2023–N–2680. The docket will close on September 18, 2023. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 18, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Comments received on or before September 5, 2023, will be provided to the Committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments 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:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–N–2680 for ''Pediatric Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9