

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 December 23, 2022.

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-10609 Medicaid Program Face-to-Face Requirements for Home Health Services and Supporting Regulations

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:* Extension of a currently approved collection; *Title of Information Collection:* Medicaid Program Face-to-Face Requirements for Home Health Services and Supporting Regulations; *Use:* Physicians (or for medical equipment, authorized non-physician practitioners (NPPs) including nurse practitioners, clinical nurse specialists and physician assistants) must document that there was a face-to-face encounter with the Medicaid beneficiary prior to the physician making a certification that home health services are required. The burden associated with this requirement is the time and effort to complete this documentation. The burden also includes writing, typing, or dictating the face-to-face documentation and signing/dating the documentation. *Form Number:* CMS-10609 (OMB control number: 0938-1319); *Frequency:* Occasionally; *Affected Public:* Private sector (business or other for-profits); *Number of Respondents:* 381,148; *Total Annual Responses:* 1,143,443; *Total Annual Hours:* 190,955. For policy questions regarding this collection contact Alexandra Smilow at 410-786-0790.

Dated: October 17, 2022.

William N. Parham, III,

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

[FR Doc. 2022-23001 Filed 10-21-22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB No. 0970-0345]

Proposed Information Collection Activity; Temporary Assistance for Needy Families (TANF) Financial Report, ACF-196T

AGENCY: Office of Family Assistance, 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) is requesting a 3-year extension of the Temporary Assistance for Needy Families (TANF) Financial Report, Form ACF-196T (Office of Management and Budget (OMB) #0970-0345, expiration April 30, 2023). ACF is proposing minor updates to the form to remove a reporting line-item reference that was associated with an expired program expenditure and minor edits to the instructions and formatting to better the presentation of the document.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act (PRA) of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing infocollection@acf.hhs.gov. Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: Grantees of the TANF program are required by statute to report financial data on a quarterly basis. Form ACF-196T is used by tribal agencies administering the TANF program to report these quarterly expenditure data and to request quarterly grant funds. Failure to collect the data would seriously compromise the Office of Family Assistance and ACF's ability to monitor TANF expenditures and compliance with statutory requirements. These data are also needed to estimate outlays and to prepare reports and budget submissions for Congress.

Respondents: Tribal agencies receiving a direct grant from OFA to administer a TANF program.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
TANF Financial Report, Form ACF-196T	51	4	1.5	306

Estimated Total Annual Burden Hours: 306.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency’s estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Social Security Act, Section 409; 45 CFR 286,245–286.285.

Mary B. Jones,
ACF/OPRE Certifying Officer.

[FR Doc. 2022-23013 Filed 10-21-22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-5553]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Annual Summary Reporting Requirements Under the Right to Try Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget

(OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by November 23, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910-0893. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Annual Summary Reporting Requirements Under the Right to Try Act

OMB Control Number 0910-0893

This information collection helps to implement provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act), added by the Right to Try Act, which requires sponsors and manufacturers who provide an “eligible investigational drug” under the Right to Try Act to submit to FDA an annual summary of such use. Regulations under § 300.200 (21 CFR 300.200) will require that sponsors and manufacturers submit to FDA an annual summary no later than March 31 of each year, including

data for the preceding calendar year, that includes the following data elements:

- The name of the eligible investigational drug and applicable investigational new drug application number.
- The number of doses supplied to the eligible patient.
- The number of eligible patients treated.
- The use for which the eligible investigational drug was made available to the eligible patient.
- Any known serious adverse events and outcomes that the eligible patient treated with an eligible investigational drug experienced.

Description of Respondents: Respondents to the information collection are sponsors and manufacturers who provide an eligible investigational drug to eligible patients in accordance with the Right to Try Act and will submit to FDA annual summaries.

In the **Federal Register** of September 14, 2022 (87 FR 56269), we published a final rule (RIN 0910-AI36), including an analysis of the information collection, and discussed the development of an associated form to facilitate submission of the requisite information. Accordingly, we have developed Form FDA 5023 entitled “Right To Try Reporting Requirement: Annual Summary,” which is currently available in the docket for comment purposes only, and we are inviting public comment. As required by the applicable statute, section 561B of the FD&C Act (21 U.S.C. 360bbb-0a), the information is submitted to an FDA-designated point of contact, and in accordance with instructions to be posted at: <https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/right-try>.

We estimate the burden of this collection of information as follows: