

**SUPPLEMENTARY INFORMATION:**

*Description:* The Children’s Justice Act (CJA) Program Instruction, prepared in response to the enactment of the CJA, Title I of Public Law 111–320, Child Abuse Prevention and Treatment Act Reauthorization of 2010, provides direction to the states and territories to accomplish the purposes of assisting states in developing, establishing and operating programs designed to improve: (1) the assessment and investigation of suspected child abuse and neglect cases, including cases of suspected child sexual abuse and exploitation, in a manner that limits additional trauma to the child and the child’s family; (2) the assessment and investigation of cases of suspected child abuse-related fatalities and suspected child neglect-related fatalities; (3) the

investigation and prosecution of cases of child abuse and neglect, including child sexual abuse and exploitation; and (4) the assessment and investigation of cases involving children with disabilities or serious health-related problems who are suspected victims of child abuse or neglect. This Program Instruction contains information collection requirements that are found in Public Law 111–320 at sections 107(b) and 107(d), and pursuant to receiving a grant award. The information being collected is required by statute to be submitted pursuant to receiving a grant award. The information submitted will be used by the agency to ensure compliance with the statute; to monitor, evaluate and measure grantee achievements in addressing the investigation and

prosecution of child abuse and neglect; and to report to Congress.

*Respondents:* State Governments.

**Annual Burden Estimates**

The length of the CJA Program Instruction has been reduced by about 67 percent from 17 pages to 5.5 pages. Edits have been made to remove unnecessary information, remove requests for information not required by statute, clarify requirements, reduce duplicative information and requests for information, and simplify language. As a result of the reduction in the length of time needed to both read and respond to the Program Instruction, the estimated response burden has been lowered by 33 percent from 60 hours to 40 hours per response.

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
Annual Report and Application .....	52	1	40	2,080

*Authority:* 42 U.S.C. 5106c section 107 (b)4; and 42 U.S.C. 5106 section 107 (B)5.

**Mary C. Jones,**

*ACF/OPRE Certifying Officer.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

[Office of Management and Budget #: 0970–0589]

**Submission for Office of Management and Budget Review; Low Income Home Energy Assistance Program (LIHEAP) Quarterly Reports**

**AGENCY:** The Office of Community Services, 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 form Low Income Home Energy Assistance Program (LIHEAP) Quarterly Reports (Office of Management and Budget (OMB) #: 0970–0589, expiration October 31, 2025). Changes are proposed, which would reduce redundancy and administrative burden for respondents.

**DATES:** *Comments due April 3, 2026.*

**ADDRESSES:** The public may view and comment on this information collection request at: [https://www.reginfo.gov/public/do/PRAViewICR?ref\\_nbr=202602-0970-013](https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202602-0970-013). You can also obtain copies of the proposed collection of information by emailing [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). Identify all emailed requests by the title of the information collection.

**SUPPLEMENTARY INFORMATION:**

*Description:* The LIHEAP Quarterly Report assists the Office of Community Services in receiving data and information about LIHEAP during the federal fiscal year (FFY). This almost real time data ensures ACF can continue to:

- (1) Track key information, such as the number of households served, in “real time” versus in the new fiscal year.
- (2) Effectively address challenges in a timely manner, including supporting emerging training and technical assistance needs, addressing challenges with obligating funds, and addressing outreach and intake issues, such as reaching newly eligible households.
- (3) Ensure accountability and transparency by using the information to regularly update public dashboards and keep key decision makers informed of grantee progress.

All grant recipients, including states, tribes, and territories, will submit brief quarterly reports with critical information on the status of LIHEAP.

The Quarterly Report forms will include questions on:

- Total households assisted;
- Performance management including the number of occurrences in which LIHEAP funding prevented the loss of or restored home energy services; and
- The estimated percentage of LIHEAP funds that have been obligated by funding component.

Grant recipients will also have an opportunity to highlight additional training/technical assistance needs/suggestions, which the Office of Community Services uses to inform support such as training and resources.

ACF also proposes several small changes to the LIHEAP Quarterly Report beginning with the Quarter 4 report due October 31, 2025, and beyond. Those changes only affect Section III of the Quarter 3 (due July 31st, and beyond) and Quarter 4 reports (due October 31st, and beyond). The changes to section III involve inclusion of the primary data elements from the separate LIHEAP Carryover and Reallotment Report (OMB #: 0970–0106), which ACF wishes to discontinue use of in favor of only obtaining such data through the LIHEAP Quarterly Report. Section III would more clearly distinguish “carryover” fund estimated (Quarter 3) and final amounts (Quarter 4) from “reallotment” fund estimated and final amounts. The Quarter 3 and 4 section III also includes a “remarks” field for grant recipients to complete only if they are indicating a request to carryover funds to obligate in

the next FFY. The federal LIHEAP statute requires all grant recipients requesting carryover to explain why they wish to carryover and how they intend to use such carryover funds in the next year (42 U.S.C. 8626(b)(2)(A)).

*Respondents:* States and tribes  
**Annual Burden Estimates**  
 The estimated time per response for this report was increased from 12 to 16 hours to account for the proposed

changes. These changes are expected to reduce effort overall, however, by eliminating the Carryover and Reallotment Report, as discussed above.

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
LIHEAP Quarterly Report .....	185	4	16	11,840

*Authority:* (42 U.S.C. 8626 and 8629) and Federal regulations (45 CFR 96.92)

**Mary C. Jones,**  
*ACF/OPRE Certifying Officer.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**  
**[Docket No. FDA-2024-D-2754]**

**M14 General Principles on Planning, Designing, Analyzing, and Reporting of Non-Interventional Studies That Utilize Real-World Data for Safety Assessment of Medicines; International Council for Harmonisation; Guidance for Industry; Availability**

**AGENCY:** Food and Drug Administration, HHS.  
**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled “General Principles on Planning, Designing, Analyzing, and Reporting of Non-interventional Studies That Utilize Real-World Data for Safety Assessment of Medicines.” The guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The guidance outlines general principles on planning, designing, analyzing, and reporting non-interventional studies that utilize real-world data for safety assessment of medicines (*i.e.*, drugs, vaccines, and other biological products). The recommendations in this guidance, while focused on safety, are applicable to non-interventional studies assessing effectiveness and are aligned and complementary with the FDA’s other guidances on the generation real world evidence. The guidance includes recommendations and high-level best practices for the conduct of these

studies, including articulating the research question, selecting appropriate data sources, defining key variables, addressing potential biases and confounding, conducting analyses, reporting, and submission. The guidance is intended to streamline the development and regulatory assessment of postmarketing non-interventional safety studies that include real-world data. The guidance replaces the draft guidance “M14 General Principles on Plan, Design, and Analysis of Pharmacoepidemiological Studies that Utilize Real-World Data for Safety Assessment of Medicines” issued in July 2024. FDA is also announcing the withdrawal of the guidance entitled “Best Practices for Conducting and Reporting Pharmacoepidemiologic Safety Studies Using Electronic Healthcare Data Sets,” published May 2013.

**DATES:** The announcement of the guidance is published in the **Federal Register** on March 4, 2026.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances at any time 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-2024-D-2754 for “M14 General Principles on Plan, Design and Analysis of Non-interventional Studies That Utilize Real-World Data for Safety Assessment of Medicines.” Received comments 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 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

• *Confidential Submissions—*To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on