

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Average burden per response (in hours)	Total/annual burden (in hours)
1. Provider telephone script and recruitment information collection	204	1	0.33	67
2. Provider telephone script and recruitment information collection including observations	150	1	.42	63
3. HBCC-NSAC Toolkit provider questionnaire	150	1	.75	113
4. Family survey	166	1	0.25	42

Estimated Total Annual Burden Hours: 285.

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: 42 U.S.C. 9858.

Mary B. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Application Requirements for the Low Income Home Energy Assistance Program (LIHEAP) Model Plan Application (Office of Management and Budget #0970-0075)

AGENCY: Office of Community Services, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Office of Community Services (OCS), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is requesting to extend the currently approved Low Income Home Energy Assistance Program

(LIHEAP) Model Plan Application (OMB #0970-0075, expiration 12/31/2023) through August 31, 2024, and then making significant revisions to the FY 2025 application to be effective September 1, 2024. This notice outlines the proposed revisions for FY 2025.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: Copies of the proposed collection of information can be obtained and comments may be forwarded by emailing infocollection@acf.hhs.gov. Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: States, including the District of Columbia, tribes, tribal organizations, and U.S. territories applying for LIHEAP block grant funds must, prior to receiving federal funds, submit an annual application (Model Plan) that meets the LIHEAP statutory and regulatory requirements. In addition to the Model Plan, grant recipients are also required to complete the Mandatory Grant Application, SF-424—Mandatory, which is included as the first section of the Model Plan.

The LIHEAP Model Plan is an electronic form and is submitted to ACF/OCS through the On-Line Data Collection (OLDC) system within GrantSolutions, which is currently being used by all LIHEAP grant recipients to submit other required LIHEAP reporting forms. To reduce the reporting burden, all data entries from each grant recipient's prior year's submission of the Model Plan in OLDC are saved and re-populated into the form for the following fiscal year's application.

OCS is requesting the current LIHEAP Model Plan form to be extended through August 31, 2024. The currently approved form and justification package can be reviewed here: [https://](https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202009-0970-011)

www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202009-0970-011.

OCS proposes the following changes to the LIHEAP Model Plan form beginning with FY 2025 reporting effective September 1, 2024:

SF-424 Model Plan

- *4a:* Change from “Federal Entity Identifier” to “Unique Entity Identifier (UEI).”
- *7b and c:* Remove UEI is requested in 4a.
- *7f:* Add after current language “(This person will be listed on Notice of Funding Awards and on the U.S. Department of Health and Human Services’ LIHEAP contact list web page)”
 - Remove Prefix, Suffix, Middle Name and Organizational Affiliation.
- *8a:* Remove the “a” after 8 “Type of Applicant”
- *Add:* 8a Is the applicant a Tribal Consortium?
 - *Add:* 8b If yes, please attach at least one the following documentation:
 - (1) Current State-Tribe Agreement between their state and the Consortium, signed by the State Chief Executive Officer (such as a Governor or the delegate) and the Consortium President;
 - (2) Consortium letter listing the Tribes and signed by the elected Tribal Chief or President of each Tribe in the Consortium and signed by the Consortium President;
 - (3) A current resolution letter from each tribe in the Consortium, signed by the elected Tribal Chief or President of that Tribe. Each resolution letter needs to state that the Consortium has the Tribes’ permission to apply for, and administer, LIHEAP on their behalf; needs to designate a time period for the permission or until rescinded or revoked.
- *8b:* Remove, not utilized.
- *9:* Remove “Name of Federal Agency”—not used.
- *13:* Change to “CONGRESSIONAL DISTRICTS OF APPLICANT”
 - Eliminate 13a and b.—Already answered in #7; and Eliminate “Attach

an additional list of Program/Project Congressional Districts, if needed.”

- 15 a and b: Remove.
- 17: At the end of the question, change “explanation” to “If Yes, explain.”

Section 1—Program Components

Introduction: Remove reference to grant recipient filing abbreviated plan. LIHEAP does not use abbreviated plans any longer.

- 1.1 *Crisis assistance:* Create one question for “Summer crisis assistance,” one question for “Winter crisis assistance,” and one for “Year-round assistance.” We are receiving increase data request to understand the type of crisis programs provided.

- 1.2:
 - Add a data entry column and provide the breakdown of funding from the previous year’s plan. This information is useful for the data dashboard.

- Add language for “Tribal grant recipients: direct-grant tribes, tribal organizations, or territories with allotments of \$20,000 or less may use for planning and administration up to 20% of the funds payable. Grant recipients that are direct-grant tribes, tribal organizations, or territories with allotments over \$20,000 may use for planning and administration purposes up to 20% of the first \$20,000 (or \$4,000) plus 10% of the funds payable that exceeds \$20,000. Any administrative costs in excess of these limits must be paid from non-Federal sources.”

- Change “Crisis Assistance” to “Summer crisis assistance,” one question for “Winter crisis assistance,” and one for “Year-round assistance.”

- 1.4:
 - Remove Other and entire column. All allowable options are listed, other is not applicable.

- Insert “at least” before the word “one” in two places in this question. The edited question would be “Do you consider households categorically eligible if at least one household member receives at least one of the following categories of benefits in the left column below?”

- 1.4a—Add a text box “Provide your definition of categorical eligibility. Please explain how households are categorically eligible (*i.e.*, do all household members need to receive the benefits or just one member, is there a data exchange in place?) and how categorical eligibility streamlines the LIHEAP application process.” This will ensure grant recipients understand categorical eligibility and answer the question appropriately.

- If 1.4 is answered no, do not allow the table to be completed. Caused data inconsistencies in the data dashboard and requires manual review.

- 1.7:
 - Hyperlink the word “nominal” to a description of the word: Nominal benefits are LIHEAP payments over \$20 made to SNAP households with an energy burden that allow the household to claim the SNAP “heating/cooling standard utility allowance” (SUA).
- 1.8—Add “Other—Describe.” Grant recipients indicated there are exceptions and this box will allow those exceptions to be described and understood more clearly.

- 1.9—Remove SNAP and WIC as they cannot be counted as income.

- Add: 1.10 Do you have an online application process (Yes/No)?

- Add: 1.10a If yes, describe the type of online application (Select all boxes that apply).

- A PDF version of the application is available online and can be downloaded, filled out, and mailed in for processing.

- A state-wide online application that allows a customer to complete data entry and submit an application electronically for processing.

- One or more locally available online applications that allows a customer to complete data entry and submit an application electronically for processing.

- Online application that is also mobile friendly.

- Other, please describe.

- If any of the above boxes are checked, please include a link here:

- Add: 1.10b Can all program components be applied for online (Yes/No)? If no, explain which components can and cannot be applied for online.

- 1.11 Do you have a process for conducting and completing applications by phone (Yes/No)?

- 1.12 Do you or any of your subrecipients require in-person appointments in order to apply (Yes/No)? If yes, please provide more information.

- 1.13 How can applicants submit documentation for verification? Select all that apply (in-person, mail, email, portal application, other-describe).

Section 2—Heating Assistance

- 2.2—Correct the spelling of “assistance”

- 2.3—Change “Elderly” to “Older Adults” (60 years or older)

- 2.3—Change “Disabled” to “Individuals with a disability”

- 2.4—Add space between “to” and “vulnerable”

- 2.6—Add the following sentence: “Please note: the maximum and

minimum benefits must be shown in the payment matrix.”

Section 3—Cooling Assistance

- 3.3—Change “Elderly” to “Older Adults”

- 3.3—Change “Disabled” to “Individuals with a disability”

- 3.4—Add space between “to” and “vulnerable”

- 3.6—Add the following sentence: “Please note: the maximum and minimum benefits must be shown in the payment matrix.”

Section 4—Crisis Assistance

- 4.2—Add to narrative, “If you administer multiple crisis assistance programs (winter, summer, and/or year-round), include all program definitions.”

- 4.6–4.7 and 4.10–4.13—Modify so that it is no longer “yes or no” but mirrors question 4.15 so they can select which program the response is applicable. If the component is not selected under 1.2, the boxes will be grayed out so they cannot select that option. Modify the instructions for the section to be “Check appropriate boxes below to indicate type(s) of assistance provided”

- 4.6—Remove all CAPS from Crisis Assistance

- 4.7—Change “Elderly” to “Older Adults”

- 4.7—Change “Disabled” to “Individuals with a disability”

- 4.8—Modify “Fast Track” to “Benefit Fast Track, no separate amount of crisis funds is issued. Rather benefits are issued to crisis customers within crisis response time frames”

- 4.9—Add a box next to the question, “Amount to resolve crisis, up to a maximum amount”

- 4.11—Change “Physically Disabled” to “Individuals with a disability”

- 4.18—Add question that says, “Do you intend to utilize LIHEAP crisis funds to address disaster related crisis situations? “Yes” or “No” If yes, describe.” Add hover over box that states “OCS’ block grant funding has built in flexibility to support grant recipients in disaster response. Please visit <https://ocs-emergency-assistance-hhs-acf.hub.arcgis.com/> for additional information” (508 compliant hyperlink).

Section 5—Weatherization

- 5.3—Modify to “If yes, name the agency and attach a copy of the Internal Agreement or Contract.”

- 5.8—Change “Elderly” to “Older Adults”

- 5.8—Change “Disabled” to “Individuals with a Disability”

- 5.9—Add a 5.9a replace with current 5.10 “If yes, what is the maximum”
- 5.10—Change to “Do you use an Average Cost per Unit (ACPU).”
 - 5.10a If so, what is the ACPU amount?
- 5.11—This section needs two boxes for roof top solar and community solar projects.

Section 6—Outreach

- 6.1—This section needs to include other outreach including web posting, email, texting, events, and social media.

Section 7—Coordination

- 7.1—This section needs to include data entry field next to the first two boxes.
- Joint application for multiple programs (indicate programs included)
- Intake referrals to/from other programs (indicate programs)

Section 8—Agency Designation

- 8.1—
 - Add “Economic Development Agency”
 - Change “Welfare” to “State Department of Welfare (administers TANF, SNAP, and/or Medicaid)”
 - Eliminate space between “Energy” and “/” and “Environment Agency”
- *New Attachment:* Include current list of subrecipient name, main office address (do not list P.O. Box), phone number, county(s) served, Congressional District, and UEI number. Used for Near hotline and OCS Service Provider Tool and clearinghouse.
- *Add 8.10:* “If an agency is no longer providing LIHEAP, are you aware of prior-year LIHEAP funds being mismanaged or misspent? Yes or No”
 - 8.10a “If yes, please explain.”
 - 8.10b “Were other federal programs impacted such as CSBG, SSBG, Head Start, TANF, and Dept. of Energy Weatherization funding, etc.? Yes or No”
 - 8.10c “If yes, please explain.”
 - Questions added due to previous situations and questions needing a response to these specific items.

Section 9—Energy Suppliers

- Add option at the end of the section to attach a copy of the vendor agreement.

Section 10—Program, Fiscal Monitoring and Audit

- 10.1—Revise the question as, “How do you ensure proper fiscal accounting and tracking of funds?” Add the following instructional sentence: “Be specific about tracking of grant award, tracking of expenditures, tracking

vendor (benefit) refunds, fiscal reporting process, and fiscal software system being used.” Clarification for grant recipients.

- *10.1a—New Question:* “Provide your definitions of the following:
 - Obligation (insert explanation box)
 - Expenditures (insert explanation box)
 - Expenditure timeframe (insert explanation box)
 - Administrative costs (insert explanation box)”
- *10.2a—Add question:* “If yes, describe your auditor selection process.”
- 10.3—Change wording to “Describe any audit findings of the grant recipient (*i.e.*, State/Tribe/Territory) rising to the level of material weakness or reportable condition cited in the single audits, inspector general reviews, or other government agency reviews from the most recently audited fiscal year.”
- 10.5—Change question to “Describe your monitoring process for compliance at each level below.”
 - Change “Grant recipient employees” check box to state:
 - Grant recipients have a policy in place for appropriate separation of duties and internal controls
 - Other, describe
- 10.7—Rewrite the question as “Describe how you select local agencies for monitoring reviews. Attach a risk assessment if subrecipients are utilized.”
- 10.8—Add boxes “Annually,” “Bi-annually,” “Tri-annually,” and “Other.” Please attach a monitoring schedule if one has been developed.
- 10.9 and 10.10—Remove.
- 10.11—Revise the question to, “How many local agencies are currently on corrective action plans?”
- 10.12—Remove.

Section 11—Timely and Meaningful Public Participation

- 11.1—Add explanation that Tribes do not need to hold a public hearing but must ensure participation through other means.
- 11.2—Remove. Removing because question is duplicative of 11.6.
- 11.3—Insert an option to add rows for additional dates and locations that they held public hearings on the proposed use and distribution of their LIHEAP funds.
- 11.6—Revise the question as follows: “What changes did you make to your LIHEAP plan as a result of public participation and solicitation of input?”

Section 12—Fair Hearing

- *12.4—Change question:* “Describe your fair hearing procedures for

households whose applications are denied and/or not acted upon in a timely manner.”

- 12.5—Remove.
- 12.6—Remove.

Section 13—Reduction of Home Energy Needs

- 13.3—Add the following instructional sentence: “Impact can be measured in many different ways by using: logic model, data tracking system, process evaluation, impact evaluation, number of households served vs applied, and performance management, etc.”
- 13.4—Add a space between “of” and “direct”
- 13.5—Remove.

Section 14—Leveraging Incentive Program

- 14.3—Add a space between “of” and “45”

Section 15—Training

- 15.1a–c—Change question to be consistent with each entity type (grant recipient, local agency, vendor)
 - Formal training provided virtually, on-site, and/or formal training conference
- Annually
- Biannually
- As needed
- Other, describe

Section 17—Program Integrity

- 17.1b—Add “Posted in local administering agencies offices.”
- 17.4—Change “aliens” to “qualified non-citizens” in intro text. The second option in the question is phrased as “legal residence” but it needs to be changed to “U.S. Citizen or Qualified Non-Citizen.” The second box option should read “Client’s submission of certain Social Security Administration cards is accepted as proof of U.S. Citizen or Qualified Non-Citizen.”
- 17.4—Rewrite the question as “What are your procedures for ensuring LIHEAP recipients are U.S. citizens or qualified non-citizens who are eligible to receive LIHEAP benefits?”
- 17.6—Should also include how electronic files are protected in a secure location.

Section 19—Certification Regarding Drug-Free Workplace Requirements

- 19.1—Place of Performance: Add instructional sentence that this must be physical address. No PO Boxes allowed.

Section 21—New Change Assurances to Section 21

- 21.1—Add the following acknowledgment statement and a check

box: “By checking this box, the prospective primary participant is agreeing to the Assurances set out above.”

Section 22—Attachments

- Add optional attachment section for the following items: Policy Manual;

Subrecipient Contract; Model Plan Participation Notes for Tribes.

Respondents: States, the District of Columbia, U.S. territories, and tribal governments.

Annual Burden Estimates

The estimated time per response for the FY 2025 Model Plan has been increased based on the revisions. The estimated time per response for the FY 2026 Model Plan will reduce back after revisions are in place and respondents can duplicate response in OLDC.

Instrument	Total annual number of respondents	Total annual number of responses per respondent	Average burden hours per response	Annual burden hours for each form
LIHEAP Detailed Model Plan—FY24	210	1	.5	105
LIHEAP Detailed Model Plan—FY25	206	1	1	206
LIHEAP Detailed Model Plan FY26	206	1	.5	103
Estimated Total Burden Hours:				414
Average Annual Burden Hours:				138

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: 42 U.S.C. 8621.

Mary B. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3976]

Support for Clinical Trials Advancing Rare Disease Therapeutics Pilot Program; Program Announcement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA or Agency) Center for Biologics Evaluation and Research's (CBER) Office of Therapeutic Products (OTP) and Center for Drug Evaluation and Research's (CDER) Office of New Drugs are announcing the opportunity for a limited number of

development programs to participate in the Support for clinical Trials Advancing Rare disease Therapeutics (START) Pilot Program, with the goal of further accelerating the pace of development of certain CBER- and CDER-regulated products (novel drug and biological products) that are intended to treat a rare disease. Because each Center has identified specific needs concerning regulated products for rare diseases, the eligibility criteria for the pilot differ between CBER and CDER. This pilot would augment the currently available formal meetings between FDA and sponsors by addressing issues related to the development of individual products through more rapid, ad-hoc communication mechanisms. Sponsors, if selected for the pilot, would receive more frequent advice related to such specific issues through additional interactions to facilitate novel drug and biological product program development and generate high quality and reliable data intended to support a Biologics License Application (BLA) or New Drug Application (NDA). This notice outlines the eligibility criteria, what to submit in a request to participate in the pilot, selection criteria, process, and FDA-Sponsor interactions expected to occur for programs participating in the pilot. **DATES:** From January 2, 2024, to March 1, 2024, FDA will accept requests to participate in the START Pilot Program and select no more than three participants from each Center (CBER and CDER). See the “Participation” section for eligibility criteria, instructions on how to submit a request to participate, and information regarding the selection process.

FOR FURTHER INFORMATION CONTACT:

Andrew Harvan, Center for Biologics Evaluation and Research, Food and

Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7268, Silver Spring, MD 20993–0002, 240–402–7911; or Quyen Tran, Center for Drugs Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6301, Silver Spring, MD 20993–0002, 301–796–2771.

For general questions about the START Pilot Program for CBER: Industry.biologics@fda.hhs.gov. *For general questions about the START Pilot Program for CDER:* CDER.STARTProgram@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The purpose of the START Pilot Program is to further accelerate the pace of development of novel drug and biological products that are intended to address an unmet medical need as a treatment for a rare disease. The pilot is designed to be milestone-driven (*i.e.*, to facilitate the progression of a development program to pivotal clinical study stage or the pre-BLA or pre-NDA meeting stage) where product development programs selected would benefit from enhanced communications with FDA. Participation in the pilot will be considered concluded when the development program has reached a significant regulatory milestone such as initiation of the pivotal clinical study stage or the pre-BLA or pre-NDA meeting stage as agreed upon with the sponsor. Pilot participants will be selected based on demonstrated development program readiness. The START Pilot Program is intended to provide a mechanism for addressing clinical development issues that otherwise would delay or prevent a promising novel drug or biological product from progressing to the pivotal