

and Affordable Care Act, Public Law 111–148, enacted on March 23, 2010, and the Health Care and Education Reconciliation Act, Public Law 111–152, enacted on March 30, 2010 collectively, “Affordable Care Act”, expanded access to health insurance for individuals and employees of small businesses through the establishment of new Affordable Insurance Exchanges (Exchanges), including the Small Business Health Options Program (SHOP). Beginning January 1, 2014, the Exchanges became operational. The Exchanges enhance competition in the health insurance market, expand access to affordable health insurance for millions of Americans, and provide consumers with a place to easily compare and shop for health insurance coverage.

States can choose to establish and operate a State-based Exchange (SBE) or a State-based Exchange on the Federal Platform (SBE–FP). States electing to operate as an SBE–FP rely on the Federal Healthcare.gov platform to carry out eligibility and enrollment functions. For states that do not elect to operate either an SBE or SBE–FP, the Secretary of the U.S. Department of Health and Human Services (HHS) will establish and operate a Federally-facilitated Exchange (FFE) in those states. *Form Number:* CMS–10371 (OMB control number: 0938–1119; *Frequency:* Occasionally; *Affected Public:* State, Local or Tribal Government; *Number of Respondents:* 23; *Total Annual Responses:* 343; *Total Annual Hours:* 7,317. (For policy questions regarding this collection contact Tiffany Y. Animashaun at Tiffany.Animashaun@cms.hhs.gov).

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Low Income Home Energy Assistance Program (LIHEAP) Performance Data Form (Office of Management and Budget #0970–0449)

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 Administration for Children and Families (ACF) Office of Community Services (OCS) within the U.S. Department of Health and Human Services (HHS) is requesting an extension without change to the current version of the Low Income Home Energy Assistance Program (LIHEAP) Performance Measures (Office of Management and Budget (OMB) #0970–0449) for use through June 30, 2025, and for approval of a revised version to use beginning July 1, 2025.

DATES: *Comments due* January 31, 2025. In compliance with the requirements of the Paperwork Reduction Act 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: OCS administers LIHEAP at the Federal level. The *LIHEAP Performance Data Form* (LPDF) is an annual report in response to section 2610(b) of the Low-Income Home Energy Assistance Act of 1981 (42 U.S.C. 8629(b)(2))(LIHEAP statute), which requires the Secretary of HHS to submit, no later than June 30 of each Federal fiscal year, a report to Congress on LIHEAP for the prior Federal fiscal year. The completeness, accuracy, consistency, and timeliness of responses to data collections are needed for HHS to do the following:

- Provide reliable and complete fiscal and household data to Congress in the Department’s *LIHEAP Report to Congress* for the Federal fiscal year; and
- Respond to questions from the Congress, Department, OMB, White House, and other interested parties in a timely manner; and
- Report LIHEAP performance results as part of the Administration’s annual Congressional Justification.

In response to the 2010 Government Accountability Office (GAO) report, *Low Income Home Energy Assistance Program—Greater Fraud Prevention Controls are Needed* (GAO–10–621), and in consideration of the recommendations issued by the LIHEAP Performance Measures Implementation Work Group, OCS required the collection and reporting of these performance measures by State LIHEAP grant recipients, including the District of Columbia. The original LPDF was approved by OMB in November 2014

and has been in use since. The LPDF provides for the collection of data on State grant recipients’ sources and uses of LIHEAP funds, including average benefit amounts, as well as data for the following performance measures:

1. The benefit targeting index for high burden households receiving LIHEAP fuel assistance;
2. The burden reduction targeting index for high burden households receiving LIHEAP fuel assistance;
3. The number of households where LIHEAP prevented a potential home energy crisis; and
4. The number of households where LIHEAP benefits restored home energy.

All State LIHEAP grant recipients, including the District of Columbia, are required to complete the LPDF on an annual basis through ACF’s web-based data collection and reporting system, the Online Data Collection, which is available at the GrantSolutions homepage (<https://home.grantsolutions.gov/home>). The reporting requirements will be described through the LIHEAP Forms and Funding Applications page (<https://www.acf.hhs.gov/ocs/form/liheap-forms-and-funding-applications>) of ACF’s website.

This request will (1) continue approval to collect information using the currently approved version of the LPDF through June 30, 2025; and (2) incorporate changes to the LPDF designed to collect performance data on the impacts of supplemental Federal LIHEAP funds and to improve form fields and language. The changes proposed would go into effect in July 2025 and consist of (1) changing the name of Module 1 of the form from “Grantee Survey” to “Grant Recipient Survey”; (2) adding an item for reporting carryover of Residential Energy Assistance Challenge (REACH) funds to the following FY; (3) adding an item for reporting non-administrative information technology enhancements; (4) removing maximum income cutoffs from funding uses; (5) replacement of sources and uses of Coronavirus Aid, Relief, and Economic Security Act (CARES Act) funds and American Rescue Plan Act of 2021 (ARPA) funds with the Infrastructure Investment and Jobs Act (IIJA) funds; and (6) minor wording and structural changes.

Module 1 Grant Recipient Survey

Module 1 of the LPDF will continue to require the following data from each State for the Federal fiscal year:

- Grant recipient information.
- Sources and uses of LIHEAP funds, by funding type.

- Average LIHEAP household benefits, by funding type.

Modules 2, 2A, and 2B Required LIHEAP Performance Measures

Modules 2, 2A, and 2B of the LPDF will continue to require the following data from each State for the Federal fiscal year:

- Grant recipient information;
- Energy burden targeting;
- Restoration of home energy service; and
- Prevention of loss of home energy.

Modules 2, 2A, and 2B require reporting on households that received benefits from, respectively, non-

supplemental funds, CARES Act funds, and ARPA funds.

Module 3 LIHEAP Performance Measures (Optional Reporting)

Module 3 of the LIHEAP LPDF will continue to voluntarily collect the following additional information from each interested grant recipient for the Federal fiscal year:

- Average annual energy usage;
- Unduplicated number of households using supplemental heating fuel and air conditioning;
- Unduplicated number of households that had restoration of home energy service, and

- Unduplicated number of households that had prevention of loss of home energy.

LIHEAP grant recipients will be able to compare their own results to the results for other States, as well as to regional and national results, through the Data Warehouse of the LIHEAP Performance Management website as they manage their programs.

Respondents

State governments, including the District of Columbia; the largest five electricity and natural gas vendors by State; the largest ten fuel oil and propane vendors by State; and State sub-grant recipients.

ANNUAL BURDEN ESTIMATES

LIHEAP performance data form	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
State Grant Recipients—Module I	51	1	30	1,530
State Grant Recipients—Modules II and III	51	1	158.6	8,088.6
Sub-Grant Recipients (in States with sub-grant recipient managed systems)—Modules II and III	100	1	6.3	630
Energy Vendors (largest 5 electric, 5 natural gas, 10 fuel oil, and 10 propane vendors per State-average)—Modules II and III	1,530	1	8.5	13,005

Estimated Total Annual Burden Hours: 23,253.6.

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. 8629(b); 42 U.S.C. 8624(b); 42 U.S.C. 8623(c).

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–N–1636]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product; KEBILIDI (eladocagene exuparvovec-tneq)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that KEBILIDI (eladocagene exuparvovec-tneq), approved on November 13, 2024, manufactured by PTC Therapeutics Inc., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Myrna Hanna, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New

Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined that KEBILIDI (eladocagene exuparvovec-tneq), manufactured by PTC Therapeutics Inc., meets the criteria for a priority review voucher. KEBILIDI (eladocagene exuparvovec-tneq) is indicated for treatment of adult and pediatric patients with aromatic L-amino acid decarboxylase deficiency.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to <https://www.fda.gov/industry/developing-products-rare-diseases-conditions/rare-pediatric-disease-rpd-designation-and-voucher-programs>. For further information about KEBILIDI (eladocagene exuparvovec-tneq), go to the Center for Biologics Evaluation and Research’s Approved Cellular and Gene Therapy Products website at <https://www.fda.gov/vaccines-blood-biologics/>