DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA Number: 93.568]

Proposed Reallotment of Fiscal Year 2023 Funds for the Low Income Home Energy Assistance Program

AGENCY: Office of Community Services (OCS), Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

ACTION: Notice for public comment.

SUMMARY: The ACF, OCS, Division of Energy Assistance announces a preliminary determination that funds from the federal fiscal year 2023 (FY23) Low Income Home Energy Assistance Program (LIHEAP) are available for reallotment to states, territories, tribes, and tribal organizations that received FY24 direct LIHEAP awards. The purpose of this award is to redistribute FY23 annual LIHEAP funds that recipients were unable to obligate or carry over to FY24. No sub-recipients of these recipients or other entities may apply for these funds.

DATES: *Comments are due by:* October 21, 2024.

ADDRESSES: Comments may be submitted to: Peter Edelman, Program Analyst, Office of Community Services, Administration for Children and Families, 330 C Street SW, 5th Floor; Mail Room 5425; Washington, DC 20201 or via email: *peter.edelman@acf.hhs.gov.* Comments may also be faxed to 202–401–5661.

FOR FURTHER INFORMATION CONTACT: Akm Rahman, Program Operations Branch Chief, Division of Energy Assistance, Office of Community Services, 330 C Street SW, 5th Floor; Mail Room 5425; Washington, DC 20201. Telephone: 202–401–5306; email: *Akm.Rahman@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION: After receiving Federal Financial Reports (FFRs), Carryover and Reallotment Reports (CRRs), and fourth-quarter Quarterly Reports (QRs) from FY23 LIHEAP recipients, ACF has determined that $18,363,980 in FY23 LIHEAP funds may be available for reallotment for FY24. This determination was based on the reports of 75 recipients and the total obligations of 4 recipients. LIHEAP recipients submitted the FY23 CRRs to OCS, as required by regulations applicable to LIHEAP at 45 CFR 96.81(b).

The LIHEAP statute allows recipients who have funds unobligated at the end of the FY for which they are awarded to request that they be allowed to carry over up to 10 percent of their full-year allotments to the next FY (42 U.S.C. 8626(b)(2)). Funds in excess of this amount must be returned to the U.S. Department of Health and Human Services and are subject to reallotment under 42 U.S.C. 8626(b)(1).

In accordance with 42 U.S.C. 8626(b)(3), ACF notified each of the 79 recipients that reported or, in the absence of reporting, had potentially $18,363,980 of unobligated funds above their carryover caps. In these notices, ACF told each recipient about the amount that, according to the recipients' reports, it needed to return for de-obligation and redistribution to FY24 recipients as part of the reallotment. It also gave each recipient 30 calendar days to provide comments directly to ACF.

All LIHEAP recipients that receive a portion of these funds will be notified of the final reallotment amount redistributed to them for FY24. This decision will also be published in the **Federal Register** and in a Dear Colleague Letter that is posted to ACF's website under LIHEAP Dear Colleague Letters.

The FY23 LIHEAP funds that ACF preliminarily expects to become available for reallotment determination come from the following recipients in the following amounts:

Name of recipient that has funds to be returned for reallotment	Preliminary amount available for reallotment [1]
Alaska	$4,917,545
Idaho	4,896,940
Michigan	55,139
Commonwealth of the Northern Mariana Islands	47,429
Absentee Shawnee Tribe of Indians of Oklahoma	14,595
Alabama-Quassarte Tribal Town	18,204
Aniak Traditional Council	49,847
Berry Creek Rancheria	11,727
Big Valley Band of Pomo Indians	3,150
Bishop Paiute Tribe	17,447
Blackfeet Tribe	66,242
Catawba Indian Nation	14,656
Cheyenne and Arapaho Tribes	7,692
Choctaw Nation of Oklahoma	80,195
Chuathbaluk Traditional Council	34,383
Cocopah Indian Tribe	20,605
Coeur d'Alene Tribe	18,278
Comanche Nation	4,726
Confederated Salish and Kootenai Tribes	360,718
Confederated Tribes of Siletz Indians of Oregon	42,360
Confederated Tribes of the Grand Ronde Community of Oregon	15,524
Cow Creek Band of Umpqua Tribe of Indians	511
Dena'Nena'Henash—Tanana Chiefs Conference	26,018
Eastern Shoshone Tribe	135,825
Fort Peck Assiniboine and Sioux Tribes	584,537
Gila River Indian Community	73,461
Hoh Tribe	2,212
Hoopa Valley Tribe	12,878
Hopland Band of Pomo Indians	2,852
Houlton Band of Maliseet Indians	201,488
Indian Township Tribal Government	528,130

Name of recipient that has funds to be returned for reallotment	Preliminary amount available for reallotment [1]
Inter-Tribal Council of MI, Inc	129,655
Jicarilla Apache Nation	42,275
Karuk Tribe	1,746
Kaw Nation	5,017
Kiowa Tribe of Oklahoma	89,127
Little River Band of Ottawa Indians	10,074
Lower Elwha Klallam Tribe	7,986
Lummi Nation	19,363
Makah Tribe	25,257
Mashpee Wampanoag Tribe	171,286
Mi'kmaq Nation	44,858
Mississippi Band of Choctaw Indians	8,426
Modoc Nation	1,426
Muckleshoot Indian Tribe	1,110
Navajo Nation	800,838
Nooksack Indian Tribe	36,196
Northern Arapaho Tribe	19,950
Northern California Indian Development Council, Inc	846
Northern Cheyenne Tribe	25,583
Oglala Sioux Tribe	28,490
Orutsararmiut Native Council	276,283
Otoe-Missouria Tribe of Indians	6,087
Paiute Indian Tribe of Utah	140,249
Pawnee Nation of Oklahoma	6,740
Pleasant Point Tribal Government	50,685
Poarch Band of Creek Indians	146,887
Pueblo of Jemez	12,562
Pueblo of Zuni	28,337
Quapaw Nation	22,161
Quileute Tribe	69,502
Quinault Indian Nation	17,503
Riverside-San Bernardino County Indian Health, Inc	6,645
Sac and Fox Nation of Oklahoma	6,573
Samish Indian Nation	14,590
San Carlos Apache Tribe	8,904
Sault Ste. Marie Tribe of Chippewa Indians	1,064
Sitka Tribe of Alaska	53,222
Spirit Lake Nation	101,127
Spokane Tribe of Indians	23,773
Standing Rock Sioux Tribe	2,896,833
Swinomish Indian Tribal Community	39,631
The Delaware Tribe of Indians	4,501
The Klamath Tribes	162,427
Tonkawa Tribe of Oklahoma	3,374
Turtle Mountain Band of Chippewa Indians	69,032
United Cherokee Ani-Yun-Wiya Nation	55,932
Ute Indian Tribe	8,647
Yankton Sioux Tribe	395,886
Total	18,363,980

[1] Preliminary funds for reallotment consist of the funds in excess of LIHEAP's 10 percent carryover cap that (1) 75 recipients indicated on the FFRs or reported on the CRRs or QRs as unobligated; or (2) amounted to 100 percent of regular funds or IIJA funds for the 4 recipients that failed to submit the associated FFRs and their CRRs or QRs.

If funds are reallotted, then they will be allocated in accordance with 42 U.S.C. 8623 and must be treated by LIHEAP recipients that receive them as funds appropriated for FY24. As FY24 funds, they will be subject to all requirements of the LIHEAP statute, including 42 U.S.C. 8626(b)(2), which requires that a recipient obligate at least 90 percent of its total block grant allocation for a fiscal year by the end of the fiscal year for which the funds are appropriated; that is, by September 30, 2024. Furthermore, recipients that receive these funds may use these funds for any purpose authorized under LIHEAP and must add them to their total LIHEAP funds payable for FY24 for purposes of calculating statutory caps on administrative costs, carryover, Assurance 16 activities, and weatherization assistance.

Additionally, all recipients of these funds must (1) ensure that these funds are included in the amounts on Lines 1.1 of their FY24 CRRs; (2) reconcile these funds, to the extent that they received them, on their corresponding FFRs; and (3) record, on their FY24 Household Reports, households that receive benefits at least partly from these funds. State recipients must also ensure that these funds are included in the Grantee Survey sections of their FY24 LIHEAP Performance Data Forms.

Statutory Authority: 42 U.S.C. 8626(b).

Anthony Petruccelli,

Senior Grants Policy Specialist, Office of Grants Policy, Office of Administration.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–4246]

Fee Rate for Using a Priority Review Voucher in Fiscal Year 2025

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the fee rate for using a priority review voucher for fiscal year (FY) 2025. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended, authorizes FDA to determine and collect priority review user fees for certain applications for review of human drug or biological products when those applications use a tropical disease, rare pediatric disease, or material threat medical countermeasure (MCM) priority review voucher. These vouchers are awarded to the sponsors of tropical disease, rare pediatric disease, or material threat MCM product applications, respectively, that meet the requirements of the FD&C Act, upon FDA approval of such applications. The amount of the fee for using a priority review voucher is determined each fiscal year, based on the difference between the average cost incurred by FDA to review a human drug application designated as priority review in the previous fiscal year, and the average cost incurred in the review of an application that is not subject to priority review in the previous fiscal year. This notice establishes the FY 2025 priority review fee rate applicable to submission of eligible applications for review of human drug or biological products using a rare pediatric disease, material threat MCM, or tropical disease priority review voucher and outlines the payment procedures for such fees.

DATES: This rate is effective on October 1, 2024, and will remain in effect through September 30, 2025.

FOR FURTHER INFORMATION CONTACT: Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., 6th Floor, Beltsville, MD 20705–4304, 240–402–4989; or the User Fees Support Staff at *OO-OFBAP-OFM-UFSS-Government@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A. Establishment of the Tropical Disease Priority Review Voucher

Section 1102 of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85) added section 524 to the FD&C Act (21 U.S.C. 360n). In section 524 of the FD&C Act, Congress encouraged development of new human drug and biological products for prevention and treatment of tropical diseases by offering additional incentives for obtaining FDA approval of such products. Under section 524 of the FD&C Act, the sponsor of an eligible human drug application for a tropical disease (as defined in section 524(a)(3) of the FD&C Act) shall receive a priority review voucher upon approval of the tropical disease product application (as defined in section 524(a)(4) of the FD&C Act).

B. Establishment of the Rare Pediatric Disease Priority Review Voucher

Section 908 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) added section 529 of the FD&C Act (21 U.S.C. 360ff). In section 529 of the FD&C Act, Congress encouraged development of new human drugs and biological products for prevention and treatment of certain rare pediatric diseases by offering additional incentives for obtaining FDA approval of such products. Under section 529 of the FD&C Act, the sponsor of an eligible human drug for a rare pediatric disease (as defined in section 529(a)(3)) shall receive a priority review voucher upon approval of the rare pediatric disease product application (as defined in section 529(a)(4) of the FD&C Act).[1]

C. Establishment of the Material Threat MCM Priority Review Voucher

Section 3086 of the 21st Century Cures Act (Pub. L. 114–255) added section 565A to the FD&C Act (21 U.S.C. 360bbb–4a). In section 565A of the FD&C Act, Congress encouraged development of material threat MCMs by offering additional incentives for obtaining FDA approval of such products. Under section 565A of the FD&C Act, the sponsor of an eligible material threat MCM application (as defined in section 565A(a)(4)) shall receive a priority review voucher upon approval of the material threat MCM application.[2]

D. Transferability of the Priority Review Voucher

The recipient of a priority review voucher may either use the voucher for a future human drug application submitted to FDA under section 505(b)(1) of the FD&C Act (21 U.S.C. 355(b)(1)) (or section 351(a)) of the Public Health Service Act (PHS Act) (42 U.S.C. 262(a)), or transfer (including by sale) the voucher to another party. The voucher may be transferred repeatedly until it ultimately is used for a human drug application submitted to FDA under section 505(b)(1) of the FD&C Act or section 351(a) of the PHS Act. As further described below, a priority review is a review conducted with a Prescription Drug User Fee Act (PDUFA) goal date of 6 months after the receipt or filing date, depending on the type of application. Information regarding review goals for FY 2025 is available at: *https://www.fda.gov/media/151712/download.*

The sponsor that uses a priority review voucher is entitled to a priority review of its eligible human drug application, but must pay FDA a priority review user fee in addition to any other fee required by PDUFA. FDA published information on its website about how the priority review voucher program operates.[3] [4] [5]

This notice establishes the FY 2025 priority review fee rate for use of

[1] The FD&C Act includes a sunset of authority to award rare pediatric disease priority review vouchers. Section 529(b)(5) of the FD&C Act provides that after September 30, 2024, FDA may not award any rare pediatric disease priority review vouchers unless a rare pediatric disease product application: (1) is for a drug that, not later than September 30, 2024, is designated under section 529(d) of the Act as a drug for a rare pediatric disease, and (2) is, not later than September 30, 2026, approved under section 505(b)(1) of the FD&C Act or section 351(a) of the PHS Act. This limit of FDA's authority to award rare pediatric disease vouchers does not affect the ability to use rare pediatric disease priority review vouchers issued by FDA.

[2] Although under section 565A(g) of the FD&C Act, material threat MCM priority review vouchers may not be awarded after October 1, 2023, this ''sunset'' of authority to award vouchers does not affect the ability to use material threat MCM priority review vouchers that have already been issued.

[3] Information regarding the tropical disease priority review voucher program is available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/tropical-disease-priority-review-vouchers.*

[4] Information regarding the rare pediatric disease priority review voucher program is available at: *https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm375479.htm.*

[5] Information regarding the material threat MCM priority review voucher program is available at: *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/21st-century-cures-act-mcm-related-cures-provisions.*