

during the scheduled open public hearing session, we may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak no later than 1 week from the speaker registration deadline specified in the **DATES** section of this notice. Your comments must focus on issues specific to the list of topics that we have proposed to the Committee. The list of research topics to be discussed at the meeting will be available on the following website prior to the meeting <http://www.cms.gov/medicare-coverage-database/indexes/medcac-meetings-index.aspx?bc=BAAAAAAAAAAAA&>. We require that you declare at the meeting whether you have any financial involvement with manufacturers (or their competitors) of any items or services being discussed. Speakers presenting at the MEDCAC meeting must include a full disclosure slide as their second slide in their presentation for financial interests (for example, type of financial association—consultant, research support, advisory board, and an indication of level, such as minor association <\$10,000 or major association > \$10,000) as well as intellectual conflicts of interest (for example, involvement in a federal or nonfederal advisory committee that has discussed the issue) that may pertain in any way to the subject of this meeting. If you are representing an organization, we require that you also disclose conflict of interest information for that organization. If you do not have a PowerPoint presentation, you will need to present the full disclosure information requested previously at the beginning of your statement to the Committee.

The Committee will deliberate openly on the topics under consideration. Interested persons may observe the deliberations, but the Committee will not hear further comments during this time except at the request of the chairperson. The Committee will also allow a 15-minute unscheduled open public session for any attendee to address issues specific to the topics under consideration. By the conclusion of the second day, the panel members will vote and the Committee will make its recommendation(s) to CMS.

III. Registration Instructions

CMS' Coverage and Analysis Group is coordinating meeting registration. While there is no registration fee, individuals must register to attend. You may register online at <https://cms.zoomgov.com/webinar/register/WN/CsJL7k7kQcyYOZ20OR6eqw> or by phone by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the deadline listed in the **DATES** section of this notice. Please provide your full name (as it appears on your state-issued driver's license), address, organization, telephone number(s), and email address. You will receive a registration confirmation with instructions for your participation at the virtual public meeting.

IV. Collection of Information

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35).

The Chief Medical Officer and Director of the Center for Clinical Standards and Quality for the Centers for Medicare & Medicaid Services (CMS), Lee A. Fleisher, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: December 1, 2022.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA Number: 93.568]

Reallotment of Fiscal Year 2021 Funds for the Low Income Home Energy Program—Final

AGENCY: Office of Community Services (OCS), Administration for Children and

Families (ACF), Department of Health and Human Services (HHS).

ACTION: Notice of final issuance.

SUMMARY: The ACF, OCS, Division of Energy Assistance (DEA) announces that \$323,063 of funds from the fiscal year (FFY) 2021 Low Income Home Energy Assistance Program (LIHEAP) were reallotted to States, Territories, Tribes, and Tribal Organizations that received FFY 2022 direct LIHEAP grants.

DATES: This notice became effective on September 28, 2022, which is the day on which ACF awarded these reallotments.

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: In accordance with Section 2607(b)(1) of the Low Income Home Energy Assistance Act (the Act), Title XXVI of the Omnibus Budget Reconciliation Act of 1981 (42 U.S.C. 8626(b)(1)), as amended, ACF published a notice in the **Federal Register** on September 30, 2022, 87 FR 59438, announcing the Secretary's preliminary determination that \$711,932 of FFY 2021 funds for LIHEAP may be available for reallotment. No comments were received on this notice, nor did any recipients report additional funds for reallotment. However, after such publication, ACF discovered that one grant recipient could not adequately complete its necessary reporting, another grant recipient reported less unobligated funds in a revision, and three grant recipients had insufficient balances in their accounts in the Payment Management System.

These funds became available from the following grant recipients in the following amounts:

Name of grant recipient that returned funds for reallotment	FY 2021 reallotment amount
Bishop Paiute Tribe	\$17,531
Colorado River Indian Tribes	16,914

Name of grant recipient that returned funds for reallocation	FY 2021 reallocation amount
Cow Creek Band of Umpqua Tribe of Indians	7,302
Hopland Band of Pomo Indians	1,755
Jicarilla Apache Nation	16,873
Kalispel Tribe of Indians	7,921
Makah Tribe	31,196
Muckleshoot Indian Tribe	37,669
Nooksack Indian Tribe	38,535
Paiute Indian Tribe of Utah	61,183
Quileute Tribe	1,673
Round Valley Indian Tribes	558
Sac and Fox Nation of Oklahoma	44,538
Samish Indian Nation	331
Shawnee Tribe	3,600
Spokane Tribe of Indians	19,905
The Delaware Tribe of Indians	15,579
Total	323,063

The list of grant recipients that were awarded these funds was published in a Dear Colleague Letter that is posted to ACF's website at <https://www.acf.hhs.gov/ocs/resource/dear-colleagues>.

Pursuant to the statute cited above, these funds were reallocated on September 28, 2022, to all but three types of FFY 2022 LIHEAP grant recipients by distributing them under the formula that Congress set for FFY 2022 funding. The three types of recipients that did not receive funds were (1) those whose allocations would have been less than \$25; (2) tribes or tribal organizations that agreed with their co-territorial states to receive set amounts for the entire fiscal year; and (3) states or territories that were held to the additional minimum floor required by the FY 2022 appropriations act after including the reallocation amount. No sub-recipients of these recipients or other entities may apply for these funds.

The reallocated funds may be used for any purpose authorized under LIHEAP. Grant recipients must add these funds to their total LIHEAP funds payable for FFY 2022 for purposes of calculating statutory caps on administrative costs, carryover, Assurance 16 activities, and weatherization assistance. Grant recipients must also (1) ensure that these funds are included in the amounts that ACF pre-populated on Line 1.1 of their FFY 2022 Carryover and Reallocation Reports; (2) reconcile these funds, to the extent that they received them, on a separate Federal Financial Form (SF-425); and (3) record, on their FFY 2022 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 FFY 2022 LIHEAP Performance Data Forms.

OCS recommends that, after receiving them, grant recipients obligate these funds before obligating any other federal LIHEAP funds.

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

Karen D. Shields,
Senior Grants Policy Specialist, Office of Grants Policy, Office of Administration.
 [FR Doc. 2022-26447 Filed 12-5-22; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-D-0691]

Pharmacokinetic-Based Criteria for Supporting Alternative Dosing Regimens of Programmed Cell Death Receptor-1 or Programmed Cell Death-Ligand 1 Blocking Antibodies for Treatment of Patients With Cancer; 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 "Pharmacokinetic-Based Criteria for Supporting Alternative Dosing Regimens of Programmed Cell Death Receptor-1 (PD-1) or Programmed Cell Death-Ligand 1 (PD-L1) Blocking Antibodies for Treatment of Patients with Cancer." This guidance provides recommendations for sponsors of investigational new drug applications (INDs) and biologics license

applications (BLAs) on the use of pharmacokinetic (PK)-based criteria to support the approval of alternative dosing regimens for programmed cell death receptor-1 (PD-1) or programmed cell death-ligand 1 (PD-L1) blocking antibodies. This guidance is based on accumulated scientific and regulatory experience for PD-1 and PD-L1 drugs, and as such, does not address development of alternative dosing regimens for other drugs or biologics, changes in route of administration, or novel formulations of previously approved PD-1/PD-L1 products. This guidance finalizes the draft guidance of the same title issued on August 26, 2021.

DATES: The announcement of the guidance is published in the **Federal Register** on December 6, 2022.

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