

**ACTION:** Notice of public comment.

**SUMMARY:** The ACF, OCS, Division of Energy Assistance (DEA) announces a preliminary determination that funds from the federal fiscal year (FFY) 2021 Low Income Home Energy Assistance Program (LIHEAP) are available for reallocation to states, territories, tribes, and tribal organizations that received FFY 2022 direct LIHEAP grants. The purpose of this award is to redistribute FFY 2021 annual LIHEAP funds that grant recipients were unable to obligate or carry over to FFY 2022. No sub-recipients of these grant recipients or other entities may apply for these funds.

**DATES:** Comments are due by: October 31, 2022.

**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](mailto: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](mailto:Akm.Rahman@acf.hhs.gov).

**SUPPLEMENTARY INFORMATION:** After receiving Carryover and Reallocation Reports from FFY 2021 LIHEAP recipients and reconciling the unobligated funds on those reports with the respective Federal Financial Reports, ACF has determined that \$711,932 in FFY 2021 LIHEAP funds were available for reallocation for FFY 2022. This determination is based on the reports of 20 recipients, minor corrections to certain amounts available for carryover, and the amounts of funds that these recipients had in their Payment Management System (PMS) accounts. LIHEAP grant recipients submitted the FFY 2021 Carryover and Reallocation Reports to OCS, as required by regulations applicable to LIHEAP at 45 CFR 96.81(b).

The LIHEAP statute allows grant recipients who have funds unobligated at the end of the federal fiscal year 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 federal fiscal year, (42 U.S.C. 8626(b)(2)). Funds in excess of this amount must be returned to HHS and are subject to reallocation under 42 U.S.C. 8626(b)(1).

FFY 2021 funds appropriated under the American Rescue Plan Act of 2021 (Pub. L. 117-2) were not subject to 42 U.S.C. 8626(b)(2)(B), which caps carryover at 10 percent. Therefore, these funds were not included in the reallocation calculation.

In accordance with 42 U.S.C. 8626(b)(3), ACF notified each of the 20 grant recipients that reported \$711,932 of unobligated funds above their carryover caps. In these notices, ACF told each about the amount it returned for de-obligation and the amount that will be redistributed to FFY 2022 grant recipients as part of the reallocation. It also gave each recipient 30 calendar days to provide comments directly to ACF.

If funds are reallocated, then they will be allocated in accordance with 42 U.S.C. 8623 and must be treated by LIHEAP grant recipients that receive them as an amount appropriated for FFY 2022. As FFY 2022 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, 2022.

All LIHEAP grant recipients that receive a portion of these funds will be notified of the final reallocation amount redistributed to them for obligation in FFY 2022. This decision will also be published in the **Federal Register** and in a Dear Colleague Letter that is posted to ACF's website at <https://www.acf.hhs.gov/ocs/resource/dear-colleagues>.

The FFY 2021 LIHEAP funds that ACF preliminarily expects to become available for reallocation determination come from the following grant recipients in the following amounts:

Name of grant recipient that reported funds to be returned for reallocation	Amount available for reallocation
Bishop Paiute Tribe .....	\$17,531
Colorado River Indian Tribes .....	16,914
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
Little River Band of Ottawa Indians	106,187
Makah Tribe .....	36,164
Muckleshoot Indian Tribe .....	37,669
Nooksack Indian Tribe .....	38,535
Oglala Sioux Tribe .....	268,413
Paiute Indian Tribe of Utah .....	61,183
Pit River Tribe .....	9,255
Quileute Tribe .....	1,673
Round Valley Indian Tribes .....	558
Sac and Fox Nation of Oklahoma ...	44,538
Samish Indian Nation .....	331

Name of grant recipient that reported funds to be returned for reallocation	Amount available for reallocation
Shawnee Tribe .....	3,600
Spokane Tribe of Indians .....	19,951
The Delaware Tribe of Indians .....	15,579
<b>Total .....</b>	<b>711,932</b>

If funds are reallocated, then grant recipients may use them for any purpose authorized under LIHEAP and 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.

Additionally, all recipients of these funds must (1) ensure that they are included in the amounts on Lines 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.

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

**Karen D. Shields,**

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

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Community Living**

**Agency Information Collection Activities: Proposed Collection; Public Comment Request; Traumatic Brain Injury (TBI) State Partnership Program Performance Measures (OMB Control Number 0985-0066)**

**AGENCY:** Administration for Community Living, Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** The Administration for Community Living (ACL) is announcing an opportunity for the public to comment on the proposed collection of information listed above. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of

information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice.

This IC Extension solicits comments on the information collection requirements relating to the Traumatic Brain Injury (TBI) State Partnership Program.

**DATES:** Comments on the collection of information must be submitted electronically by 11:59 p.m. (EST) or postmarked by November 29, 2022.

**ADDRESSES:** Submit electronic comments on the collection of information to: Elizabeth Leef at [Elizabeth.Leef@acl.hhs.gov](mailto:Elizabeth.Leef@acl.hhs.gov). Submit written comments on the collection of information to Administration for Community Living, 330 C Street SW, Washington, DC, 20201, Attention: Elizabeth Leef.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Leef, phone (202) 475-2482 or email [Elizabeth.Leef@acl.hhs.gov](mailto:Elizabeth.Leef@acl.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. The PRA requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, ACL is publishing a notice of the collection of information set forth in this document.

With respect to the following collection of information, ACL invites comments on our burden estimates or any other aspect of this collection of information, including:

(1) whether the proposed collection of information is necessary for the proper performance of ACL's functions, including whether the information will have practical utility;

(2) the accuracy of ACL's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used to determine burden estimates;

(3) ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

The purpose of the Federal Traumatic Brain Injury (TBI) State Partnership Program is to create and strengthen a system of services and supports that maximizes the independence, well-being, and health of people with TBIs across the lifespan and all other demographics, their family members, and support networks. The TBI State Partnership Program funds the development and implementation of statewide systems that ensure access to TBI related services, including transitional services, rehabilitation, education and employment, and long-term community support. To best monitor, guide, and support TBI State Partnership Program grantees, ACL needs regular information about the grantees' activities and outcomes. The simplest, least burdensome, and most useful way to accomplish this goal is to require grantees to submit information as part of their required semiannual reports via the proposed electronic data submission instrument (appendix A).

In 1996, the Public Health Service Act was amended "to provide for the conduct of expanded studies and the establishment of innovative programs with respect to traumatic brain injury, and for other purposes" (Pub. L. 104-166). This legislation allowed for the implementation of "grants to States for the purpose of carrying out

demonstration projects to improve access to health and other services regarding traumatic brain injury." The TBI Reauthorization Act of 2014 (Pub. L. 113-196) allowed the Department of Health and Human Services Secretary to review oversight of the Federal TBI programs (TBI State Partnership Grant program and the TBI Protection and Advocacy program) and reconsider which operating division should lead them. With avid support from TBI stakeholders, the Secretary found that the goals of the Federal TBI programs closely align with ACL's mission to advance policy and implement programs that support the rights of older Americans and people with disabilities to live in their communities. As a result, on Oct. 1, 2015, the Federal TBI programs moved from the Health Resources and Services Administration to ACL. These programs were reauthorized again by the Traumatic Brain Injury Reauthorization Act of 2018 (Pub. L. 115-377).

The performance measures are consistent with both the TBI State Partnership Program's purpose and ACL's mission. The 2010 Government Performance Results Modernization Act<sup>1</sup> requires Federal agencies to develop annual and long-term performance outcome measures and to report on these measures annually. ACL sees the GPRM Modernization Act as an opportunity to document annually the results that are produced through the programs it administers under the authority for the TBI State Partnership Program. It is the intent and commitment of ACL, in concert with grantees, to use the performance measurement tools of GPRAMA to continuously improve its programs and services.

The proposed data collection tools may be found on the ACL website for review at: <https://www.acl.gov/about-acl/public-input>.

*Estimated Program Burden:* ACL estimates the burden of this collection of information as follows:

Instrument	Number of respondents	Number of responses (per respondent)	Average burden hours (per response)	Total burden hours
Semiannual Performance Measures Report .....	27	2	8	432
Estimated Total Annual Burden Hours: .....	.....	.....	.....	432

States will likely expend varying amounts of time completing data

submissions. The estimate above is based upon states that invest

considerable attention to submitting comprehensive, accurate data.

<sup>1</sup> [http://www.gao.gov/key\\_issues/managing\\_for\\_results\\_in\\_government/issue\\_summary](http://www.gao.gov/key_issues/managing_for_results_in_government/issue_summary).

The estimate of future levels of effort assumes the following:

- The length of the grant funding is three years, except for the three grants awarded in FY19 that will only have funding for two years.
- The annual burden may decrease after the first entry of data into the system by the grantees. Once the data for the first report has been entered, subsequent reports will only require updated data and, therefore, less effort.
- The annual burden may decrease if the same individuals compile the required data, because they will become more adept at finding the information and submitting the report.

The estimated Performance Measures Report annual burden is based upon an average hourly salary of \$46.00 for state programmatic staff. Across all respondents, assuming a group of 27 grantees, the programmatic staff total average annual burden is estimated at 432 hours at \$46 per hour for a total of \$19,872.

Dated: September 23, 2022.

**Alison Barkoff,**

*Acting Administrator and Assistant Secretary for Aging.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0655]

#### Animal Generic Drug User Fee Act; Public Meeting; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public meeting; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public meeting entitled “Animal Generic Drug User Fee Act.” The purpose of the meeting is to discuss the proposed recommendations for the reauthorization of the Animal Generic Drug User Fee Act (AGDUFA IV) for fiscal years 2024 through 2028.

**DATES:** The public meeting will be held virtually on October 26, 2022, from 2 p.m. to 4 p.m. eastern time. Either electronic or written comments on this meeting must be submitted by November 9, 2022. See the

**SUPPLEMENTARY INFORMATION** section for registration dates and further information.

**ADDRESSES:** The public meeting will be hosted via a live virtual webcast.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. eastern time at the end of Wednesday, November 9, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

#### 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-2011-N-0655 for “Animal Generic Drug User Fee Act; Public Meeting; Request for Comments.” Received comments, those filed in a timely manner (see **ADDRESSES**), 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 <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

**FOR FURTHER INFORMATION CONTACT:** Lisa Kable, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-6888, [lisa.kable@fda.hhs.gov](mailto:lisa.kable@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing a virtual public meeting to discuss proposed recommendations for the reauthorization of AGDUFA, which authorizes FDA to collect user fees and use them for the process of reviewing new animal generic drug applications