service for use with a particular beneficiary. When an NCD requires CED under 1862(a)(1)(E), it is because the available evidence about a particular item or service is insufficient to support coverage outside the context of a well-designed clinical research study. Sponsors could build interim analyses and final analyses into their study design and communicate these results to CMS.

Section 1142 of the Act describes the authority of the Agency for Healthcare Research and Quality (AHRQ) to conduct and support research on outcomes, effectiveness, and appropriateness of services and procedures to identify the most effective and appropriate means to prevent, diagnose, treat, and manage diseases, disorders, and other health conditions. That section includes a requirement that the Secretary assure that AHRQ research priorities under Section 1142 appropriately reflect the needs and priorities of the Medicare program.

The coordination of AHRQ priorities under section 1142 with the needs and priorities of the Medicare program is accomplished through direct collaboration between the AHRQ and CMS. AHRQ reviews all CED NCDs established under Section 1862(a)(1)(E) of the Act. Consistent with section 1142, AHRQ also indicates its support for clinical research studies that CMS determines address the CED questions and meet the general standards for CED studies. In order for CMS (or its designated entity) to determine if the Medicare coverage criteria are met, as described in our regulations, CMS (or its designated entity) must review the study protocol and supporting materials, as needed. *Form Number:* CMS–10697 (OMB control number: 0938-New); *Frequency:* Yearly; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions*); Number of Respondents:* 15; *Total Annual Responses:* 15; *Total Annual Hours:* 15,000. (For policy questions regarding this collection contact Xiufen Sui at 410–786–3136.)

Dated: August 22, 2019.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2019–18415 Filed 8–26–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA NUMBER: 93.568]

Reallotment of Fiscal Year 2018 Funds for the Low Income Home Energy Assistance Program (LIHEAP)

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

ACTION: Notice of public comment.

SUMMARY: Notice is hereby given of a preliminary determination that funds from the fiscal year (FY) 2018 Low Income Home Energy Assistance Program (LIHEAP) are available for reallotment to States, Territories, Tribes, and Tribal Organizations that received FY 2019 direct LIHEAP grants. No subgrantees or other entities may apply for these funds.

DATES: Submit comments on or before September 26, 2019.

ADDRESSES: Comments may be submitted to: Clarence H. Carter, Acting Director, Office of Community Services, Administration for Children and Families, Department of Health and Human Services, 330 C Street SW, 5th Floor; Mail Room 5425; Washington, DC 20201 or via email: *Clarence.Carter@acf.hhs.gov.* Comments may also be faxed to (202) 401–5661.

FOR FURTHER INFORMATION CONTACT: Lauren Christopher, Director, Division of Energy Assistance, Office of Community Services, Administration for Children and Families, Department of Health and Human Services, 330 C Street SW, 5th Floor; Mail Room 5425; Washington, DC 20201. Telephone: (202) 401–4870. Email: *lauren.christopher@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION: According to Section 2607(b)(1) of the Low Income Home Energy Assistance Act, (42 U.S.C. 8626(b)(1)), if the Secretary of HHS determines as of September 1, of any fiscal year, an amount in excess of 10 percent of the amount awarded to a grantee for that fiscal year (excluding Leveraging and REACH funds) will not be used by the grantee during that fiscal year, then the Secretary must notify the grantee and publish a notice in the **Federal Register** that such funds may be reallotted to LIHEAP grantees during the following fiscal year. If reallotted, the LIHEAP block grant allocation formula will be used to distribute the funds. No funds may be allotted to entities that are not direct LIHEAP grantees during FY 2019.

It has been determined that $1,839,128 in LIHEAP funds may be available for reallotment during FY 2019. This determination is based on FY 2018 Carryover and Reallotment Reports which showed that seven grantees reported reallotment funds. These grantees were Alaska; Five Sandoval Indian Pueblos, INC.; Hoh Indian Tribe; Little River Band of Ottawa Indians; Northern Cheyenne Tribe; Three Affiliated Tribes; and Turtle Mountain Band of Chippewa Indians. Grantees submitted the FY 2018 Carryover and Reallotment Reports to the OCS, as required by regulations applicable to LIHEAP at 45 CFR 96.81(b).

The LIHEAP statute allows grantees 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. Funds in excess of this amount must be returned to HHS and are subject to reallotment under section 2607(b)(1) of the Low Income Home Energy Assistance Act, (42 U.S.C. 8626(b)(1)). The amount described in this notice was reported by grantees as unobligated FY 2018 funds in excess of the amount that these grantees could carry over to FY 2019.

In accordance with section 2607(b)(3) of the Act (42 U.S.C. 8626(b)(3)), comments will be accepted for a period of 30 days from the date of publication of this notice.

After considering any comments submitted, all current LIHEAP grantees will be notified of the final reallotment amount redistributed to them for obligation in FY 2019. This decision will be published in the **Federal Register** and in a Dear Colleague Letter that gets posted to ACF's website: *https://www.acf.hhs.gov/ocs/resource/dear-colleagues.*

If funds are reallotted, they will be allocated in accordance with section 2604 of the Act (42 U.S.C. 8623) and must be treated by LIHEAP grantees receiving them as an amount appropriated for FY 2019. As FY 2019 funds, they will be subject to all requirements of the Act, including section 2607(b)(2) (42 U.S.C. 8626(b)(2)), which requires that a grantee 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, 2019.

ESTIMATED REALLOTMENT AMOUNTS OF FY 2018 LIHEAP FUNDS

Grantee name	Reallotment amount
Alaska	$1,579,924
Five Sandoval Indian Pueblos, INC	16,089
Hoh Indian Tribe	4,378
Little River Band of Ottawa Indians	47,440
Northern Cheyenne Tribe	45,607
Three Affiliated Tribes	140,582
Turtle Mountain Band of Chippewa Indians	5,108
Total	$1,839,128

Statutory Authority: 42 U.S.C. 8626.

Elizabeth Leo,

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

[FR Doc. 2019–18374 Filed 8–26–19; 8:45 am]

BILLING CODE 4184–80–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3612]

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) announces a forthcoming public advisory committee meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC). The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. At least one portion of the meeting will be closed to the public. Members will participate via teleconference.

DATES: The meeting will be held on October 9, 2019, from 8:30 a.m. to 3:30 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Avenue, Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. For those unable to attend in person, the meeting will also be webcast and will be available at the following link: *https://collaboration.fda.gov/vrbpac100919/.* Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FOR FURTHER INFORMATION CONTACT: Capt. Serina Hunter-Thomas, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6338, Silver Spring, MD 20993–0002, 240–402–5771, *serina.hunter-thomas@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On October 9, 2019, under topic I, the Center for Biologics Evaluation and Research's (CBER) VRBPAC will meet in open session to hear an overview of the research programs in the Laboratory of Hepatitis Viruses (LIR) and the Laboratory of Vector-Borne Viral Diseases (LVVD), Division of Viral Products, Office of Vaccines Research and Review, CBER, FDA. Also, on October 9, 2019, under topic II, the committee will meet in open session to discuss and make recommendations on the selection of strains to be included in an influenza virus vaccine for the 2020 southern hemisphere influenza season.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: On October 9, 2019, from 8:30 a.m. to approximately 10 a.m. and from 11 a.m. to 3:30 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 2, 2019. Oral presentations from the public will be scheduled between approximately 9:45 a.m. and 10 a.m. for the overview portion of the LHV/LVVD Site Visit (topic I), and from 1:30 p.m. to 2:15 p.m. for the influenza strain selection portion of the meeting (topic II). Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before September 24, 2019. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA 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 by September 25, 2019.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Capt. Serina Hunter-Thomas at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 16, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–18410 Filed 8–26–19; 8:45 am]

BILLING CODE 4164–01–P