

situations and appropriateness of facility actions to mitigate IJ risk factors prior to the exit of the survey team.

- Section 488.28(a), to ensure that the corrective action plan submitted by hospitals fully addresses the deficiencies cited and that the hospital's corrective actions are hospital wide and not focused solely on the area in which the deficiency was identified.

- Section 488.28(d), to ensure that all corrective action plans contain an expected correction completion date, consistent with CMS requirements.

- Section 488.18(a), to ensure all observations of non-compliance are adequately documented in the survey report and ensure corrective action is required by the hospital.

**B. Term of Approval**

Based on our review and observations described in section III of this final notice, we approve DNV GL as a national accreditation organization for hospitals that request participation in the Medicare program, effective August 17, 2018 through September 26, 2022.

To verify DNV GL's continued compliance with the provisions of this final notice, CMS will conduct a follow-up corporate on-site visit and survey observation within 18 months of the publication date of this notice.

**V. Collection of Information Requirements**

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. 3501 *et seq.*).

Dated: August 6, 2018.

**Seema Verma,**

*Administrator, Centers for Medicare & Medicaid Services.*

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**BILLING CODE P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Proposed Information Collection Activity; Comment Request**

*Proposed Projects:* LIHEAP Household Report FRN1 Clearance.

*Title:* Annual Report on Households Assisted by the Low Income Home Energy Assistance (LIHEAP).

*OMB No.:* 0970-0060.

*Description:* This report is an annual activity required by statute (42 U.S.C. 8629) and Federal regulations (45 CFR 96.92) for the Low Income Home Energy Assistance Program (LIHEAP). Submission of the completed report is one requirement for LIHEAP grantees applying for Federal LIHEAP block grant funds.

States, the District of Columbia, and the Commonwealth of Puerto Rico are required to report statistics for the previous Federal fiscal year on:

- Assisted and applicant households, by type of LIHEAP assistance;
- Assisted and applicant households, by type of LIHEAP assistance and poverty level;
- Assisted households receiving nominal payments of \$50 or less;
- Assisted households receiving only utility payment assistance; this information will automatically be

transferred to the grantee's Performance Data Form.

- Assisted households, regardless of the type(s) of LIHEAP assistance, excluding households that only receive nominal payments of \$50 or less;

- Assisted households, by type of LIHEAP assistance, having at least one vulnerable member who is at least 60 years or older, disabled, or five years old or younger;

- Assisted households, by type of LIHEAP assistance, with at least one member age 2 years or under;

- Assisted households, by type of LIHEAP assistance, with at least one member ages 3 years through 5 years; and

- Assisted households, regardless of the type(s) of LIHEAP assistance, having at least one member 60 years or older, disabled, or five years old or younger. Insular areas (other than the Commonwealth of Puerto Rico) and Indian Tribal Grantees are required to submit data only on the number of households receiving heating, cooling, energy crisis, and/or weatherization benefits.

The information is being collected for the Department's annual LIHEAP Report to Congress. The data also provides information about the need for LIHEAP funds. Finally, the data are used in the calculation of LIHEAP performance measures under the Government Performance and Results Act of 1993. The data elements will allow the accuracy of measuring LIHEAP targeting performance and LIHEAP cost efficiency.

*Respondents:* State Governments, Tribal Governments, Insular Areas, and the District of Columbia.

**ANNUAL BURDEN ESTIMATES**

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Assisted Household Report-Long Form .....	56	1	39	2,184
Assisted Household Report-Short Form .....	160	1	1	160
Estimated Total Annual Burden Hours .....				2,344

In compliance with the requirements of the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. Chap. 35), the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and

Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201. Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov*. All requests should be identified by the title of the information collection.

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.

**Robert A. Sargis,**  
Report Clearance Officer.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Proposed Information Collection Activity; Comment Request**

*Proposed Projects:* LIHEAP Carryover and Reallotment Report FRN1 Clearance.

*Title:* Low Income Home Energy Assistance Program (LIHEAP) Carryover and Reallotment Report.

*OMB No.:* 0970-0106.

*Description:* The LIHEAP statute and regulations require LIHEAP grantees to report certain information to HHS concerning funds forwarded and funds subject to reallotment. The 1994 reauthorization of the LIHEAP statute, the Human Service Amendments of 1994 (Pub. L. 103-252), requires that the carryover and reallotment report for one fiscal year be submitted to HHS by the grantee before the Allotment for the next fiscal year may be awarded.

We are requesting no changes in the collection of data with the Carryover and Reallotment Report for FY 2018, a form for the collection of data, and the Simplified Instructions for Timely

Obligations of FY 2019 LIHEAP Funds and Reporting Funds for Carryover and Reallotment. The form clarifies the information being requested and ensures the submission of all the required information. The form facilitates our response to numerous queries each year concerning the amounts of obligated funds. Use of the form is voluntary. Grantees have the option to use another format.

*Respondents:* State, Local or Tribal Government.

**ANNUAL BURDEN ESTIMATES**

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Carryover & Reallotment .....	177	1	3	531
Estimated Total Annual Burden Hours .....				531

In compliance with the requirements of the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. Chap 35), the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington DC 20201. Attn: ACF Reports Clearance Officer. Email address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). All requests should be identified by the title of the information collection.

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.

**Robert A. Sargis,**  
Reports Clearance Officer.  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2018-N-0001]

**Science and Regulation of Live Microbiome-Based Products Used To Prevent, Treat, or Cure Diseases in Humans; Public Workshop**

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

**ACTION:** Notice of public workshop.

**SUMMARY:** The Food and Drug Administration (FDA) Center for Biologics Evaluation and Research and the National Institutes of Health, National Institute of Allergy and Infectious Diseases (NIAID) are announcing a public workshop entitled "Science and Regulation of Live Microbiome-Based Products Used to Prevent, Treat, or Cure Diseases in Humans." The purpose of the public workshop is to exchange information

with the scientific community about the clinical, manufacturing, and regulatory considerations associated with live microbiome-based products, when administered to prevent, treat, or cure a disease or condition in humans. The public workshop will bring together government Agencies, academia, industry, and other stakeholders involved in research, development, and regulation of live microbiome-based products for such uses.

**DATES:** The public workshop will be held on September 17, 2018, from 9 a.m. to 5 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

**ADDRESSES:** The public workshop will be held at the NIAID Conference Center, 5601 Fishers Lane, Rm. 1D13, Rockville, MD 20852. Entrance for public workshop participants is through the lobby, where routine security check procedures will be performed. For parking and security information, please refer to <https://www.niaid.nih.gov/about/visitor-information>.

**FOR FURTHER INFORMATION CONTACT:** Loni Warren Henderson or Sherri Revell, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 1118, Silver Spring, MD 20993, 240-402-8010, email: [CBERPublicEvents@fda.hhs.gov](mailto:CBERPublicEvents@fda.hhs.gov) (subject