

proposing updates to Module 2 to collect additional performance data related to supplemental LIHEAP funds.

*Respondents:* State governments, including the District of Columbia; the largest five electricity and natural gas

vendors by state; the largest ten fuel oil and propane vendors by state; and state sub-grantees.

#### ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
<b>Module 1 (Grantee Survey)</b>				
State Grantees—Module I .....	51	1	36	1,836
<b>Modules 2 and 3 (LIHEAP Performance Measures)</b>				
State Grantees—Modules II and III .....	51	1	200	10,200
Sub-Grantees (in states with sub-grantee managed systems)—Modules II and III .....	100	1	8	800
Energy Vendors (largest 5 electric, 5 natural gas, 10 fuel oil, and 10 propane vendors per state-average)—Modules II and III .....	* 1,530	1	8.5	13,005

\* Estimate.

*Estimated Total Annual Burden Hours:* 25,841.

*Authority:* 42 U.S.C. 8629(b); 42 U.S.C. 8624(b); 42 U.S.C. 8623(c).

**Mary B. Jones,**

*ACF/OPRE Certifying Officer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Community Living

#### Agency Information Collection Activities; Submission for OMB Review; Public Comment Request; National Center on Law and Elder Rights-Resource Support and User Satisfaction; OMB# 0985-0060

**AGENCY:** Administration for Community Living, HHS.

**ACTION:** Notice.

**SUMMARY:** The Administration for Community Living (ACL) is announcing that the proposed collection of information listed above has been submitted to the Office of Management and Budget (OMB) for review and clearance as required under section 506(c)(2)(A) of the Paperwork Reduction Act of 1995. This 30-Day notice collects comments on the information collection requirements related to the information collection requirements for the National Center on Law and Elder Rights-Resource Support and User Satisfaction [OMB# 0985-0060].

**DATES:** Submit written comments on the collection of information by January 18, 2022.

**ADDRESSES:** Submit written comments and recommendations for the proposed

information collection within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find the information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. By mail to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW, Room 10235, Washington, DC 20503, Attn: OMB Desk Officer for ACL.

#### FOR FURTHER INFORMATION CONTACT:

Aiesha Gurley, Administration for Community Living, Washington, DC 20201, (202) 795-7358 or by email: [Aiesha.Gurley@acl.hhs.gov](mailto:Aiesha.Gurley@acl.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

In compliance with 44 U.S.C. 3507, ACL has submitted the following proposed collection of information to OMB for review and clearance.

ACL is requesting approval to collect data for the National Center on Law and Elder Rights-Resource Support and User Satisfaction [OMB# 0985-0060]. ACL contracts with a national legal assistance resource center, the National Center on Law and Elder Rights, to provide the required services. Through the contract, ACL provides aging, disability, and related legal professionals with training, technical assistance, complex case consultations and support for demonstration projects regarding contractually identified priority legal topics. The purpose of the information requested is for ACL to ensure that the resource center creates and prioritizes the training, case consultations and technical assistance resources it was contracted to provide and to ensure that the center targets the contractually designated aging network

practitioners about the priority subject matters.

This approach enables ACL to make data-informed decisions about the deployment of its resource center assets. These data are necessary for ACL to evaluate contractual compliance with established performance indicators.

These metrics include quantifiable increases in uptake by stakeholders of training, case consultation and technical assistance, and measures of satisfaction with and perceived benefit from these services. For example, the metrics measure successful problem resolution as a result of the services provided and quantifiable data on fulfillment of requests for training, technical assistance, and consultation related to the contractually designated legal and systems development topic areas. The information requested by ACL from legal and aging/disability professionals falls into the following areas: (1) Requests for training, case consultation, and technical assistance; (2) general requests for legal training (including the volume of webinar registrations), and case consultations.

#### Comments in Response to the 60-Day Federal Register Notice

A notice published in the **Federal Register** on, August 30, 2021 in 86 FR 48427. There were zero (0) public comments received during the response period for the 60-day notice.

*Estimated Program Burden:* The burden hours are calculated at *one (1) minute 42 seconds* for each respondent to make a request for training, case consultation, or technical assistance. ACL estimates a high end of *20,000* responses with burden hours totaling *700* hours, annually.

ACL estimates the burden associated with this collection of information as follows:

Respondent/data collection activity	Number of respondents	Minutes per response	Annual burden hours
Legal Training, Case Consultation, Technical Assistance Requests .....	20,000	1 min 42 sec .....	700
Outcome Measurement .....	5,000	1 min 3 sec .....	71.59
Total .....	25,000	4 min 39 sec .....	700

Dated: December 12, 2021.

**Alison Barkoff,**

*Principal Deputy Administrator.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2021-D-0997]

#### Referencing the Definition of “Device” in the Federal Food, Drug, and Cosmetic Act in Guidance, Regulatory Documents, Communications, and Other Public Documents; Draft Guidance for Industry and Food and Drug Administration Staff; 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 the draft guidance entitled “Referencing the Definition of ‘Device’ in the Federal Food, Drug, and Cosmetic Act in Guidance, Regulatory Documents, Communications, and Other Public Documents.” FDA is issuing this draft guidance to promote clarity regarding references to the terms “device” and “counterfeit device” in guidance, regulatory documents, communications, and other public documents. This draft guidance is not final nor is it in effect at this time.

**DATES:** Submit either electronic or written comments on the draft guidance by February 14, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance 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 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-2021-D-0997 for “Referencing the Definition of ‘Device’ in the Federal Food, Drug, and Cosmetic Act in Guidance, Regulatory Documents, Communications, and Other Public Documents.” Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a