

are codified in Subpart K of 42 CFR 423 entitled “*Application Procedures and Contracts with PDP Sponsors*.”

The information will be collected under the solicitation of proposals from PDP, MA–PD, Cost Plan, Program of All Inclusive Care for the Elderly (PACE), and EGWP applicants. The collected information will be used by CMS to: (1) Ensure that applicants meet CMS requirements for offering Part D plans (including network adequacy, contracting requirements, and compliance program requirements, as described in the application), (2) support the determination of contract awards. *Form Number:* CMS–10137 (OMB control number: 0938–0936); *Frequency:* Yearly; *Affected Public:* Businesses or other for-profits, Not-for-profit institutions; *Number of Respondents:* 716; *Total Annual Responses:* 382; *Total Annual Hours:* 1,716. (For policy questions regarding this collection contact Arianne Spaccarelli at 410–786–5715.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Prescription Drug Benefit Program; *Use:* Plan sponsor and State information is used by CMS to approve contract applications, monitor compliance with contract requirements, make proper payment to plans, and ensure that correct information is disclosed to potential and current enrollees. *Form Number:* CMS–10141 (OMB control number: 0938–0964); *Frequency:* Once; *Affected Public:* Private sector (Business or other for-profit and Not-for-profit institutions); *Number of Respondents:* 11,771,497; *Total Annual Responses:* 675,231,213; *Total Annual Hours:* 9,312,314. (For policy questions regarding this collection contact Maureen Connors at 410–786–4132.)

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Non-Quantitative Treatment Limitation Analyses and Compliance Under MHPAEA; *Use:* The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) (Pub. L. 110–343) generally requires that group health plans and group health insurance issuers offering mental health or substance use disorder (MH/SUD) benefits in addition to medical and surgical (med/surg) benefits do not apply any more restrictive financial requirements (e.g., co-pays, deductibles) and/or treatment limitations (e.g., visit limits, prior authorizations) to MH/SUD benefits than those requirements and/or

limitations applied to substantially all med/surg benefits. The Patient Protection and Affordable Care Act, Public Law 111–148, was enacted on March 23, 2010, and the Health Care and Education Reconciliation Act of 2010, Public Law 111–152, was enacted on March 30, 2010. These statutes are collectively known as the “Affordable Care Act.” The Affordable Care Act extended MHPAEA to apply to the individual health insurance market. MHPAEA does not apply directly to small group health plans, although its requirements are applied indirectly in connection with the Affordable Care Act’s essential health benefit requirements. The Consolidated Appropriations Act, 2021 (the Appropriations Act) was enacted on December 27, 2020. The Appropriations Act amended MHPAEA, in part, by expressly requiring group health plans and health insurance issuers offering group or individual health insurance coverage that offer both med/surg benefits and MH/SUD benefits and that impose non-quantitative treatment limitations (NQTLs) on MH/SUD benefits to perform and document their comparative analyses of the design and application of NQTLs. Further, beginning 45 days after the date of enactment of the Appropriations Act, group health plans and health insurance issuers offering group or individual health insurance coverage must make their comparative analyses available to the Departments of Labor, Health and Human Services (HHS), and the Treasury or applicable state authorities, upon request. The Secretary of HHS is required to request the comparative analyses for plans that involve potential violations of MHPAEA or complaints regarding noncompliance with MHPAEA that concern NQTLs and any other instances in which the Secretary determines appropriate. The Appropriations Act also requires the Secretary of HHS to submit to Congress, and make publicly available, an annual report on the conclusions of the reviews. *Form Number:* CMS–10773 (OMB control number: 0938–1393); *Frequency:* On Occasion; *Affected Public:* State, Local, or Tribal Governments, Private Sector; *Number of Respondents:* 250,137; *Total Annual Responses:* 36,461; *Total Annual Hours:* 1,013,184. (For policy questions regarding this collection, contact Usree Bandyopadhyay at 410–786–6650.)

4. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Exchange Functions: Standards for Navigators and

Non-Navigator Assistance Personnel–CAC; *Use:* Section 1321(a)(1) of the Affordable Care Act directs and authorizes the Secretary to issue regulations setting standards for meeting the requirements under title I of the Affordable Care Act, with respect to, among other things, the establishment and operation of Exchanges. Pursuant to this authority, regulations establishing the certified application counselor program have been finalized at 45 CFR 155.225. In accordance with 155.225(d)(1) and (7), certified application counselors in all Exchanges are required to be initially certified and recertified on at least an annual basis and successfully complete Exchange required training. *Form Number:* CMS–10494 (OMB control number: 0938–1205); *Frequency:* On Occasion; *Affected Public:* State, Local, or Tribal Governments, Private Sector (not-for-profit institutions); individuals or households; *Number of Respondents:* 278,072; *Total Annual Responses:* 278,072; *Total Annual Hours:* 918,024. (For policy questions regarding this collection contact Evonne Muoneke at 301–492–4402.)

Dated: October 21, 2021.

William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Expedited OMB Review and Public Comment: Office of Community Services Data Collection for the Low Income Household Water Assistance Program Reports (New Collection)

AGENCY: Office of Community Services, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Office of Community Services, Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is requesting expedited review of an information collection request from the Office of Management and Budget (OMB) and inviting public comment on the proposed collection. The proposed forms are necessary to provide data to the Administration and Congress in its oversight of recipients’ performance in administering the Low Income

Household Water Assistance Program (LIHWAP) program. The information collection is essential to the mission of the agency for this emergency assistance effort and the use of normal clearance procedures is reasonably likely to disrupt and prevent the collection of information.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described in this notice.

ADDRESSES: Copies of the proposed collection of information can be obtained and comments may be submitted by emailing infocollection@acf.hhs.gov. All requests should identify the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: ACF is requesting that OMB grant a 180-day approval for this request under procedures for expedited processing. A request for review under normal procedures will be submitted

within 180 days of the approval for this request. The LIHWAP effort was authorized under two separate appropriations as part of an emergency effort to prevent and respond to COVID-19: The Consolidated Appropriations Act, 2021 (Pub. L. 116-260) and the American Rescue Plan Act of 2021 (Pub. L. 117-2). As a result of the emergency nature, the timeline to implement the program was very short and the time to develop and submit related performance measures is similarly short. The proposed LIHWAP Quarterly Performance and Management Report and the LIHWAP Annual Report are conducted in accordance with the LIHWAP statute (Pub. L. 116-260) and will provide ACF and Congress information necessary for oversight of recipients' performance in administering the LIHWAP program. The completeness, accuracy, consistency, and timeliness of responses to data collections are needed for the agency to do the following:

- Ensure that LIHWAP, an emergency and temporary program, is implemented effectively and efficiently;
- Provide reliable and complete fiscal and household data for OCS analysis and reporting to Congress and the public; and
- Respond to questions from the Congress, Department, OMB, White House, and other interested parties in a timely and accurate manner.

This information collection package also includes a burden estimate related to the information collected from households. While grant recipients will collect necessary information from households using a variety of intake systems and local forms, OCS is providing technical assistance in this area and has included a sample application template in supplementary materials. This is a sample template; there will be no mandated household application format and OCS will not receive or analyze copies of individual household application materials.

Respondents: LIHWAP grant recipients.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Quarterly Report	157	4	13	8,164	8,164
Annual Report	157	2	211	66,254	33,127
Household Application	1,200,000	1	.5	600,000	200,000

Estimated Total Annual Burden Hours: 241,291 (for first year with Quarterly reports), 233,127 (for subsequent years without Quarterly reports).

Comments: 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. Comments will be considered and any necessary updates to materials made prior to, and responses provided in, the submission to OMB that will follow this public comment period.

Authority: Public Law 116-260 and LIHWAP Terms and Conditions Section 10 (<https://www.acf.hhs.gov/sites/>

default/files/documents/LIHWAP%20Terms%20and%20Conditions%20for%20States.pdf).

Mary B. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0008]

Neurological Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Neurological Devices

Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will take place virtually on December 10, 2021, from 9 a.m. to 6 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID-19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions including information regarding special accommodations due to a disability may be accessed at: <https://www.fda.gov/advisory-committees/about-advisory-committees/common-questions-and-answers-about-fda-advisory-committee-meetings>.

FOR FURTHER INFORMATION CONTACT: James Swink, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5214, Silver Spring,