Health Options Program; *Use:* On March 23, 2010, the President signed into law H.R. 3590, the Patient Protection and Affordable Care Act, Public Law 111–148, as amended by the Health Care and Education Reconciliation Act of 2010, Public Law 111–152. The Patient Protection and Affordable Care Act (PPACA) expands access to health insurance coverage through improvements to the Medicaid and Children's Health Insurance (CHIP) programs, the establishment of Affordable Insurance Exchanges (Exchanges), and the coordination between Medicaid, CHIP, and Exchanges. Small business employers may participate in and provide health coverage through the Small Business Health Options Program (SHOP), so long as the small business employer obtains a positive eligibility determination from SHOP. Employers will work with SHOP-registered agents/brokers or Issuers offering Qualified Health Plans (QHPs) and Qualified Dental Plans (SADPs), to enroll in SHOP coverage and to select coverage options to offer their employees. SHOP Exchanges became operational on October 1, 2013.

HHS has developed a single, streamlined form that employers use to obtain a SHOP eligibility determination, which is included as an appendix to this Information Collection Request. 45 CFR 155.731 provides more detail about this ''single employer application,'' which is used to determine employer eligibility. Since publication of the last package, no updates have been made in regulation concerning what information should be collected on the single employer application to determine employer eligibility under 45 CFR 155.731. When an employer completes the SHOP Eligibility Determination Form, the form and its results are retained by SHOP for future use, if needed (*e.g.,* reconciliation with issuer records, SHOP employer appeals, etc.). *Form Number:* CMS–10439 (OMB control number 0938–1193); *Frequency:* Annually; *Affected Public:* Private Sector (business or other for-profits, not-for-profit institutions); *Number of Respondents:* 2,100; *Number of Responses:* 2,100; *Total Annual Hours:* 336. (For questions regarding this collection contact Elliot Klein at 410–786–0415).

Dated: October 25, 2022.

William N. Parham, III,

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

[FR Doc. 2022–23553 Filed 10–27–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities: Proposed Collection; Public Comment Request; Evaluation of the National Paralysis Resource Center (NPRC) and Performance Management Support, OMB Control Number 0985–New

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 information collection (IC) request solicits comments on the information collection requirements relating to the Evaluation of the National Paralysis Resource Center (NPRC) and Performance Management Support.

DATES: Comments on the collection of information must be submitted electronically by 11:59 p.m. (EST) or postmarked by December 27, 2022.

ADDRESSES: Submit electronic comments on the collection of information to: Amanda Cash, 202–795–7369 *Amanda.Cash@acl.hhs.gov.* Submit written comments on the collection of information to Administration for Community Living, 330 C Street SW, Washington, DC 20201, Attention: Amanda Cash.

FOR FURTHER INFORMATION CONTACT: Amanda Cash, 202–795–7369, *Amanda.Cash@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 proposed 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 Administration for Community Living (ACL) is conducting process and outcome evaluations of the National Paralysis Resource Center (NPRC) to understand how and to what extent the NPRC is meeting its goals. The NPRC provides resources to people living with paralysis, their caregivers, and their support network. ACL is responsible for oversight of the NPRC, which has been administered by the Christopher and Dana Reeve Foundation since its authorization in 2009. This data collection effort will be focused on evaluating specific major activities of the NPRC: (a) the Quality of Life (QOL) Grants Program; (b) the Peer and Family Support Program (PFSP); and (c) the Promotional Activities, Outreach, and Collaboration program. This evaluation seeks to identify barriers and challenges to operating the NPRC, document best practices for other Resource Centers, and recommend areas for improvement.

Specifically, this IC will help ACL to understand *how* each major NPRC activity aims to achieve the following goals, and *to what extent* the activities affect related outcomes:

a. Improving the health and quality of life of individuals living with paralysis of all ages, their families, and their support network
b. Raising awareness of members of the target populations about paralysis

c. Increasing access of members of the target populations to services relevant to individuals with paralysis
d. Increasing the empowerment, confidence, and independence of individuals living with paralysis
e. Strengthening support networks for individuals living with paralysis
f. Improving and increasing opportunities for community living for individuals living with paralysis and their caretakers

To gain an in-depth understanding of the perspectives of mentors and peers participating in the PFSP, QOL program subgrantees, and people who serve as regional champions in the Promotional Activities, Outreach, and Collaboration program, eight focus groups will be conducted with no more than eight people per focus group. Additionally, a web-based survey will be administered to a maximum of 330 PFSP peers, 150 PFSP mentors, and 850 people served by QOL subgrantees to understand respondents' experiences with the NPRC.

This data will contribute to documenting how each of the NPRC's major activities are delivered and the extent to which they improve the quality of life of people living with paralysis, their caregivers, and their support networks.

Findings can inform practice for the NPRC and other Resource Centers. This evaluation will also help to identify how the NPRC can better meet the stated goals of the Department of Health and Human Services (HHS) to, ''protect and strengthen equitable access to high quality and affordable healthcare,'' and to, ''strengthen social well-being, equity, and economic resilience.'' [1]

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:

The eight focus groups together will include no more than 64 total individuals representing three major activities of the NPRC: the QOL Grants Program; the PFSP; and the Promotional Activities, Outreach, and Collaboration program. The burden for their participation is estimated at 1.5 hours per participant, for a total of 96 hours.

A maximum of 150 PFSP mentors, 330 PFSP peers, and 850 people served by QOL subgrantee programs are expected to respond to the web-based survey, for a total of 1,330 respondents. The approximate burden for survey completion is 15 minutes for the peer mentor survey, and 10 minutes for the peer survey and QOL end-user survey per respondent.

This results in a total survey burden estimate of 14,050 minutes (234.17 hours). The estimated survey completion burden includes time to review the instructions, read the questions, and complete responses.

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours *
Focus groups	64	1	1.50	96.00
Survey—Peer Mentor	150	1	0.25	37.50
Survey—Peers	330	1	0.17	55.00
Survey—Quality of Life End-User	850	1	0.17	141.67
Total	1,394	1	2.09	330.17

* Annual burden hours were calculated from total minutes for each activity divided by sixty.

Dated: October 24, 2022.

Alison Barkoff,

Acting Administrator and Assistant Secretary for Aging.

[FR Doc. 2022–23484 Filed 10–27–22; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–1261]

Clostridioides difficile Infection: Developing Drugs for Treatment, Reduction of Recurrence, and Prevention; Draft Guidance for Industry; 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 a draft guidance for industry entitled ''*Clostridioides difficile* Infection: Developing Drugs for Treatment, Reduction of Recurrence, and Prevention.'' The purpose of this draft guidance is to assist sponsors in the clinical development of drugs for the treatment of *Clostridioides difficile* infection (CDI), reduction of recurrence, or prevention of CDI.

DATES: Submit either electronic or written comments on the draft guidance by December 27, 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'').

[1] *FY 2023 Evaluation Plan* (p. 3). (2022). U.S. Department of Health & Human Services. *https://aspe.hhs.gov/reports/fy-2023-hhs-evaluation-plan.*