(NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC) Division of Global Migration and Quarantine (DGMQ) is requesting a three-year revision of a currently approved generic clearance to conduct evaluation research. This will help CDC plan and implement health communication, education, and training activities to improve health and prevent the spread of disease. These activities include communicating, educating, and training with international travelers and other mobile populations, training healthcare providers, and educating public health departments, federal partners, and other stakeholders.

The information collection for which the revision is sought is in accordance with DGMQ's mission to reduce morbidity and mortality among immigrants, refugees, travelers, expatriates, and other globally mobile populations, and to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States. This mission is supported by delegated legal authorities outlined in the Public Health Service (PHS) Act (42 U.S.C. 264) and in regulations that are codified in 42 Code of Federal Regulations (CFR) parts 70 and 71, and 34.

Approval of this revision request will allow DGMQ to continue collecting, in an expedited manner, information about the knowledge, attitudes, and behaviors of key audiences (such as refugees, immigrants, migrants, international travelers, travel industry partners, healthcare providers, non-profit agencies, customs brokers and forwarders, schools, state and local health departments) to help improve and inform these activities during both routine and emergency public health events. This generic OMB clearance will help DGMQ continue to refine these efforts in a timely manner, and will be especially valuable for communication activities that must occur quickly in response to public health emergencies.

DGMQ staff will use a variety of data collection methods for this proposed project: interviews, focus groups, surveys, and pre/post-tests. Depending on the research questions and audiences involved, data may be gathered in-person, by telephone, online, or using some combination of these formats. Data may be collected in quantitative and/or qualitative forms. Numerous audience variables will be assessed under the auspices of this generic OMB clearance. These include, but are not limited to, knowledge, attitudes, beliefs, behavioral intentions, practices, behaviors, skills, self-efficacy, and information needs and sources. Insights gained from evaluation research will assist in the development, refinement, implementation, and demonstration of outcomes and impact of communication, education, and training activities.

DGMQ estimates that 17,500 respondents and 7,982 hours of burden will be involved in evaluation research activities each year. The information being collected will not impose a cost burden on the respondents beyond that associated with their time to provide the required data.

For this submission, requested burden has been reduced from 37,500 respondents and 17,835 burden hours to 17,500 respondents and 7,982 burden hours due to a reduction in the number of estimated number of collections per year from ten to five and a two thirds reduction in pre- and post-tests requested for both types of respondents: healthcare professionals and the general public.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
General Public	Focus Groups Screening form	1,050	1	10/60
Healthcare Professionals	Focus Groups Screening form	450	1	10/60
General Public	Focus Groups	525	1	90/60
Healthcare Professionals	Focus Groups	225	1	90/60
General Public	Interview Screening Form	700	1	10/60
Healthcare Professionals	Interview Screening Form	300	1	10/60
General Public	Interviews	350	1	1
Healthcare Professionals Interviews	Interviews	150	1	1
General Public	Survey Screening Forms	5,250	1	10/60
Healthcare Professionals	Survey Screening Forms	2,250	1	10/60
General Public	Surveys	2,625	1	45/60
Healthcare Professionals	Surveys	1,125		45/60
General Public	Pre/Post Tests	1,750	1	45/60
Healthcare Professionals	Pre/Post Tests	750	1	45/60

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2018–07017 Filed 4–5–18; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–18–0943]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Data Collection for the Residential Care Community and Adult Day Services Center Components of the National Study of Long-Term Care Providers to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on December 19, 2017 to obtain comments from the public and affected agencies. CDC received three comments related to the previous notice. This notice serves to

allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov*. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Data Collection for the Residential Care Community and Adult Day Services Center Components of the National Study of Long-Term Care Providers (OMB Control Number 0920–0943, Exp. Date 05/31/2019)—Revision—National Center for Health Statistics, Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Section 306 of the Public Health Service (PHS) Act (42 U.S.C. 242k), as amended, authorizes that the Secretary of Health and Human Services (DHHS), acting through NCHS, ''shall collect statistics on health resources. . . [and] utilization of health care, including extended care facilities, and other institutions.''

NCHS seeks approval to collect data for the residential care community (RCC) and adult day services center (ADSC) survey components of the 2018 National Study of Long-Term Care Providers (NSLTCP). A one year clearance is requested.

Details on the complete study design are as follows. The NSLTCP is designed to (1) broaden NCHS' ongoing coverage of paid, regulated long-term care (LTC) providers; (2) merge with existing administrative data on LTC providers and service users (*i.e.* Centers for Medicare and Medicaid Services (CMS) data on nursing homes and residents, home health agencies and patients, and hospices and patients); (3) update data more frequently on LTC providers and service users for which nationally representative administrative data do not exist; and (4) enable comparisons across LTC sectors and timely monitoring of supply, use, and characteristics of these sectors over time. Data will be collected from two types of LTC providers in the 50 states and the District of Columbia: 2,090 RCCs and 1,650 ADSCs. Data were collected in 2012, 2014, and 2016. The data to be collected in 2018 include the basic characteristics, services, staffing, and practices of RCCs and ADSCs, and demographics, selected health conditions and health care utilization, physical functioning, and cognitive functioning of RCC residents and ADSC participants. The 2018 NSLTCP will include the addition of a contact confirmation call, a call to screen and set an appointment for the services user data collection, and sampling and services user questionnaires. The provider-level data collection has been consolidated into one version of a questionnaire for each setting rather than two versions, and a data retrieval call has been eliminated.

Expected users of data from this collection effort include, but are not limited to CDC; other Department of Health and Human Services (DHHS) agencies, such as the Office of the Assistant Secretary for Planning and Evaluation, The Administration for Community Living, and the Agency for Healthcare Research and Quality; associations, such as LeadingAge, National Center for Assisted Living, American Seniors Housing Association, Argentum (formerly Assisted Living Federation of America), and National Adult Day Services Association; universities; foundations; and other private sector organizations such as the Alzheimer's Association and the AARP Public Policy Institute.

Expected burden from data collection for eligible cases is 80 minutes per respondent: 5 Minutes for a contact confirmation call; 15 minutes for a screener and appointment setting call; 30 minutes for a provider questionnaire; and 30 minutes for a sampling and services user questionnaire. We estimate an eligibility rate for ADSCs of 86% and for RCCs of 76%. One year clearance is requested to cover the collection of data. The burden for the collection is shown in the table below. There is no cost to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	No. of respondents	No. of responses per respondent	Avg. burden per response (in hours)
RCC/ADSC Director/Designated Staff Member	Contact Confirmation Call	3,740	1	5/60
RCC/ADSC Director/Designated Staff Member	Screener and Appointment Setting Call	3,740	1	15/60
RCC Director/Designated Staff Member	RCC Provider Questionnaire	1,589	1	30/60
ADSC Director/Designated Staff Member	ADSC Provider Questionnaire	1,419	1	30/60
RCC/ADSC Director/Designated Staff Member	RCC/ADSC Sampling and Services User Questionnaire.	3,008	1	30/60

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2018–07016 Filed 4–5–18; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended, and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—RFA–CE–18–002, Evaluation of Policies for the Primary Prevention of Multiple Forms of Violence.

Dates: May 23, 2018 and May 24, 2018.

Time: 9:00 a.m.–5:00 p.m., EDT.

Place: DoubleTree by Hilton Hotel Atlanta—Buckhead, 3342 Peachtree Road NE, Atlanta, GA 30326.

Agenda: To review and evaluate grant applications.

For Further Information Contact: Mikel L. Walters, M.A., Ph.D., Scientific Review Official, NCIPC, CDC, 4770 Buford Highway NE, Mailstop F–63, Atlanta, Georgia 30341, Telephone: (404)639–0913; Email: *mwalters@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2018–07051 Filed 4–5–18; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended, and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—CK18–001, Epicenters for the Prevention of Healthcare-Associated Infections (HAIs); Cycle II Multicenter Program Studies and CK18–003, Determining and Monitoring Health Conditions Among US-Bound Refugees and Other Globally Mobile Populations.

Date: May 9, 2018.

Time: 10:00 a.m.–3:00 p.m., EDT.

Place: Teleconference.

Agenda: To review and evaluate grant applications.

For Further Information Contact: Gregory Anderson, M.S., M.P.H., Scientific Review Officer, CDC, 1600 Clifton Road NE, Mailstop E60, Atlanta, Georgia 30329, (404) 718–8833, *gca5@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2018–07053 Filed 4–5–18; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0791]

Exposure-Response Analysis in Drug Development and Regulatory Decision Making; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Prescription Drug User Fee Act of 2017 (PDUFA VI), part of the FDA Reauthorization Act of 2017 (FDARA, highlights the goal of advancing model-informed drug development (MIDD). Exposure-response analysis is a MIDD strategy that has been used in drug development and regulatory decision making. The Food and Drug Administration (FDA or Agency) is opening a docket to receive public comments on experience leveraging exposure-response analysis since publishing the guidance for industry (GFI) entitled ''Exposure-Response Relationships—Study Design, Data Analysis, and Regulatory Applications,'' which was announced in the **Federal Register** on May 6, 2003. Specifically, the Agency wants to identify areas of scientific policy that may need further clarity or elaboration, as well as any obstacles that prevent use of exposure-response analyses in drug development and regulatory review.

DATES: To ensure that the Agency considers your input, submit either electronic or written comments by July 5, 2018.

ADDRESSES: You may submit comments as follows. Electronic comments must be submitted on or before July 5, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery date service acceptance receipt is on or before that date:

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