

surveillance system of such events. The objective of the project is to determine the annual number and temporal trends of SAEs associated with any treatment for LTBI in the United States.

Surveillance of such events will provide data to support periodic evaluation or potential revision of guidelines for treatment of persons with LTBI.

The CDC seeks to request OMB approval for a three-year extension of the previously approved National Surveillance for Severe Adverse Events Associated with Treatment of Latent Tuberculosis Infection—(OMB No. 0920–0773, expires January 17, 2018). This project will continue the passive reporting system for SAEs associated with therapy for LTBI. The system will rely on medical chart review and/or onsite investigations by TB control staff.

Potential respondents are any of the 60 reporting areas for the national TB surveillance system (the 50 states, the District of Columbia, New York City, Puerto Rico, and 7 jurisdictions in the Pacific and Caribbean).

CDC will collect data using the data collection form for SAEs associated with LTBI treatment. Based on previous reporting, CDC anticipates receiving an average of six responses per year from the 60 reporting areas. The data collection form is completed by healthcare providers and health departments for each reported hospitalization or death related to treatment of LTBI and contains demographic, clinical, and laboratory information.

CDC will analyze and periodically publish reports summarizing national

LTBI treatment adverse events statistics and will conduct special analyses for publication in peer-reviewed scientific journals to further describe and interpret these data.

The Food and Drug Administration (FDA) collects data on adverse events related to drugs through the FDA MedWatch Program. CDC is encouraging health departments and healthcare providers to report SAEs to FDA. Reporting will be conducted through telephone, email, or during CDC site visits.

In this request, CDC is requesting approval for approximately 36 burden hours annually. The only cost to respondents is time to gather medical records and time to complete the reporting form.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Physician	NSSAE	6	1	1	6
Nurse	NSSAE	6	1	4	24
Medical Clerk	NSSAE	6	1	1	6
Total					36

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. 2017–17708 Filed 8–21–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–17–0740; Docket No. CDC–2017–0060]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or

continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on the Medical Monitoring Project, which collects interview and medical record data on a probability sample of HIV-diagnosed persons in order to provide national estimates of access to and utilization of HIV-related medical care and services, the quality of HIV-related ambulatory care, and HIV-related behaviors and clinical outcomes.

DATES: Written comments must be received on or before October 23, 2017.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2017–0060 by any of the following methods:

- *Federal eRulemaking Portal:* *Regulations.gov*. Follow the instructions for submitting comments.

- *Mail:* Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *Regulations.gov*, including any personal information provided. For access to the docket to read background documents or comments received, go to *Regulations.gov*.

Please note: All public comment should be submitted through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Leroy Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: omb@cdc.gov.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are

publishing this notice of a proposed data collection as described below.

Comments are invited 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) ways to enhance the quality, utility, and clarity of the information to be collected; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

Medical Monitoring Project (MMP)—(OMB Control Number 0920–0740 Expiration 6/30/2018)—Revision—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC), Division of HIV/AIDS Prevention (DHAP) requests a revision of the currently approved Information Collection Request: “Medical Monitoring Project” expiring June 30, 2018. This data collection addresses the need for national estimates of access to and utilization of HIV-related medical care and services, the quality of HIV-related ambulatory care, and HIV-related behaviors and clinical outcomes.

For the proposed project, the same data collection methods will be used as for the currently approved project. Data would be collected from a probability sample of HIV-diagnosed adults in the U.S. who consent to an interview and abstraction of their medical records. As for the currently approved project, de-identified information would also be extracted from HIV case surveillance records for a dataset, referred to as the minimum dataset, which is used to assess non-response bias, for quality control, to improve the ability of MMP to monitor ongoing care and treatment of HIV-infected persons, and to make inferences from the MMP sample to HIV-diagnosed persons nationally.

No other Federal agency collects such nationally representative population-based information from HIV-diagnosed adults. The data are expected to have significant implications for policy, program development, and resource allocation at the state/local and national levels.

The changes proposed in this request update the data collection system to meet prevailing information needs and enhance the value of MMP data, while remaining within the scope of the currently approved project purpose. The result is a 11% reduction in burden, or a reduction of 786 total burden hours annually. Specifically, the removal of three unfunded project areas reduces

the number of interviews conducted and the number of persons for whom healthcare facility staff will be asked for contact information, assistance with approaching for participation, and pulling medical records.

Changes were made that did not affect the burden, listed below:

- Sampled persons found to have resided in a non-funded project area on the date of sampling will be considered ineligible for the project, because non-funded project areas were deemed ineligible in the first stage of sampling.
- Tracking data reports will no longer be sent to CDC, as this information is no longer needed.
- The average token of appreciation for participants has been increased from \$25 to \$50.
- Changes have been made to the respondent consent form to decrease the reading comprehension level and clarify whom participants should contact for different concerns.
- Forty-two data elements were removed from the minimum data set and forty data elements were added. Because these data elements are extracted from the HIV surveillance system from which they are sampled, these changes do not affect the burden of the project.

This proposed data collection would supplement the National HIV Surveillance System (NHSS, OMB Control No. 0920–0573, Exp. 6/30/2019) in 23 selected state and local health departments, which collect information on persons diagnosed with, living with, and dying from HIV infection and AIDS.

The participation of respondents is voluntary. There is no cost to the respondents other than their time. Through their participation, respondents will help to improve programs to prevent HIV infection as well as services for those who already have HIV.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average hours per response	Total response burden (hours)
Sampled, Eligible HIV-Infected Persons	Interview Questionnaire	7,760	1	45/60	5,820
Facility office staff looking up contact information	N/A	1,940	1	2/60	65
Facility office staff approaching sampled persons for enrollment.	N/A	970	1	5/60	81
Facility office staff pulling medical records	N/A	7,760	1	3/60	388
Total					6,354

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.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Application Requirements for the Low Income Home Energy Assistance Program (LIHEAP) Plan.

OMB No.: 0970-0075.

Description: States, including the District of Columbia, tribes, tribal organizations, and U.S. territories

applying for LIHEAP block grant funds must, prior to receiving federal funds, submit an annual application (Model Plan, ACF-122) that meets the LIHEAP statutory and regulatory requirements. In addition to the Model Plan, grantees are also required to complete the Mandatory Grant Application SF-424-Mandatory, which is the first section of the Model Plan.

The LIHEAP Model Plan is an electronic form and is submitted to the Administration for Children and Families (ACF), Office of Community Services (OCS) through the On-line Data Collection (OLDC) system within GrantSolutions, which is currently being used by all LIHEAP grantees to submit other required LIHEAP reporting forms. In order to reduce the reporting burden, all data entries from each grantee's prior year's submission of the Model Plan in OLDC is saved and re-populated (cloned) into the form for the following fiscal year's application.

OCS seeks renewal of this form without any changes. A sample model plan showing these proposed changes can be found on the U.S. Department of Health and Human Services, ACF/OCS LIHEAP Program Resources page at: <https://www.acf.hhs.gov/ocs/resource/funding-applications>.

On April 3, 2017, ACF published a **Federal Register** Notice seeking 60 days of public comment on this proposed information collection. One state grantee provided comments. ACF revised the Plan to address the comments by ensuring that open field boxes and attachment capability are available if the answer choices are insufficient to address the questions.

The revised model plan can be viewed on the OCS Web site at: <http://www.acf.hhs.gov/programs/ocs/programs/liheap>.

Respondents: State, the District of Columbia, U.S. Territories and Tribal governments.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
LIHEAP Detailed Model Plan	210	1	0.50	105

Estimated Total Annual Burden Hours (all respondents): 105.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201. Attention Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: infocollection@acf.hhs.gov.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: OIRA_SUBMISSION@OMB.EOP.GOV, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2017-17681 Filed 8-21-17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-4885]

Pediatric Advisory Committee; Notice of Meeting; 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 Food and Drug Administration (FDA or the Agency) announces a forthcoming public advisory committee meeting of the Pediatric Advisory Committee (PAC). 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. FDA is establishing a docket for public comments.

DATES: The meeting will be held on September 11, 2017, from 8:30 a.m. to 5:30 p.m. and September 12, 2017, from 8:30 a.m. to 1 p.m.

ADDRESSES: Hilton Washington DC/ Rockville Hotel & Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20852. The hotel's telephone

number is 301-468-1100. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at <http://www3.hilton.com/en/hotels/maryland/hilton-washington-dc-rockville-hotel-and-executive-meeting-ctr-IADMRHF/index.html>.

FDA is establishing a docket for public comment on this document. The docket number is FDA-2017-N-4885. The docket will close on September 13, 2017. Submit either electronic or written comments on this public meeting by that date. Late, untimely comments will not be considered. Electronic comments must be submitted on or before September 13, 2017. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of September 13, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before August 28, 2017, will be provided to the committee. Comments received after that date will be taken into consideration by FDA.