

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                  |
| <b>Total .....</b>  |             |                       |                                    |  | <b>36</b>          |

**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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**BILLING CODE 4163–18–P**

**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](mailto: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                           |
| <b>Total .....</b>  | .....                   | .....                 | .....                              | .....                      | <b>6,354</b>                  |

**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. 2017-17699 Filed 8-21-17; 8:45 am]

BILLING CODE 4163-18-P

**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](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](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<br>respondents | Number of<br>responses per<br>respondent | Average<br>burden hours<br>per response | Total burden<br>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](mailto: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](mailto: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]

BILLING CODE 4184-01-P

**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](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.