

Dated: August 14, 2017.

**Allison Fahrenkopf Brigati**,  
Associate Administrator, Office of  
Government-wide Policy, General Services  
Administration.

[FR Doc. 2017-17680 Filed 8-21-17; 8:45 am]

BILLING CODE 6820-14-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[60Day-17-0773; Docket No. CDC-2017-  
0061]

#### Proposed Data Collections 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 efforts 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  
comments on the information collection  
extension request titled “Adverse  
Events among Persons on Treatment of  
Latent Tuberculosis Infection.”

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

**ADDRESSES:** You may submit comments,  
identified by Docket No. CDC-2017-  
0061 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 comments  
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 A.  
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, Information  
Collection Request Procedures Manual  
33 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

National Surveillance for Severe  
Adverse Events among Persons on  
Treatment of Latent Tuberculosis  
Infection—(OMB Control No. 0920-  
0773, expires 01/17/2018)—Extension—  
Division of Tuberculosis Elimination  
(DTBE), National Center for HIV, Viral  
Hepatitis, STD, and TB Prevention  
NCHHSTP), Centers for Disease Control  
and Prevention (CDC).

#### Background and Brief Description

As part of the national tuberculosis  
(TB) elimination strategy, the American  
Thoracic Society and CDC have  
published recommendations for targeted  
testing for TB and treatment for latent  
TB infection (LTBI) (Morbidity and  
Mortality Weekly Report (MMWR)  
2000;49[RR06];1-54). However, between  
October 2000 and September 2004, the  
CDC received reports of 50 patients with  
severe adverse events (SAEs) associated  
with the use of the two or three-month  
regimen of rifampin and pyrazinamide  
(RZ) for the treatment of LTBI; 12 (24%)  
patients died (MMWR 2003;52[31]:735-  
9). In 2004, CDC began collecting  
reports of SAEs among persons on  
treatment regimen for LTBI.

For surveillance purposes, an SAE  
was defined as any drug-associated  
reaction resulting in a patient’s  
hospitalization or death after at least  
one treatment dose for LTBI. During  
2004-2016, CDC received 66 reports of  
SAEs among recipients of isoniazid  
(INH)-only (n=44), INH-rifapentine  
(RPT) (n=20), rifampin (RIF) (n=1) and  
INH/Levofloxacin (n=1) for LTBI.  
Among INH-only recipients, seven died;  
five, including one child, underwent  
liver transplantation. Among INH-RPT,  
RIF, and INH/Levofloxacin recipients,  
length of hospitalization ranged 1-20  
(median: 3) days; no liver transplants or  
deaths were reported. The RIF recipient  
had an acute kidney injury but  
recovered after three hemodialysis  
treatments [Severe Adverse Events  
(Hospitalization or Death) Among  
Persons on Treatment for Latent  
Tuberculosis Infection, United States,  
January 2004-December 2016. Presented  
at the NAR/IUATLD Conference,  
Vancouver, Canada, February 2017].  
Ten of the SAEs were published in  
Powell, K, et al. Severe Isoniazid-  
associated Liver Injuries among Persons  
Being Treated for Latent Tuberculosis  
Infection-United States, 2004-2008.  
MMWR 2010; 59:224-9.

Reports of SAEs related to LTBI  
treatment regimens have prompted a  
need for this project—a national

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.

[FR Doc. 2017–17708 Filed 8–21–17; 8:45 am]

**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