

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]

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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
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.

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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:*
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