



BILLING CODE: 4163-18-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 [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

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, N.E., 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, N.E., 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, e-mail, 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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