Billing Code: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-14-0773]

Proposed Data Collections Submitted for

Public Comment and Recommendations

The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden, 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. To request more information on the below proposed project or to obtain a copy of the information collection plan and instruments, call 404-639-7570 or send comments to Leroy Richardson, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget (OMB) approval. 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. Written comments should be received within 60 days of this notice.

Proposed Project

National Surveillance for Severe Adverse Events Associated with Treatment of Latent Tuberculosis Infection (OMB No. 0920-0773, expires 11/30/2014) — 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 associated with any 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 2004–2008, CDC received 17 reports of SAEs in 15 adults and two children; all patients had received isoniazid (INH) and had experienced severe liver injury MMWR 2010; 59:224-9).

Reports of SAEs related to RZ and INH 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.

On December 9, 2011, CDC published the *Recommendations for Use of an Isoniazid-Rifapentine Regimen with Direct Observation to Treat Latent Mycobacterium tuberculosis Infection* in MMWR 2011;60(48);1650-1653. Isoniazid-Rifapentin (3HP) is a new biweekly 3-month treatment regimen for LTBI. Since 2011, there have been 28 reports of SAE; 26 of these were associated with 3HP.

The CDC requests approval for a 3-year extension of the previously approved National Surveillance for Severe Adverse Events Associated with Treatment of Latent Tuberculosis Infection. 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).

Data will be collected using the data collection form for SAEs associated with LTBI treatment. Based on previous reporting, CDC anticipates receiving an average of 10 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 also 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 MedWatch: The FDA Medical Products Reporting Program (OMB# 0910-0291, exp. 6/30/2015). 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.

CDC is requesting approval for approximately 60 burden hours annually. The only cost to respondents is time to gather medical records and time to complete the reporting form. There are no costs to respondents other than their time.

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	10	1	1	10
Nurse	NSSAE	10	1	4	40
Medical Clerk	NSSAE	10	1	1	10
Total					60

_____

Leroy 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. 2014-14787 Filed 06/24/2014 at 8:45 am; Publication Date: 06/25/2014]