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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-15-0773]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of

the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 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)

Physician	NSSAE	10	1	1
Nurse	NSSAE	10	1	4
Medical Clerk	NSSAE	10	1	1

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