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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-18-0773]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled National Surveillance for Severe Adverse Events Among Persons on Treatment of Latent Tuberculosis Infection to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on August 22, 2017 to obtain comments from the public and affected agencies. CDC received one substantive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(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. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

National Surveillance for Severe Adverse Events Associated with Treatment of Latent Tuberculosis Infection-(0920-0773, expiration 01/31/2018) — 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

This project seeks a three-year extension to continue the passive reporting system for severe adverse events (SAEs) associated with therapy for Latent Tuberculosis Infection (LTBI). The system will rely on medical chart review and/or onsite investigations by TB control staff. 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. Reports of SAEs related to rifampicin plus pyrazinamide (RZ) and isoniazid (INH) 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.

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. 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. Reporting of SAEs will be conducted through telephone, e-mail, or during CDC site visits.

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.

In this extension request, CDC is requesting approval for approximately 60 burden hours annually. There is no cost to respondents.

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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