



BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-18-18KG; Docket No. CDC-2018-0013]

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 the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Information Collection for U.S. Tuberculosis Follow-up Worksheet for Newly-Arrived Persons with Overseas Tuberculosis Classifications - CDC is proposing a TB follow-up worksheet to capture domestic TB examination data for persons arriving to the U.S. with overseas TB classifications.

DATES: CDC must receive written comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2018-0013 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. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments 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; E-mail: 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 the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. 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;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. 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 submissions of responses.

5. Assess information collection costs.

Proposed Project

Information Collection for U.S. Tuberculosis Follow-up Worksheet for Newly-Arrived Persons with Overseas Tuberculosis Classifications - Existing Information Collection in Use Without an OMB Control Number - National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC highly recommends that persons with overseas classification A or B for TB receive U.S. follow-up evaluations to prevent new transmission of TB. This information will assist CDC in fulfilling its regulatory responsibility to prevent the importation and spread of communicable diseases from foreign countries (42 CFR Part 71) and interstate control of communicable diseases in humans (42 CFR Part 70).

Section 361 of the Public Health Service (PHS) Act (42 USC 264) authorizes the Secretary of Health and Human Services to make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable disease

from foreign countries into the United States. Under its delegated authority in 42 CFR Parts 70 and 71, the Division of Global Migration and Quarantine (DGMQ) works to fulfill this responsibility through numerous activities that include monitoring the arrival of persons with Class A and Class B tuberculosis (TB) conditions and coordinating domestic follow-up examinations to prevent new transmission of TB in the United States.

The Secretary of Health and Human Services also has the legal authority to establish regulations outlining the requirements for the medical examination of aliens before they may be admitted into the United States. This authority is provided under Section 212(a)(1)(A) of the Immigration and Nationality Act (8 U.S.C. § 1182(a)(1)(A)) and Section 325 of the Public Health Service Act 42 U.S.C. 252. These regulations are codified in 42 CFR Part 34, which establish requirements that determine whether aliens can be admitted into the United States, which includes health examinations when aliens attempt to adjust status to lawful permanent residents.

The TB follow-up worksheet is designed to capture U.S. TB examination data for newly arriving persons to the U.S. with overseas classification A and B for TB. The information collected by the TB follow-up worksheet will provide a method of performing several TB prevention activities, both international

and domestic in nature.

The U.S. foreign born population had the highest incidence of TB compared to the U.S. non-foreign born population. CDC strongly recommends incoming persons receive follow-up examinations for TB in the U.S. This data collection will facilitate the methodical collection of TB follow-up outcome data to monitor and track persons with overseas classification A and B for TB and will assist in the national effort to prevent new transmission of TB. To accurately determine rates of TB, recent U.S. arrivals receive domestic follow-up evaluations. U.S. health departments will provide domestic follow-up outcome information to CDC. Without this data, DGMQ will not have a method of tracking and monitoring newly arrived persons with overseas classification A or B for TB. DGMQ will use information reported on the worksheet to ensure that TB programs are effectively tracking new foreign arrivals and coordinating follow-up evaluations with local clinicians. To monitor and evaluate domestic TB program performance, CDC needs to collect data on all elements of TB domestic follow-up up evaluations including CXR, diagnosis, and U.S. treatment outcomes.

The Division of Global Migration and Quarantine (DGMQ) staff along with other federal partners will also use this information to evaluate overseas panel physician performance and overseas prevention activities. To evaluate panel physician

performance and overseas TB prevention activities, CDC needs to know the results of domestic chest x-ray (CXR), CXR comparison sputum smear and culture, and TB diagnosis along with domestic reviews of overseas treatment.

There are no costs to respondents except their time to complete the questionnaires. The annualized burden for this data collection is 2,200 hours.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
EDN data entry staff at state and local health departments	U.S. Tuberculosis Follow-up Worksheet for Newly-Arrived Persons with Overseas Tuberculosis Classifications	550	48	5/60	2,200
Total					2,200

*Leroy A. Richardson,
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 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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