

Prevention and the Agency for Toxic Substances and Disease Registry.

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[FR Doc. 2024–19624 Filed 8–30–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–24–1102]

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 “Information Collection for Tuberculosis Data from Panel Physicians” 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 June 4, 2024 to obtain comments from the public and affected agencies. CDC received two 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. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. 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

Information Collection for Tuberculosis Data from Panel Physicians (OMB Control No. 0920–1102, Exp. 12/31/2024)—Revision—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention’s (CDC), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Global Migration Health (DGMH), Immigrant and Refugee Health Branch (IRHB), requests approval for Revision to an approved information collection. CDC requests this data collection approval for three years.

Respondents for this data collection request are U.S. panel physicians. Panel physicians are medically trained, licensed, and experienced medical doctors practicing overseas who are appointed by the local U.S. Embassy or Consulate General to perform medical examinations for prospective immigrants to the United States. More than 760 panel physicians perform overseas pre-departure medical examinations at 333 panel sites, in accordance with requirements, referred to as Technical Instructions, provided by the CDC’s DGMH, Quality Assessment Program (QAP). The QAP is housed in the IRHB. The role of QAP is to assist and guide panel physicians in the implementation of the Technical Instructions; evaluate the quality of the overseas medical examination for U.S.-bound immigrants and refugees; assess potential panel physician sites; and provide recommendations to the U.S. Department of State in matters of immigrant medical screening.

Screening for tuberculosis (TB) is a particularly important component of the immigration medical exam and allows panel physicians to diagnose active TB disease prior to arrival in the United States. As part of the Technical Instructions requirements, panel physicians perform chest x-rays and laboratory tests that aid in the identification of tuberculosis infection (Class B1 applicants) and diagnosis of active tuberculosis disease (Class A, inadmissible applicants). CDC uses these classifications to report new immigrant and refugee arrivals with a higher risk of developing TB disease to U.S. state and local health departments for further follow-up. Some information that panel physicians collect as part of the medical exam is not reported on the standard Department of State forms (DS-forms), thereby preventing CDC from evaluating TB trends in globally mobile populations and monitoring program effectiveness.

In 2007, CDC revised the Tuberculosis Technical Instructions to include several new requirements for Mycobacteria tuberculosis (MTB) testing and treatment. Important changes included the requirements for: (1) sputum cultures in addition to sputum smears; (2) tuberculin skin tests or interferon gamma release assays (beginning in 2009) for certain children aged 2–14 years examined in countries where the World Health Organization (WHO) estimated TB incidence is ≥ 20 per 100,000 persons; (3) drug-susceptibility testing of positive isolates; and (4) treatment being delivered as directly observed therapy (DOT) throughout the entire course.

Since implementation of these new Culture and Directly Observed Therapy TB Technical Instructions (CDOT TB TI), overseas TB case detection has increased by an estimated 60% and allowed U.S. public health programs to save millions of dollars annually. Overseas TB screening data (referred to by DGMH as ‘TB Indicator data’) is critical to support the continued analysis of these trends and the monitoring of TB control efforts in the U.S. DGMH’s TB Indicator data provides valuable epidemiologic data on globally mobile populations and allows CDC to monitor the effectiveness and impact of CDC’s Technical Instructions in diagnosing applicants with TB disease. This data will be used to:

- Improve quality assurance efforts and monitor proficiency of TB screening programs overseas
- Estimate the impact of the CDOT TB TI on the immigrant screening program by analyzing the number of smear negative/culture positive TB

cases. These cases represent the number of TB cases that would have been missed under the old screening program.

- Compare TB Indicator incidence rates to WHO country-specific TB incidence rates for internal quality assessment purposes only.

- Detect and resolve problems at panel sites demonstrating lower than expected TB detection rates.

Data will primarily be used internally to monitor program impact, but may also be shared with state and local health authorities involved in TB control. Information dissemination may

include abstract submission to scientific conferences, including the Union World Conference on Lung Health, the National TB Controllers Association and the Panel Physician Training Summits.

Information will be collected from each Panel Physician site using a web form created with REDCap on an annual basis. The TB-related information that is sent to CDC is aggregate in nature, and no personal identifying information (PII) from any applicant for U.S. immigration is included. Information to be collected using the spreadsheet includes:

- number of applicants screened,
- age categories of applicants,

- number of abnormal chest x-rays,
- acid fast bacilli (AFB) smear results,
- mycobacterium tuberculosis (MTB) cultures,
- drug susceptibility test (DST) results, and
- TB treatment disposition.

The changes in this Revision include the additional collection of molecular testing data. CDC requests OMB approval for an estimated 999 annual burden hours. There is no cost to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondents | Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hours) |
|--------------------------------------|-------------------------------------|-----------------------|------------------------------------|--|
| International Panel Physicians | TB Indicators REDCap Web Form | 333 | 1 | 3 |

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[FR Doc. 2024-19612 Filed 8-30-24; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-24-23FN; Docket No. CDC-2024-0061]

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, Menthol-Flavored Tobacco Products Policy Evaluation. The proposed activity aims to collect data on menthol-flavored tobacco product use, any tobacco use, quit rates, and product

switching behaviors among adults 18 years of age and older.

DATES: CDC must receive written comments on or before November 4, 2024.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2024-0061 by either of the following methods:

- *Federal eRulemaking Portal:* www.regulations.gov. Follow the instructions for submitting comments.

- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21-8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to www.regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (www.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 Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21-8, Atlanta, Georgia 30329; Telephone: 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 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;

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; and

5. Assess information collection costs.