

**Information Collection for  
The EDN Tuberculosis Follow-Up Worksheet for Newly-  
Arrived Persons with Overseas Tuberculosis  
Classifications**

Request for OMB Approval of an Information Collection in Use without an  
OMB Control Number

**April 3, 2018**

**Supporting Statement A**

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- **Goal of the study:** The purpose of this data collection is to follow-up with and assess newly-arrived persons in the United States who received overseas tuberculosis classifications in order to assist in the national effort to prevent new transmission of tuberculosis. Tuberculosis classification and US tuberculosis follow-up medical examination information on newly-arrived persons in the United States is available through the Electronic Disease Notification System (EDN).
- **Intended use of the resulting data:** The information collected by “The EDN Tuberculosis Follow-Up Worksheet for Newly-Arrived Persons with Overseas Tuberculosis Classifications,” also commonly known as the TB Follow-Up Worksheet, will provide outcomes for improving national tuberculosis prevention programs. The Division of Global Migration and Quarantine (DGMQ) staff, along with other federal partners will use this information to assess overseas panel physician performance, overseas prevention activities, and tuberculosis control program performance in the United States. Specifically, to improve overseas panel physician performance and tuberculosis prevention activities, the Centers for Disease Control and Prevention (CDC) needs information on the US domestic chest x-rays, chest x-ray comparison sputum smears and cultures, and diagnosis results along with US domestic reviews of overseas treatment. To monitor and assess US domestic tuberculosis program performance, CDC needs to collect data on all elements of US tuberculosis follow-up medical examination information, including chest x-rays, diagnosis, and US treatment outcomes.
- **Methods to be used to collect:** Data for each person with overseas tuberculosis classification requiring follow-up will be collected by state and local health departments through the Electronic Disease Notification (EDN) System.
- **The subpopulation to be studied:** Persons requiring overseas medical examinations, including, but not limited to, immigrants and refugees newly arriving to the United States with noted Class A or B tuberculosis classification recommended for follow up by state/local health departments.
- **How data will be analyzed:** CDC will analyze patient outcome data on a quarterly basis and share aggregate reports with state and local health departments.

## 1. Circumstances Making the Collection of Information Necessary

This information collection was initiated in 2008 without the Office of Management and Budget (OMB) approval based on the Centers for Disease Control and Prevention’s (CDC) understanding of the clinical exemption from Paperwork Reduction Act review. After OMB visited CDC in 2017, CDC received clarification regarding the intent of the clinical exemption and began to develop an information collection request (ICR) to bring the collection into compliance.

This ICR is composed of “The EDN Tuberculosis Follow-Up Worksheet for Newly-Arrived Persons with Overseas Tuberculosis Classifications” (Attachment 3). This worksheet is needed to ensure that newly arriving persons who have undergone the required medical screening examinations prior to coming to the United States are examined and further assessed in the United States.

The Secretary of Health and Human Services has the legal authority and delegates that authority to the CDC director to establish regulations outlining the requirements for the medical examination of persons 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)) (Attachment 1A) and Section 325 of the Public Health Service Act 42 U.S.C. 252 (Attachment 1B). These regulations are codified in 42 CFR Part 34 (Attachment 1C), which establishes requirements that determine whether persons can be admitted into the United States, which includes health examinations when persons attempt to adjust status to lawful permanent residents. In addition, the Public Health Service Act, Section 325 “Examination of Alien’s” (42 U.S.C. 252), the “Immigration and Nationality Act,” Section 212(g), and the “Application for Waiver of Grounds of Inadmissibility” (8 U.S.C. 1182(g)) authorizes CDC to maintain a system for the surveillance and periodic medical evaluation of immigrant persons with tuberculosis.

Due to the highly infectious nature of tuberculosis, it is imperative to implement measures of preventing new transmission from recently arrived persons to the general US population. According to CDC, the 2016 tuberculosis case rate was 14.6 per 100,000 for foreign-born persons compared to 1.1 per 100,000 for US-born persons.<sup>1</sup> The proportion of tuberculosis cases occurring in the foreign-born population was found to be approximately 67.9% of the national case total.<sup>1</sup> Given the high-case rate of tuberculosis in the US foreign-born population, it is essential to provide domestic follow-up examinations for tuberculosis in persons within thirty days of their arrival to help reduce the risk of transmitting tuberculosis to the general US population.

There is no other federal level surveillance system that collects data on tuberculosis follow-up outcomes for newly arriving individuals. The closest surveillance system, the Report of Verified Case of Tuberculosis (RVCT) surveillance reporting form (OMB Control No. 0920-0026), only collects information on tuberculosis cases, not those diagnosed with other tuberculosis conditions such as latent tuberculosis infection (LTBI) or no tuberculosis exposure or infection.

## **2. Purpose and Use of Information Collection**

A visa medical examination is one means of evaluating the health of persons applying for entry into the United States. Through this examination, individuals are classified as Class A, B, or no class. Class A individuals are not granted a visa unless they have a signed treatment agreement with a receiving physician in the United States. Only under these circumstances are these individuals granted a waiver for visa approval. Those assigned a Class B for tuberculosis classification have received treatment prior to arrival in the United States and are highly recommended to receive US follow-up medical examination information to prevent new transmission of tuberculosis. This is the primary rationale for collecting US domestic tuberculosis follow-up information.

The Division of Global Migration and Quarantine (DGMQ) collaborated closely with several partners including the National TB Controllers Association (NTCA), Electronic Disease Notification (EDN) System workgroup, and the Division of Tuberculosis Elimination (DTBE) to develop the proposed

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<sup>1</sup> Schmit KM, Wansaula Z, Pratt R, Price SF, Langer AJ. Tuberculosis — United States, 2016. *MMWR Morb Mortal Wkly Rep* 2017;66:289–294. DOI: <http://dx.doi.org/10.15585/mmwr.mm6611a2>

worksheet which captures US follow-up medical examination information after a person with tuberculosis classification has arrived in the US as described below. The overseas medical examination determines whether the applicant has an inadmissible condition of public health significance (a Class A condition) or has a health-related condition that is admissible but that might require extensive medical treatment or follow-up (a Class B condition), such as treated tuberculosis. Applicants with Class A (inadmissible) conditions can only enter the United States if they are granted a waiver. Applicants who have Class A conditions include those who 1) have a communicable disease of public health significance, 2) do not have documentation of having received vaccinations against vaccine-preventable diseases, 3) have a physical or mental disorder with associated harmful behavior, or 4) abuse or are addicted to drugs (42 USC 252, 8 USC 1182, and 8 USC 1222 provide for the physical and mental examination of applicants in accordance with regulations prescribed by the HHS Secretary.)<sup>2</sup>

Individuals applying for US immigration are screened abroad by Panel Physicians according to CDC Technical Instructions and carry copies of their immigrant medical examination documentation. Upon arrival to the United States, a copy of this documentation is given to Customs and Border Protection (CBP). If the individual has a Class condition that was identified during his/her overseas medical examination, CBP provides the medical examination documentation to CDC. CDC transcribes this information into EDN and forwards the relevant information to the states where the arriving immigrants settle. US public health departments and other authorized healthcare providers access EDN and use this information during CDC-recommended post-arrival medical examinations for immigrants and refugees. After the exam, US health departments complete The EDN Tuberculosis Follow-Up Worksheets for Newly-Arrived Persons with Overseas Tuberculosis Classifications, which assists 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).

The TB follow-up worksheet is designed to capture domestic tuberculosis examination data for persons arriving to the United States with overseas tuberculosis classification. The information collected by the tuberculosis follow-up worksheet will provide a method of performing several tuberculosis prevention activities. DGMQ staff, along with other federal partners, use this information to assess overseas panel physician performance, overseas prevention activities, and US domestic tuberculosis program performance. To assess panel physician performance and overseas tuberculosis prevention activities, CDC needs to know US domestic chest x-rays, chest x-ray comparison sputum smears and cultures, and diagnosis results along with US domestic reviews of overseas treatment. To monitor and assess US domestic tuberculosis program performance, CDC needs to collect data on all elements of US domestic tuberculosis follow-up medical examination information, including chest x-rays, diagnoses, and US treatment outcomes.

Indicators will be assessed to measure US domestic tuberculosis program performance, including the percentage of persons with class B tuberculosis classifications with complete US evaluations of medical

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<sup>2</sup> Lee D, Philen R, Wang Z, McSpadden P, Posey DL, Ortega LS, Weinberg MS, Brown C, Zhou W, Painter JA. Disease Surveillance Among Newly Arriving Refugees and Immigrants — Electronic Disease Notification System, United States, 2009. MMWR Morb Mortal Wkly Rep 2013;62:1-20.  
<https://www.cdc.gov/mmwr/preview/mmwrhtml/ss6207a1.htm>

examinations. This program performance monitoring activity will be ongoing throughout the year. State and local health departments will voluntarily report evaluation outcome findings on a continuous basis once evaluation results for an individual become available.

The proposed worksheet contains sections that allow US physicians to review overseas chest x-rays and treatment and indicate any concerns or errors. A negative consequence of not collecting this information is that DGMQ will not be able to quickly analyze data to determine which panel physicians have inaccuracies. Plans for formal evaluation of US panel physicians are contingent on OMB approval of “The EDN Tuberculosis Follow-Up Worksheet for Newly-Arrived Persons with Overseas Tuberculosis Classifications.”

If instructions for tuberculosis diagnosis and treatment are followed properly overseas, immigrants and refugees with class B tuberculosis classifications should not have tuberculosis disease during their US follow-up examinations. The form will help DGMQ understand what factors may contribute to a US domestic diagnosis of tuberculosis. The worksheet contains a section that collects patient diagnoses and treatment recommendations. Without this information, DGMQ staff will not be able to accurately pinpoint what factors contributed to a tuberculosis disease diagnosis domestically. This form of monitoring is ongoing and will occur with every instance a person is diagnosed with tuberculosis disease during follow-up examinations.

### **3. Use of Improved Information Technology and Burden Reduction**

All (100%) responses will be collected electronically through the secure EDN website to reduce the burden at the state and local level in accordance with the Government Paperwork Elimination Act (GPEA), Public Law 105-277, title XVII. The information in the follow-up worksheet will be collected by state and local health departments from their respective local health clinicians. Follow-up outcome information will be collected either in-person, fax, or over the telephone by the state or local health departments. Once the state and local health departments receive information regarding domestic examination results, their designated EDN data entry staff will report data electronically in the secure EDN system.

### **4. Efforts to Identify Duplication and Use of Similar Information**

There is no other federal level surveillance system that collects data on tuberculosis follow-up outcomes for this distinct population.

The CDC Division of Tuberculosis Elimination (DTBE) uses several data collection systems to obtain tuberculosis information from state and local health departments. Although DTBE collects information regarding tuberculosis cases in the US population through their Report of Verified Case of Tuberculosis (RVCT), it does not collect information on non-tuberculosis cases or those that are LTBI. Efforts were taken to ascertain the degree of duplication at the state and local level through direct communications with state and local health departments through informal conversations with the National Tuberculosis Controller’s Association and the EDN workgroup. Information of a similar nature may be collected by state and local health departments using their own reporting tools; however, there has been no national level data collection on US domestic tuberculosis follow-up examinations of all class A or B persons.

The follow-up worksheet not only collects information on persons who become tuberculosis cases in the United States but persons with other diagnoses as well. Essentially, the form will be used to collect information on persons who are diagnosed as LTBI; no tuberculosis exposure or infection; active tuberculosis disease; old, healed tuberculosis; and inactive tuberculosis disease.

DGMQ understands that there may be minimal duplication of reporting data for tuberculosis cases. However, DGMQ collaborates with DTBE to alleviate the burden of duplication at the state and local levels. DGMQ anticipates that the probability of a person being diagnosed with tuberculosis disease domestically is generally low considering persons cannot enter the United States with active tuberculosis unless a waiver is acquired.

#### **5. Impact on Small Businesses or Other Small Entities**

The follow-up worksheet should not have a direct impact on small businesses or other small entities given that data is collected directly from state and local health departments.

#### **6. Consequences of Collecting the Information Less Frequently**

The frequency of data collection will be ongoing and will occur when a person with an overseas Class A or B tuberculosis classification receives a US medical examination for tuberculosis. As soon as US medical examination results become available, state and local health departments should report results to CDC in a timely manner. There are several consequences of not obtaining information from state and local health departments in a routine manner. CDC staff directly involved with evaluating overseas panel physicians will not be able to effectively monitor panel physician performance. It is important for CDC to immediately target underperforming state and local tuberculosis programs to ensure that no new transmission of tuberculosis occurs. There are no legal obstacles to reducing burden. Collecting information on an ongoing basis for state and local health departments will prove to be less burdensome because it allows them to methodologically collect and report information rather than waiting to report semi-annually, which would result in an excessive backlog.

Respondents—EDN data entry staff at state and local health departments—will complete the TB follow-up worksheet, on average, 48 times per year.

#### **7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

This request fully complies with the regulation 5 CFR 1320.5.

Frequency of data collection is not inconsistent with the guidelines, as discussed in Section A6. The frequency of data collection is determined by the frequency that a person with an overseas tuberculosis classification is assessed in the United States, which occurs on a continual basis.

#### **8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency**

A. A 60-day Federal Register Notice was published in the *Federal Register* on January 31, 2018, vol. 83, No. 21, pp. 4484 (Attachment 2). CDC received nine non-pertinent comments (Attachments 2a-2j). CDC's standard response was sent.

B. EDN staff members at CDC participate in discussions with the NTCA EDN workgroup on a monthly basis. The workgroup is a forum where EDN users at state and local health departments can express feedback and concerns to other EDN users and CDC staff. These EDN users are mostly tuberculosis controllers and refugee health coordinators at state and local health departments from different regions throughout the United States. CDC was able to obtain feedback on the availability of data, frequency of collection, clarity of instruction and record keeping, disclosure, and the data elements to be recorded. EDN users reported that it would be possible to collect patient outcome data from local health clinicians. The workgroup agreed that data should be reported on an ongoing basis to ensure accurate, timely, and organized reporting. A follow-up worksheet guide was created to instruct users how to properly complete the worksheet; this worksheet was reviewed by the EDN workgroup. A sub-workgroup committee was developed to agree on which data elements would be essential to collect, how the worksheet should be formatted, and how the information would be disclosed. Disclosure may be made to state health departments, city health departments, the courts, private physicians, or other health care facilities that will provide medical care for immigrants or refugees. Disclosure may be made to a congressional office from the record of an individual in response to a verified inquiry from the congressional office made at the written request of that individual.

EDN workgroup members provided the following feedback:

1. Information collected on the TB follow-up worksheet would be useful for performing internal program performance assessments and other useful analyses.
2. The worksheet should be reported to CDC in a timely manner and on an ongoing basis.
3. Reporting should be electronic to alleviate burden at the state and local level and to adhere to the Paperwork Reduction Act.
4. The worksheet should capture reasons for treatment incompleteness along with medical examination incompleteness.

All EDN users will be able to voice their feedback during semi-monthly EDN workgroup calls, email correspondences, and directly to the EDN program management. Additional feedback will be collected from users through a qualitative EDN User Assessment (OMB Control No. 0920-1071). Information collected through the EDN User Assessment will be reviewed and considered for future system upgrades.

## **9. Explanation of Any Payment or Gift to Respondents**

Not applicable.

## **10. Protection of the Privacy and Confidentiality of Information Provided by Respondents**

The National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) reviewed this submission and determined that the Privacy Act does apply. The applicable System of Records Notice is 09-20-0103 Alien Tuberculosis Follow-Up Program.



Through Title 8 and 42 of the US Code and the Refugee Act of 1980 [Immigration and Nationality Act, Section 412. (8 U.S.C. 1522)(b)(4)], DHHS/CDC has regulatory authority for the medical examination of refugees and is responsible for providing notifications about persons with class A (such as active tuberculosis) or class B medical classifications. Care is taken to protect the personal information of newly arrived persons. The Privacy Impact Assessment for EDN is attached (Attachment 4).

## **11. Institutional Review Board (IRB) and Justification for Sensitive Questions**

### Institutional Review Board (IRB)

NCEZID’s Human Subjects Advisor has determined that information collection is not research involving human subjects. IRB approval is not required (Attachment 5).

### Justification for Sensitive Questions

“The EDN Tuberculosis Follow-Up Worksheet for Newly-Arrived Persons with Overseas Tuberculosis Classifications” will collect information on US evaluation outcomes, overseas and domestic treatment recommendations, and domestic tuberculosis diagnoses. Demographic information will be pre-populated by the EDN system to help state and local health departments locate recently-arrived persons. These data elements are important, but limited to those critical to implementing measures to reduce the risk of tuberculosis transmission in the United States.

Data will be used to assess US tuberculosis program performance. Health departments will be assessed based on attempts to reduce the risk of tuberculosis transmissions by locating persons, coordinating medical follow-up for tuberculosis, and reporting follow-up outcome data. Without this information, there will be no way to ensure health departments are successfully assessing recently-arrived persons on a national level.

## **12. Estimates of Annualized Burden Hours and Costs**

### A. Estimated Annualized Burden Hours

There were approximately 28,418 arrivals with tuberculosis class classifications in 2016. Given the National Tuberculosis Program Objectives and Performance Target for 2020’s goal of a 93% treatment initiation rate for immigrants and refugees<sup>3</sup>, the estimated target number of individuals for follow-up annually is 26,429. There are currently 550 EDN users. By dividing the target number of individuals needing follow-up by the number of EDN users, we estimate approximately 48 responses per respondent. The estimated time to complete a follow-up form is approximately thirty minutes for each worksheet. These approximations yielded 13,200 total burden hours.

| Type of Respondent      | Form Name            | No. of Respondents | No. Responses per Respondent | Avg. Burden per response (in hrs.) | Total Burden (in hrs.) |
|-------------------------|----------------------|--------------------|------------------------------|------------------------------------|------------------------|
| EDN data entry staff at | The EDN Tuberculosis | 550                | 48                           | 30/60                              | 13,200                 |

<sup>3</sup> <https://www.cdc.gov/tb/programs/evaluation/indicators/default.htm>

|                                    |  |  |  |  |        |
|------------------------------------|--|--|--|--|--------|
| state and local health departments | Follow-up Worksheet for Newly-Arrived Persons with Overseas Tuberculosis Classifications |  |  |  |        |
| <b>Total</b>                       |  |  |  |  | 13,200 |

#### B. Estimated Annualized Burden Costs

Based on the 2016 national occupational employment and wages data from the Bureau of Labor Statistics, we assumed that EDN data entry staff located at state and local health departments fell under the epidemiologist category under the state government classification in the Life, Physical, and Social Science Occupation category (<http://www.bls.gov/oes/current/oes191041.htm>). The mean income for an epidemiologist at the state level was calculated to be \$37.37 hourly. Total respondent costs were calculated to be \$493,284 per year.

| Type of Respondent   | Form Name   | Total Burden Hours | Hourly Wage Rate | Total Respondent Costs |
|--|---|--------------------|------------------|------------------------|
| EDN data entry staff at state and local health departments | The EDN Tuberculosis Follow-Up Worksheet for Newly Arrived Persons with Overseas Tuberculosis Classifications | 13,200             | \$37.37          | \$493,284              |
| <b>Total</b>   |   |                    |                  | \$493,284              |

#### 13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no costs to respondents other than their time to participate.

#### 14. Annualized Cost to the Government

The estimated annual cost to the federal government for this project specifically was calculated to be \$139,500 per year.

| Required Staff        | GS Level/GS Level Equivalent | Cost (per hour) | No. of personnel | % dedicated to project (total hours per week) | Estimated Annual Cost | Comments                            |
|-----------------------|------------------------------|-----------------|------------------|---|-----------------------|-------------------------------------|
| Public Health Advisor | 13                           | \$53.20         | 1                | 8% (3.2)                                      | \$8,700               | In charge of oversight and analyses |

|                               |    |         |   |        |           |   |
|-------------------------------|----|---------|---|--------|-----------|---|
| Epidemiologist                | 13 | \$53.20 | 1 | 5% (2) | \$5,400   | Supervises project  |
| Information Technology Staff  | 13 | \$53.20 | 1 | 5% (2) | \$5,400   | In charge of managing database and generating system report |
| Information Technology System |    |         |   |        | \$120,000 | Estimated annual running costs of EDN system                |
| <b>Total</b>                  |    |         |   |        | \$139,500 |   |

**15. Explanation for Program Changes or Adjustments**

This is the first time CDC is requesting approval for this information collection. No program changes or adjustments are requested.

**16. Plans for Tabulation and Publication and Project Time Schedule**

This collection is ongoing and the frequency of submission to CDC would depend on the number of arrivals with Class A or B tuberculosis classifications. Annual reports summarizing aggregate patient outcome data will be provided to CDC staff. Aggregate reports for state and local health departments will be generated as needed through the EDN system. Aggregated reports will not contain personal identifiable information to protect the privacy of persons receiving US domestic tuberculosis follow-up treatment. These aggregated reports will help federal, state, and local programs directly involved with tuberculosis follow-up determine their program’s performance.

**17. Reason(s) Display of OMB Expiration Date is Inappropriate**

CDC does not request an exception to the display of an expiration date.

**18. Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification.

## **Attachments**

Attachment 1A – Immigration and Nationality Act 8 U.S.C. § 1182

Attachment 1B – Public Health Service Act 42 U.S.C. 252

Attachment 1C – 42 CFR Part 34

Attachment 2 – 60-day Federal Register Notice

Attachment 2a – Public Comment

Attachment 2b – Public Comment

Attachment 2c – Public Comment

Attachment 2d – Public Comment

Attachment 2e – Public Comment

Attachment 2f – Public Comment

Attachment 2g – Public Comment

Attachment 2h – Public Comment

Attachment 2i – Public Comment

Attachment 2j – Public Comment

Attachment 3 – The EDN Tuberculosis Follow-Up Worksheet for Newly-Arrived Persons with Overseas Tuberculosis Classifications

Attachment 4 – Electronic Disease Notification System Privacy Impact Assessment

Attachment 5 – CDC Non-Research Determination