Information Collection for Tuberculosis Data from Referring Entities to CureTB

Information collection in use without a control number

OMB No. 0920-XXXX

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Statement A

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- **Goal of data collection**: To provide continuity of care for individuals affected by TB who enter US jurisdictions from foreign nations who or who leave US jurisdictions bound for foreign nations.
- **Intended use of the resulting data**: To improve the continuous and appropriate care for individuals affected by TB as they move between the US and foreign nations.
- **Methods to be used to collect**: Review of medical and demographic information provided by referring entities. Follow up with treating physicians to determine treatment outcomes.
- **The subpopulation to be included as respondents**: Individuals affected by TB who are expected to leave or enter US jurisdictions and need ongoing TB care and follow-up.
- **How data will be analyzed:** Identify demographics, clinical features and outcomes of referred individuals for quality assurance and program management purposes.

PART A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention's (CDC), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Global Migration and Quarantine (DGMQ), requests approval for information collection from entities that partner with CureTB for continuity of care services.

The respondents are nurse practitioners, registered nurses, and physicians working for organizations within the United States and other countries who provide diagnostic and treatment services to individuals affected by TB. The organizations are primarily state and local health departments, but include immigration centers, correctional facilities, and foreign national TB programs. Individual TB patients may also be respondents if critical clinical or contact information is missing from their referral and CureTB follows-up with them to fill-in gaps to complete the referral service. All 50 US states and territories may refer TB patients to the CureTB program. To date, CureTB has also received referrals from Mexico and Guatemala.

This information has been provided to CureTB by these entities for over 20 years; however, the leadership and oversight of CureTB has transitioned from the County of San Diego to CDC DGMQ, since the activities align with federal TB control priorities and with the transition of key CureTB management from San Diego County Public Health to CDC. CDC CureTB's mission is also aligned with CDC DGMQ's public health goals to reduce the spread of disease in globally mobile populations and those populations living along the U.S. Mexico border.

CDC requests this data collection approval for three years. CDC had not previously obtained OMB approval for this data collection because CureTB and key staff were previously solely within the County of San Diego and no federal collection of information was ongoing.

CureTB started in the County of San Diego's TB Control Branch to assist with continuity of care for TB patients in the immediate California-Mexico border region. CureTB expanded its services to TB programs throughout the US and for patients moving between countries beyond the Mexican border, and to immigration facilities. The program is now transitioning to CDC DGMQ to augment its mission of improving the health of migrating populations. CDC CureTB will be able to leverage national health authority partners who are accustomed to working with

national versus local levels. In addition, CDC CureTB staff can access the Quarantine Activity Reporting System data system, which is a federal database used to follow patients with infectious diseases, such as TB, which pose a risk for travel. CDC CureTB information will assist federal partners in assuring patients do not travel back to the US until they have adequate treatment.

To achieve CDC/DGMQ's mission, CDC CureTB will continue its work with domestic and international programs to protect the U.S. public by preventing the global development of drug resistance and reducing disease transmission and importation of infectious TB. These goals are accomplished through CDC CureTB referral and continuity of care services for mobile TB patients. Throughout the world, nearly 500,000 individuals have newly diagnosed multi-drug resistant TB each year, a type of TB that is extremely costly and difficult to successfully treat. Lack of treatment adherence and inappropriate selection of medications are prime reasons for the continued emergence and spread of resistant strains. To combat this, CDC CureTB assures patients understand how to remain adherent despite moving between nations and provides information to the health care team that will be continuing care about each patient's TB strain and tailored medication regimen. CDC CureTB, through the referring partners, gathers demographic and clinical information for each patient, and connects that individual to care through provision of accurate information about how to locate the correct downstream provider and assurance that real-time information is given directly to medical providers and public health authorities in receiving nations. As stated above, within CDC DGMQ, CureTB is able to leverage health authority partners in countries around the world to better assure continuity of care and can expand the countries served to a global reach.

Assurance of treatment completion is an important public health strategy for TB. Treatment length can span from 4-18 months, and protocols, drug availability, and healthcare infrastructure varies by country. Language and communication barriers also limit information sharing across nations. CDC CureTB provides up-to-date, accurate information between providers, as well as assisting patients to continue treatment as they transit between countries. One of CDC CureTB's key services is bridging the language divide that otherwise limits the ability of providers in different countries to communicate. Services are offered in all languages for patients and downstream providers. CDC CureTB has also been successful because of its strong partnerships with receiving countries, which streamlines the provision and receipt of information; critical in maintaining seamless continuity of care. The information collected by CDC CureTB provides documentation for successful patient follow-up and allows assessment of strategies for improving outcomes. This information is not reported in other systems, thereby preventing CDC from evaluating TB treatment completion outcomes in globally mobile populations and monitoring program effectiveness.

The information collection for which approval is sought is in accordance with CDC DGMQ's mission to reduce morbidity and mortality among immigrants, travelers, and other globally mobile populations, and to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the U.S. This mission is supported by the Section 361 of the Public Health Service Act regulations found in 42 Code of Federal Regulations part 70 and 71 (Attachments A1, A2, and A3, respectively).

2. Purpose and Use of Information Collection

Information will be collected from the referring entities, which are state and local health departments and federal correctional agencies, whenever the referring entities provide clinical services to an individual with TB who has imminent plans to relocate, needs continuity of care in their new location, and CDC CureTB is contacted to assist with coordinating that care. TB patients may also be a respondent if critical clinical or contact data is missing and requires follow-up by CureTB to complete a patient's referral information set. The information is as follows:

- patient name, date of birth, sex
- contact information for patient
- expected location where patient will be moving to (e.g. country, state, municipality)
- tuberculosis laboratory results
- tuberculosis treatment start date, medications
- contact information for referring entity

The request for CDC CureTB services comes from the referring entities and they supply the information at the time the patient is likely to leave their jurisdiction. The referring entities update information only if relevant information to the patient's care becomes available to them after their first communication with CDC CureTB. Therefore, information is already largely collected by CDC CureTB only at one point in time, with subsequent information only collected if departure is delayed or when initially pending information becomes available and this is beyond the control of CDC.

Post relocation of the TB patient, data is also collected from the receiving physicians to determine patient outcomes. CDC Cure TB contacts the physician an average of every two months during the standard TB treatment process. The following data is collected:
1) Is patient still on treatment? Yes or No
2) If yes, what medications?
3) What is anticipated data of treatment completion?
4) If not, what is the final outcome?
Standard international outcomes:

- Lost
- Abandoned
- Died
- Stopped for medical reasons
- Completed treatment

The data provides valuable information on globally mobile populations and allows CDC to assist in continuity of TB care and monitor the effectiveness of the program. This data will be used to:

- Assure individuals are linked for follow-up care based on accurate and complete clinical information sharing between partnering countries.
- Estimate the impact of CDC CureTB in assuring TB patients who exit the US receive appropriate continuity of care services.
- Identify key countries where establishment of high level continuity services will have the largest impact on morbidity in the US.
- Detect and resolve problems at domestic sites demonstrating lower than expected TB referral rates.

Data will primarily be used to assist in continuity of TB care for mobile populations and will, therefore, be provided to specific downstream health entities and providers responsible for continuing care and management of the patient. Data will also be used internally to monitor program impact. Aggregated data may be shared with health authorities involved in TB control and dissemination may include abstract submission to scientific conferences, including the Union World Conference on Lung Health and the National TB Controllers Association.

3. Use of Improved Information Technology and Burden Reduction

The primary method of information collection is through completion of one page referral forms that can be secure-faxed or emailed to CDC. The CDC CureTB form is adapted from one developed and already in widespread use by health departments, so the CDC CureTB form merely leverages standard practice by health departments. Federal correctional agencies developed their own form, which serves several purposes for their agency. CDC CureTB accepts their form and abstracts that data into the CDC CureTB form so, no additional burden is placed on those facilities. Any change to submission of the CDC CureTB forms to CDC will be sent to OMB for review and approval. If the changes are substantive, a revision will be submitted for public comment and OMB review and approval.

Particular emphasis will be placed on compliance with the Government Paperwork Elimination Act (GPEA), Public Law 105-277, title XVII. The data elements will be the same as the hard copy forms, but could be, for example, presented in a fillable PDF format.

The data elements collected during the referral process are the minimum required to elicit the necessary TB-related information. If a respondents leaves any critical elements described in section A2 incomplete on the form, which can happen when lab results are pending, CDC CureTB will contact the referring entity directly to gather any remaining critical information.

4. Efforts to Identify Duplication and Use of Similar Information

Because DGMQ's public heath mission is supported by public health mission dedicated to migrating populations and regulatory responsibilities related limiting the spread of infectious disease into and within the United States, it is not expected that the majority of the information collected under this proposed new clearance is available through other systems maintained by the federal government. The CureTB information provides up-to-date clinical and exposure event information, which is not available through any existing CDC system. All of the functions of the CureTB management team have moved from San Diego County Public Health to the CDC. The collection of data is being directed and managed by CDC DGMQ staff.

A private, non-profit entity, the Migrant Clinician Network, works with Immigration and Customs Enforcement (ICE) to provide out-of-country referrals for a subset of TB patients. However, there is no overlap of data collection from ICE facilities.

5. Impact on Small Businesses or Other Small Entities

Health departments, correctional and immigration facilities are the majority providers of CureTB referrals and would be the only source of TB data for these specific populations. Small businesses are not involved. Health departments and federal correctional facilities already have standard forms and practices in place for trying to locate migrating patients. CDC CureTB leverages, but does not add to the standard practices.

6. Consequences of Collecting the Information Less Frequently

CDC notes that the majority of this information is already being collected by the referring entities. CDC is collecting this information in order to assist in coordinating continuity of care for individuals infected with TB. The majority of information that CDC collects from the initial referral is performed on one time basis, with updates only performed if critical gaps are missing that would prohibit completion of the referral and appropriate medical treatment in the patients' new locations.

The consequences of not following up with the new treating physicians on a regular basis would be an absence of information on information on TB patient outcomes, patients who may be moving internationally. This would result in a reduction in the quality of care to the patient and reducing the confidence of referring health entities in the quality of CDC CureTB referral services.

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

This request fully complies with the regulation 5 CFR 1320.5.

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

A. This is a new information collection request. A 60-day Federal Register Notice was published in the Federal Register on August 10, 2016, Vol. 81, No. 154, p. 52875. No comments were received. (Attachment B)

B. Consultation

Individuals	**Title**	**Role**
Ronelle Campbell, DO	Lead TB Clinician County of San Diego TB Branch	Consulted on the need for data collection, approved necessity of project
Maria Nunez	Deputy Director	Consulted on the need for

	Yuma Health Department Yuma, Arizona	data collection, approved necessity of project
Maria Dalbey, RN	TB Nurse Consultant Kentucky TB Prevention and Control Program	Consulted on the need for data collection, approved necessity of project
Martin Castellanos, MD	Director Mexican National TB Program	Consulted on the need for data collection, approved necessity of project

9. Explanation of Any Payment or Gift to Respondents

DGMQ will not provide remuneration or incentives to participants.

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

CDC has determined that the Privacy Act does apply to this information collection. Individually identifiable data will be stored according to this system. The applicable system of record notice is Quarantine- and Traveler-Related Activities, Including Records for Contact Tracing Investigation and Notification under 42 CFR Parts 70 and 71.

DGMQ and contractors will follow procedures for ensuring and maintaining the security of the data. Eagle Medical Services currently provides contract staff for CureTB and the contractors must comply with CDC security standards. Paper data forms will be stored in locked cabinets at CDC headquarters and CDC Quarantine stations which are located in a secure area of the airport, in this case in a secured building owned by the San Diego Public Health Department used by CDC to house CDC and its contracted staff. Entry of electronic information pertinent to travel may also be entered into QARS at CDC headquarters in Atlanta. The majority of the data will be stored at the CDC office in San Diego.

Security for electronic CDC CureTB records, both on the mainframe and the National Center Local Area Network (LAN), includes programmed verification of valid user identification code and password prior to logging on to the system, mandatory password changes, limited log-ins, virus protection, and user rights/file attribute restrictions. Password protection imposes user name and password log-in requirements to prevent unauthorized access. Each user name is

assigned limited access rights to files and directories at varying levels to control file sharing. There are routine daily back-up procedures, and secure off-site storage is available. To avoid inadvertent data disclosure, measures are taken to ensure that all data are removed from electronic media containing Privacy Act information. Additional safeguards may be built into the program by the system analyst, as warranted by the sensitivity of the data.

CDC and contractor employees who maintain records are instructed to check with the system manager prior to making disclosures of data. When individually identified data are being used in a room, admittance at either CDC or contractor sites is restricted to specifically authorized personnel. Privacy Act provisions are included in contracts, and the CDC Project Director, contract officers and project officers oversee compliance with these requirements. Upon completion of the contract, all data will be either returned to CDC or destroyed, as specified by the contract.

This information collection will have no impact on a respondent's privacy. All patient data accumulated by CDC is kept secure and stored according to CDC's data security guidance and System of Records Notice.

Respondents send referrals to CDC CureTB voluntarily to enhance patient outcomes. The CDC will not require this activity. Respondents will be made aware that de-identified, aggregate data may be part of presentations or publications.

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

IRB Approval

Data collected will be only that which is required to maintain continuity of patient care and includes limited clinical data concerning the TB diagnosis and treatment, and contact information described in section A2. The collection of this data is consistent with public health practice, in particular, case management and quality management. The project description has been submitted to the National Center for Emerging and Zoonotic Infectious Disease and this collection has received a non-research determination. (Attachment C)

Justification for Sensitive Questions

There are no sensitive questions asked by CDC CureTB. Health entities will provide the information needed to assure clients get appropriate downstream care.

12. Estimates of Annualized Burden Hours and Costs

A. Health departments and partner health authorities, generally public health field (RNs and NPs), will submit CDC CureTB forms (Attachments D, CureTB Transnational Notification; and E, CureTB Contact/Source Investigation (CI/SI) Notification) as they request referral services. In correctional institutions, the respondents are also generally RNs and NPs. The number of referrals varies widely between respondents. The average time to complete and send a CureTB referral form is estimated at 30 minutes. CDC CureTB currently receives approximately 500

referrals per year. An estimated 100 respondents send referrals, with a range from 1-20 per respondent, and an average of 5 per respondent annually. One referral is sent for each patient.

CDC's CureTB program will also work with our public health partners in notifications for contacts of TB cases. This is a lesser used function of CureTB but burden is included below. These respondents are registered nurses or nurse practitioners working in health departments, and there are approximately 100 responses per year, with 20 respondents submitting approximately five notifications per year.

In approximately 20 percent of cases, CDC CureTB may need to follow up with an individual to complete missing data fields concerning clinical or contact information. This is done to ensure continuity of care. Because this missing data is not uniformly absent from the data set, CDC assumes these cases may require an additional 5 minutes to gather the information. This results in an anticipated 8 additional hours of burden per year.

CDC staff in the CureTB program also contacts the new treating physicians to determine patient outcomes using CureTB Clinician Public Health Department Follow-up Script (Attachment F). The physicians are generally contacted every two months over the course of standard 6 month TB treatment, for a total of 3 follow-up contacts per patient. This totals 1500 follow-up contacts. CDC estimates that each follow-up contact requires approximately 10 minutes. The estimated annual burden for follow-up contacts is 250 hours.

Table 12.A: Estimated Annualized Burden to Respondents

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Registered Nurses/Nurse Practitioners	CureTB Transnational Notification	100	5	30/60	250
TB patients	CureTB Transnational Notification	100	1	5/60	8
Registered Nurses/Nurse Practitioners	CureTB Contact/Source Investigation (CI/SI) Notification	20	5	30/60	50
TB treating physicians	Clinician Public Health Department Follow-up Script	500	3	10/60	250

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
TOTAL					558

B. Most of the respondents will be nurses in the public health field (RNs and NPs).Table 12.B presents the calculations for cost of respondents' time using one category of mean hourly wages for a nurse in the U.S. Hourly mean wage information is from the U.S. Department of Labor's Bureau of Labor Statistics website (http://www.bls.gov/oes/current/oes_nat.htm#29-0000). Based on BLS wage category 29-1141 Registered Nurses, average hourly wage of $34.14 and 29-1171 Nurse Practitioners, average hourly wage of $48.68; an average overall is estimated at $41.41for all respondents.

TB patients come from a variety of occupations, so CDC is using the All Occupations category from the BLS to calculate annualized cost to respondents. That mean wage is $23.23 per hour.

TB treating physicians' wages were estimated from data published by the Mexico Secretary of Health. These data were used because the majority of the referrals are made to Mexico. The category of physician used for this estimate is a Médico General "A", which commonly serves as a TB controller. The salary data is available on a monthly basis, and is 33,006 Mexican pesos per month. Using PPP data from the World Bank[1], this equates to approximately $3,477. We assume that these physicians work 40 hours per week, which result in an hour wage of approximately $21.73 per hour.

Table A.12-B shows estimated burden and cost information. The total estimated annualized respondent cost is $18,043

Table 12.B: Estimated Annualized Cost to Respondents

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondents' Costs
Registered Nurses/Nurse Practitioners	CureTB Transnational Notification	250	$41.41	$10,353
TB patients	CureTB Transnational	8	$23.23	$186

[1] http://data.worldbank.org/indicator/PA.NUS.PRVT.PP?end=2015&locations=MX&start=1990&view=chart

	Notification			
Registered Nurses/Nurse Practitioners	CureTB Contact/Source Investigation (CI/SI) Notification	50	$41.41	$2,071
TB treating physicians	Clinician Public Health epartment Follow-up Script	250	$21.73	$5,433
TOTAL				**$18,043**

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

There will be no direct costs to the respondents other than their time to complete the CureTB Transnational Notification or CureTB Contact/Source Investigation (CI/SI) Notification forms, and to respond to CDC requests for follow up with the treating physicians.

14. Annualized Cost to the Government

Describe any cost to the government

The estimated cost for the federal government is calculated to be approximately 30% of the workload of one GS-13 federal government employee salary at the San Diego, CA locality.

Table 14: Estimated Annualized Cost to the Federal Government

Contract and Personnel	Role	Average Cost
Federal employee costs, per information collection, (33% FTE of one GS-13 at $92,108/year)	3 GS-13 FTE (33%)	$92,108
IT system costs	$20,000	$20,000
Total Costs		**$112,108**

15. Explanation for Program Changes or Adjustments

This is a new information collection so there are no changes or adjustments.

16. Plans for Tabulation and Publication and Project Time Schedule

Data is entered on an ongoing manner as collected. Reports of CDC aggregate outcomes will be provided to CDC DGMQ leadership annually. There are currently no plans for scheduled or

routine peer-review publication; however, publication may be warranted as CDC DGMQ demonstrates continued impact on domestic and foreign TB-control efforts.

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

No exemption is being requested. The display of the expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

ATTACHMENTS

A1: Section 361 of the Public Health Service Act

A2: 42 CFR Part 70

A3: 42 CFR Part 71

B: 60 day notice

C: IRB Determination

D: CureTB Transnational Notification

E: CureTB Contact/Source Investigation (CI/SI) Notification

F: CureTB Physician Public Health Department Follow up Script