Aggregate Reports for Tuberculosis Program Evaluation

OMB Control Number: 0920-0457 Exp. 2/29/2020

Revision

Supporting Statement A

December 3, 2019

Kai Young, MPH
Health Scientist,
Division of TB Elimination
Centers for Disease Control and Prevention

phone: 404.639.2217
fax: 404.639.8958
email: deq0@cdc.gov

Table of Contents

List of Attachments

- The goal of this ICR is to facilitate the monitoring of national progress toward TB elimination.
- Intended use of the resulting data is to generate indicators for program evaluation, monitor the workload of tuberculosis prevention, and estimate the epidemiological status of tuberculosis in state and local public health jurisdictions
- All programs are now reporting the data for the Aggregate Reports for TB Program Evaluation (ARPE) to CDC through a secure, web-based system.
- The populations to be studied include persons in the United States with tuberculosis disease or infection and contacts to persons with tuberculosis disease.
- Data will be analyzed using descriptive methods (i.e., percentages of tuberculosis cases and contacts who met select outcomes).

A. Justification

1. Circumstances Making the Collection of Information Necessary

Background

The Centers for Disease Control and Prevention requests a 3-year approval for a revision of currently approved collection, "*Aggregate Reports for Tuberculosis Program Evaluation,*" (OMB # 0920-0457, exp. 2/29/2020). This data collection is authorized under Section 301 of the Public Health Service Act 42 U.S.C. 241, (**Attachment 1**). The changes increase the burden by 42 hours from the previously approved 226 hours.

The Division of Tuberculosis Elimination (DTBE), National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC), maintains cooperative agreements with the health departments of the 50 states, 9 large cities, and 8 trust territories and protectorates (**Attachment 7**) who submit tuberculosis (TB) program management reports. CDC also provides ongoing technical consultation about TB control for these health departments. In 2000, the "*Aggregate Reports for Tuberculosis Program Evaluation*" (ARPE) replaced several outdated reports and are now used nationwide. The changes in these reports corresponded to the evolving national TB control strategy, new data-systems technology, and advancements in science and medicine. There is no current plan for data retirement as the data is used for monitoring trends over an indefinite period of time.

The two reports (**Attachments 3a and 3b**), measure the extent, the efficiency, and the yield of TB control activities. Respondents for the reports are the 67 federal cooperative agreement sites that perform TB control activities in the United States. These sites have adopted *Aggregate Reports for Tuberculosis Program Evaluation* as their generic tool for assessing their TB prevention activities. They use the reports for generating the indicators used in program evaluation as stipulated in the 2015 cooperative agreement, for monitoring the workload of TB prevention, and for estimating the epidemiological status of TB in their jurisdictions.

Data are collected by state and local health departments as part of routine contact investigation activities for providing information on cases of TB disease or infection. Data aggregation varies by site, with computerized methods becoming the norm at large jurisdictions. Respondents provide the data following the format as outlined in ARPE and submit their aggregated data to CDC by encrypted computer

transmission via the National TB Indicators Project (NTIP).

The National Tuberculosis Indicators Project (NTIP) is a secure electronic platform developed by CDC for use by health departments. CDC uses the NTIP platform to distribute selected indicator reports and other communications. The NTIP also includes a module/portal for submitting Aggregate Tuberculosis reports to CDC.

During the previous approval period (September 2016-February 2020), CDC completed and achieved the following activities and outcomes:

- Served as the only agency collecting national data on TB contact investigations
- Achieved a response rate of 98% from TB control jurisdictions
- Disseminated an annual report of national aggregate contact investigation data to TB control jurisdictions in 2012 - 2016
- Presented aggregate contact investigation data and trends at national and international conferences (i.e. the National TB Controllers Association; the International Union for Tuberculosis and Lung Disease, North America Region)
- Published article in Morbidity and Mortality Weekly Reports: Young K, Ehman M, Reves R, et al. Tuberculosis Contact Investigations — United States, 2003–2012. MMWR 2016; 64(50):1369-74.

During the next approval period (February 2020-February 2023), CDC plans to achieve the following:

- Continue data collection and analysis as the only agency collecting national data on TB contact investigations
- Increase reporting response rate from TB control jurisdictions to 100%
- Assess nativity, adoption of new diagnostic tests and the use of new drug regimens for TB contacts
- Summarize targeted testing and treatment of latent TB infection (LTBI) among high-risk populations
- Disseminate annual reports of national aggregate contact investigation and targeted testing data to TB control jurisdictions
- Host at least one consultation session with TB control jurisdictions and/or the National TB Controllers Association regarding data collection and reporting

2. Purpose and Use of Information Collection

CDC uses the data from these reports for monitoring local, state, and national TB control programs, for planning national TB control strategy, and in estimating funding needs. The results in these reports are compared to the national performance goals, and they indicate progress toward achieving tuberculosis elimination. These data address Government Performance Results Act (GPRA) section IIH, Tuberculosis Performance Goal 1 Item 3 (“Increase the percentage of contacts of infectious acid-fast bacilli smear positive cases who are placed on treatment for latent tuberculosis infection and complete a treatment regimen”) and Item 4 (“Increase the percentage of other high risk infected persons who are placed on treatment for latent tuberculosis infection and complete a treatment regimen”). ARPE shows that in 2016 (the most recent year for complete information) approximately 77.5% of contacts of

infectious TB cases start and finish a treatment regimen, indicating that current prevention activities are not at their full potential.

CDC has disseminated the results from these reports in the following ways:

- An annual "dear-colleague" letter from the director of DTBE, for data years 2009–2016, to the 67 state, territorial, and big city TB control officials. This letter reiterates the purposes of the data collection and provides a national interpretation of the results for the year.
- Published article in Morbidity and Mortality Weekly Reports that summarized the Aggregate Reports for Tuberculosis Program Evaluation contact investigation data: Young K, Ehman M, Reves R, et al. Tuberculosis Contact Investigations — United States, 2003–2012. MMWR 2016; 64(50):1369-74.
- CDC poster presentations of the national summary results and interpretation at the annual conference of the National Tuberculosis Controllers Association (NTCA), the official organization representing the report respondents. Presentations in this forum will continue annually.
- CDC poster presentation of the national summary results and interpretation at the International Union of Tuberculosis and Lung Disease, North America Region Conference (IUATLD, NAR).
- Results from the reports are incorporated into NTIP. NTIP is a secure web-based monitoring system that allows state and local health authorities to access reports and review data. The NTIP system provides TB programs with reports to describe their progress, based on data already reported to CDC, and facilitates the use of existing data to help programs prioritize activities and focus program evaluation efforts.

CDC uses the reports for assessing the effective use of federal TB cooperative agreement funds. Reports for program evaluation are stipulated in the cooperative agreements. The CDC TB program consultants, who use the reports as the standard measurement of workload and performance, visit the 67 cooperative agreement sites at least annually to review local progress toward tuberculosis elimination.

All state health departments have adapted ARPE for their own TB control programs. Most health departments use the identical reports that they submit to CDC, while a few, such as the health departments in California and Florida, have elaborated on the reports to meet their specialized needs. Health departments that have their own comprehensive data management systems for TB control, such as in New York State and Illinois, have designed their systems so that information for ARPE are generated automatically and thus at no added burden for the respondents, who already were collecting the data for their own use.

In this Revision request, CDC proposes minor changes to the currently approved ARPE form to align with changes in TB epidemiology in the United States and the updated national TB prevention and control strategy which responds to changes in TB epidemiology.

- Changes in TB Epidemiology. Country of birth information (also called "Nativity" information) has been added to the ARPE form. National TB surveillance data (2017) show that non-US born persons with U.S. residence of 10 years or more have steadily accounted for the highest TB case counts from 2008 (35%) to 2017 (45%). These data indicate that latent TB infection can be reactivated among non-US born persons who have lived in the United States for a substantial period of time (https://www.cdc.gov/tb/statistics/reports/2017/default.htm and

https://www.cdc.gov/maso/facm/pdfs/acet/FINAL508cACETMinutesApril172018.pdf).

- According to the National Health and Nutrition Examination Survey (OMB No. 0920-0950, exp. 11/31/2021), positive TB infection test results for persons born outside the United States are considerably more frequent than for U.S.-born persons, at 15.9% among non-US-born versus 2.8% U.S.-born by interferon gamma release assay test, with even greater disparity when infection is measured by tuberculin skin test (https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0140881).
- Updated National TB Prevention and Control Strategy. Changes in TB epidemiology have resulted in updates to the national strategy for controlling TB. In 2016, the United States Preventive Services Task Force issued national screening recommendations to test for TB infection in persons born outside the United States in higher TB prevalence countries (https://jamanetwork.com/journals/jama/fullarticle/2547762).

Prior to submitting this Revision request, CDC also consulted with the Advisory Council for Elimination of Tuberculosis (ACET) regarding the acceptability and feasibility of collecting nativity data. ACET was favorable to the approach and also recommended the addition of diagnostic tests and drug regimen to the ARPE data collection. The additional elements will allow TB control experts to assess the adoption of new diagnostic tests, and assess the effectiveness of a new short-course drug regimen in increasing the initiation and completion of preventive treatment (https://www.cdc.gov/maso/facm/pdfs/acet/508cACETMinutesAugust-22-2017.pdf).

CDC therefore proposes to collect new data variables on nativity, diagnostic tests, and drug regimens. The changes are supported by epidemiologic evidence and national experts on TB control. The additional information will allow more effective use of aggregate ARPE data, including stratification and analysis with respect to additional risk factors. Finally, the revised ARPE data collection will allow CDC to assess uptake of the USPSTF's national recommendation and to estimate future resource needs.

Because the majority of technical-support questions about the ARPE have been related to data definitions, CDC addressed these questions by preparing extended instructions that are accessible on to the CDC web page (see Attachment 5: Aggregate Reports for Program Evaluation: Training Manual and User's Guide). The instruction manual includes guidance about how the respondents (i.e., the state and local public health departments) can use the reports for monitoring the results of their own tuberculosis control programs. CDC has also issued Dear Colleague letters to jurisdictions clarifying data definitions to accommodate evolving new technology and science.

Difficulties have been reported anecdotally for specific complex large TB outbreaks in institutional settings (e.g., prisons or homeless shelters) two or three times per year. The data structure required by these outbreaks is too complex for ARPE. These issues have been resolved collaboratively between the respondents and the CDC TB program consultants by collapsing the data into simpler formats that were compatible with the reports. CDC is not proposing revisions to the reports to accommodate more complex data because the current reports are sufficient for most data. If the reports were expanded for rare instances of complex data, this would increase the burden to the respondents without sufficient compensatory benefit to the respondents or to CDC.

State and local public health officials have cited improved convenience and usefulness of the current reports in comparison to the older CDC reports. The reports document that the scope of prevention activities is large: according to the most recent final reports, at least 76,567 persons in the United States were listed as exposed to TB in 2016, and approximately 15% of the persons who underwent diagnostic

testing were found to have TB infection. The reports also have shown that approximately 13% of infectious TB patients in the United States did not have contacts listed, which demonstrates a particular need for improvements in TB prevention.

These data from ARPE continue to demonstrate the scope of the public health problem and the prevention activities for which CDC is jointly accountable, in collaboration with U.S. state and local health departments. Without ARPE reports, national data on the transmission of TB infection and the quantity of work carried out by state and local TB control program to prevent TB cases would not be available. CDC needs a fair, standard assessment of the utilization of the funding disbursed through the federal TB cooperative agreements. Even if CDC could not collect the reports, state health departments would continue using them for monitoring the efforts of their own tuberculosis programs, because they have found the reports to be practical and useful.

3. Use of Improved Information Technology and Burden Reduction

The federal TB cooperative agreements include funds for computer equipment and support. CDC continues to work with the respondents in adopting new technology. In 2010 CDC launched a web-based module in NTIP to streamline reporting processes and reduce burden. The module provided a new, secure web-based option for direct data entry and electronic submission to CDC. As of 2018 100% of the responses are transmitted data electronically via NTIP.

4. Efforts to Identify Duplication and Use of Similar Information

ARPE is a comprehensive standard summary of priority tasks for controlling and eliminating tuberculosis in the United States. Some state health departments (e.g., in California, New York, Illinois, and Florida) subsequently have designed their own similar reports for program evaluation, in accordance with their specific programmatic needs. Their reports are compatible with the national reports, but those reports are either too specific or too complex for national adoption. No federal agency besides CDC collects uniform data on TB prevention nationwide. Through literature searches, attendance at national TB meetings and conferences, and ongoing consultations with TB experts nationwide, CDC has determined that ARPE reports are unique and that no other similar data are available within or outside the federal government.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this data collection. Data are requested from state, local, and territorial health departments. Data are collected only once a year and are kept to an absolute minimum to lessen the reporting burden.

6. Consequences of Collecting the Information Less Frequently

Annual reporting is linked to the annual funding cycle and program evaluation of the TB cooperative agreements. Less frequent reporting would delay feedback and technical consultation to the respondents and would leave CDC without current data for monitoring the national TB burden. The reporting frequency is once a year. The respondents collect the data for these reports continuously as part of standard public health practice. There are no legal obstacles to reducing the burden to the respondents.

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

This request fully complies with the guidelines in 5 CFR 1320.5, and no special circumstances require the information to be collected in any other manner.

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

A 60-day Federal Register Notice was published in the *Federal Register* Tuesday, April 23, 2019, Vol. 84, No. 78, Page 16859 (**see Attachment 2**). There were no public comments.

The CDC TB program consultants, who use the reports as the standard measurement of workload and performance, visit the 67 cooperative agreement sites at least annually to review local progress toward TB elimination. During the administrative site visits made by CDC TB program consultants, the consultants not only provide ongoing technical consultation about TB control for these health departments, but also may receive consultation from the programs as to the utility of the reports.

In 2009, TB control officials from California (Jennifer Flood, Chief, 510-620-3020, jennifer.flood@cdph.ca.gov); Colorado (Gayle Schack, no forwarding contact information available), New York State (Stephen Hughes, Assistant Director, 518-474-4845, seh03@health.state.ny.us), Tennessee (Katie Garmin, no forwarding information available), and Texas (Ann Tyree, no forwarding contact information available) reviewed the indicators that are in ARPE and recommended their inclusion in NTIP.

CDC launched NTIP in 2009 for returning data and reports in a convenient format to state and local public health authorities. The cumulative ARPE are integrated into NTIP. During the design and the implementation of NTIP, CDC sought consultation from public health authorities from the state health departments mentioned above and with representatives of NTCA, which advocates for the respondents for the ARPE. In these consultations, CDC was advised to continue ARPE in their current form and to make them accessible through NTIP.

In July 2018, in response to the recommendations from the Association Council for the Elimination of Tuberculosis (ACET) [Hazel Dean, Sc.D., M.P.H., Designated Federal Officer, hdd0@cdc.gov, 404-639-8000] to include nativity, diagnostic tests and drug regimen to ARPE, CDC reached out to the National Tuberculosis Controllers' Association (NTCA) [Donna Hope Wegener, Executive Director, dhwegener@tbcontrollers.org] for feedback. NTCA surveyed and conducted in-person focus group with members in the 67 jurisdictions to assess uses of ARPE data and the feasibility and burden associated with collecting these recommended data elements. NTCA found that 76% of respondents reported ARPE data are useful to their programs. While 43% of the respondents recommended no changes to the current form, most programs reported little or no challenges with regard to their ability to collect and report the recommended data elements. More specifically, 59% of respondents reported little or no difficulties in their capability to collect and report nativity; 77% of respondents reported little or no difficulties in collecting and reporting diagnostic tests used; and 73% of respondents reported little or no difficulties in collecting and reporting drug regimen used. Recognizing that jurisdictions vary in their current capacity to collect, aggregate, and report the proposed new data elements on nativity, diagnostic

test, and drug regimen, CDC has incorporated the new data elements into the revised ARPE form, but has designated them as optional.

9. Explanation of Any Payment or Gift to Respondents

The respondents do not receive payments or gifts for providing ARPE reports.

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

The CDC NCHHSTP PRA Coordinator reviewed this submission and determined that the Privacy Act does not apply to this activity because activities do not involve the collection of individually identifiable information (IIF). Respondents are state and local health departments that provide CDC with aggregate information on cases of tuberculosis disease or infection. Although health departments may collect identifiable information for local tuberculosis control purposes, consistent with state and local laws, this information is retained at those levels, and health departments do not transmit person-level data or identifiable data to CDC. No individually identifiable information is being collected.

The two reports submitted here (**Attachments 3a and 3b**) identify the types of non-individually identifiable information that will be collected. The source data for ARPE are gathered as part of standard public health practice for TB control under the authority of state and local health departments. No respondents submit these data with individual patient records to CDC. Although health departments may collect IIF for local TB control purposes, consistent with state and local laws, this information is retained at those levels, and health departments do not transmit person-level data or identifiable data to CDC. The data associated with this OMB clearance are submitted to CDC only in an aggregate format.

The aggregate data are not stratified by age, sex, or specific medical conditions except for TB, and therefore the accidental identification of any patient who is counted in the reports is extremely unlikely. CDC previously has not made any assurance of confidentiality to the respondents. Data from specific respondents will be treated in a secure and private manner and will not be disclosed unless otherwise compelled by law.

A. Through the federal cooperative agreement respondents are informed about the voluntary or mandatory nature of their response. The requirements for submission are clearly described in the cooperative agreement.

B. As the primary users of the data, the respondents are informed about the intended uses of the information collection through the cooperative agreement and are able to access the results of the aggregate reports through NTIP. The respondents requested in 1999, and CDC agreed, that local public health authorities will be notified before locality-specific data is published or shared outside CDC. CDC publishes the national data and shares the national summaries with the respondents at least annually.

C. The information submitted by respondents will be secured with the appropriate safeguards currently in place to minimize the possibility of unauthorized access, use, or dissemination of the information being collected. Technical controls include user identification, passwords, firewall, virtual private network (VPN), and encryption. All data which are submitted electronically through NTIP are encrypted and files are password protected. Any reports that are transmitted by telephone facsimile are sent unencrypted, to the CDC office where the data are collected, under the privacy-statement

cover sheet of the submitting agency as guided by state or local law. Any printed records from specific jurisdictions are kept in a locked file cabinet. The summary national reports contain no sensitive or private information.

Physical controls include security guards, identification badges, key cards, and locked file cabinets. Any printed records from specific jurisdictions are kept in a locked file cabinet. Administrative controls include training manual and user guides for information collection, completion of required security training for computer access and data collection annually by all CDC personnel, and role-based access to data.

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

IRB Approval

This submission was reviewed by the National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention and determined not to involve human subjects (**Attachment 4**). This surveillance activity does not require IRB review and approval.

Sensitive Questions

As part of their routine public health practices, health department officials (i.e., the respondents) collect sensitive information (e.g., address, occupation, country of origin, country of birth, infection with the human immunodeficiency virus and risk factors for it, and the use of alcohol or illegal drugs) from persons who have tuberculosis infection, who have been exposed to tuberculosis, or who are born outside of the United States in high TB prevalence countries For preparing the reports, the respondents interpret some of this sensitive information, but most sensitive information is not recorded per se in the reports, and it is not extractable from the reports. Although the new data reporting on nativity in the ARPE form is considered sensitive information, the aggregate format of the reports precludes linking any sensitive information to any persons who are counted in the reports.

12. Estimates of Annualized Burden Hours and Costs

A. Respondents are the 67 health departments (state, local, city, or similar jurisdiction) funded under the CDC cooperative agreement. On an annual basis each respondent will submit 2 summary reports to CDC. The summary reports are compiled from information collected by the health department's TB control program during routine operations. Burden estimates are based on the time needed to compile each summary report from the respondent's record system. Burden estimates do not include activities conducted by health departments as primary tuberculosis care and follow-up.

Each respondent will submit the *Follow-up and Treatment of Contacts to Tuberculosis Cases Form* (Attachment 3a) to CDC once per year. The estimated burden per response is 2 hours and the estimated annualized burden for this information collection is 134 hours.

Each respondent will submit the *Targeted Testing and Treatment for Latent Tuberculosis Infection Form* (Attachment 3b) to CDC once per year. The estimated burden per response is 2 hours and the estimated annualized burden for this information collection is 134 hours.

All information collection is conducted electronically. The total estimated annualized burden is 268 hours, as summarized in Table A.12-1.

Table A.12.1: Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Health Department Awardee (state, local, city, or other jurisdiction)	Follow-up and Treatment of Contacts to Tuberculosis Cases Form (3a)	67	1	2	134
	Targeted Testing and Treatment for Latent Tuberculosis Infection (3b)	67	1	2	134
Total					**268**

B. CDC does not request data on the staff who prepare or submit the reports, however, reports are typically prepared by program managers and data clerks. To estimate burden cost we have used $26.99, the mean average hourly wage of a program manager ($32.73) and a data clerk ($21.25). The estimated hourly rate for a data clerk was obtained from Department of Labor (www.dol.gov); the estimated hourly rate for a program manager was obtained from U.S. Office of Personnel Management (www.opm.gov).
The total estimated annualized burden cost to respondents is $7,233.22, as shown in Table B.12-1.

Table B.12.1: Estimated Annualized Burden Costs

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Average Hourly Wage	Total Burden Cost
Health Department Awardee (state, local, city, or other jurisdiction)	Follow-up and Treatment of Contacts to Tuberculosis Cases Form (3a)	67	1	2	$26.99	$3,616.66
	Targeted Testing and Treatment for Latent Tuberculosis Infection (3b)	67	1	2	$26.99	$3616.66
	Total					$7,233.32

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

None. The reports do not cause additional capital and maintenance costs to the respondents. The systems that are used for data collection, collation, and storage are already in place for routine public health practice.

14. Annualized Cost to the Government

The annualized cost to the government is $106,720.67. The reporting is recurrent and ongoing. The costs that are estimated here reflect a public health system that is assumed to be stable. The upkeep for NTIP is minimal because programming is complete. Routine checks on the functionality of the reporting system are part of routine annual site visits made by CDC tuberculosis program consultants for the Tuberculosis Elimination and Laboratory federal cooperative agreements, and the costs of these visits are not shown because the visits would be made regardless of ARPE.

Table A.14.1: Estimated Annualized Study Hours and Cost

Activity		**Total Respondent Costs**
NTIP programming maintenance		$40, 000.00
Subtotal		
Federal Employee Time Cost		
One third time health scientist One third time epidemiologist	GS-13 @ $100,081/yr GS-13 @ $100,081/yr	$33,360.33 $33,360.33
Average Annualized Cost		$**106,720.67**

This amount reflects an increase of $31,680.17 due to updates in electronic data system and staff time for conducting training and data analysis since the last ICR approval ($75,040.50). This increase does not affect the burden on respondents. Funding for NTIP maintenance and epidemiologists salary come from the Division of Tuberculosis Elimination, National Center for HIV, Viral Hepatitis, STDs and Tuberculosis, Centers for Disease Control and Prevention.

15. Explanation for Program Changes or Adjustments

The following changes are proposed in this Revision ICR:

1. Decrease the number of health department awardees

CDC is currently approved to collect information from 68 cooperative agreement awardees. In the next approval period, the number of sites will decrease to 67 **(Attachment 7)**.

2. Add 3 types of questions to each form (3a and 3b)

These questions were recommended by the Advisory Council for Elimination of Tuberculosis (ACET). Reporting this information to CDC will be standardized but optional.

Type of question	Question	How Information Will Be Used
Nativity	# contacts who are U.S.-born # contacts who are non-U.S.-born # persons sought, enlisted or registered for LTBI testing who are U.S.-born # persons sought, enlisted or registered for LTBI testing who are non-U.S.-born	To improve understanding of the epidemiology among TB contacts To assess the uptake of national recommendation on targeted testing of persons born outside of the U.S. in high TB prevalence countries To estimate resource needs for culturally competent staff
Diagnostic tests	# contacts evaluated using TST # contacts evaluated using IGRA	To assess the adoption of new diagnostic tests
Drug regimens	# contacts diagnosed with LTBI who started treatment using - INH (9 months)	To assess the effectiveness of new short-course drug regimens in increasing the initiation and

	- 3HP - RIF (4 months) - Other - Unknown # contacts diagnosed with LTBI who started treatment and completed using - INH (6 months) - INH (9 months) - 3HP - RIF (4 months) - Other - Unknown	completion of preventive treatment

3. Change the method of describing respondents in the burden table

In the most recent approval (February 2017), CDC estimated receipt of data on 136 cases annually (100 + 18 + 18). The cases were distributed among the 68 cooperative agreement awardees, with each awardee reporting on the proportion of cases followed by that site. Each awardee compiled information and submitted to CDC (1) an aggregate Follow-up and Treatment of Contacts to Tuberculosis Cases Form and (2) an aggregate Targeted Testing and Treatment for Latent Tuberculosis Infection Form. Each Form was represented by 3 entries in the burden table. The entries allowed CDC to distinguish (A) response burden for manual vs. electronic submissions, and (B) wage categories of personnel who prepared the reports. However, this format did not express burden in terms of a site (awardee).

Previous organization of the burden table (3 row entries per Form)

Type of Respondent	Form Name	No. Respondents	No. Responses	Average Burden per Response	Total Burden in Hours
Data clerks and Program Managers (electronic)	Form	100	1	30/60	50
Program Managers (manual)	Form	18	1	30/60	9
Data clerks (manual)	Form	18	1	3	54

In this Revision, manual reporting methods are being discontinued and all information will be reported to CDC electronically. Each aggregate Form is represented by one row in the burden table. The Type of Respondent column is a cooperative agreement site (N=67), not the job title of the individual who participated in report preparation. The burden table entry for each form has been simplified as follows:

Revised organization of the burden table (1 row entry per Form)

Type of Respondent	Form Name	No. Respondents	No. Responses	Average Burden per Response	Total Burden in Hours
Health Department Awardee (state, local, city, or other jurisdiction)	Form	67	1	2	134

4. Change the estimated burden per response

   In the previous approval, estimated burden per response ranged from 30 minutes to 3 hours. With the transition to a uniform electronic method for preparing each aggregate report, the estimated average burden per response has been standardized at 2 hours per form.

In this Revision request, the total estimated annualized burden will increase from 226 hours to 268 hours (+42 hours).

16. Plans for Tabulation and Publication and Project Time Schedule

The data accumulation is intermittent, it represents continuous public health practice throughout the United States, and the reporting is annual and recurrent. A 3-year clearance cycle is requested.

Local public health authorities will be notified before locality-specific data is published or shared outside CDC. CDC publishes the national data and shares the national summaries with the respondents at least annually after combining and summarizing the aggregate reports.

No analytical methods beyond simple tabulation and trend description are applied to the results of the reports. The indices that are used for program evaluation are unadjusted. The interpretation of the results from each reporting area is discussed between the respondents and their CDC TB program consultants. Specific data from one respondent are not shared with other respondents by CDC without prior notification because the data ownership (i.e., intellectual property) remains with the respondents as per general agreement between CDC and the Council of State and Territorial Epidemiologists.

The data that are reported to CDC are summed up for the U.S. national TB program statistics, which are sent to all the respondents annually. At least annually, the program consultants from CDC use the data that are reported by their TB cooperative agreement project sites for reviewing the effectiveness of existing TB control programs and for planning new local strategies for TB control.

Table A.16.1: Project Time Schedule

Activity	Time Schedule
Notification of Respondents	1 week after OMB approval
Earliest data collection by Respondents	1 month after OMB approval
Webinar on data collection and submission	8 months after OMB approval
Earliest reports submitted to CDC	9 months after OMB approval
Data validation	13 months after OMB approval
Data analysis	15 months after OMB approval
Year 1 published summary report by CDC	17 months after OMB approval
Year 2 data collection by Respondents	15 months after OMB approval

Year 2 reports submitted to CDC	21 months after OMB approval
Year 2 data validation	23 months after OMB approval
Year 2 data analysis	25 months after OMB approval
Year 2 published summary report by CDC	27 months after OMB approval
Year 3 data collection by Respondents	25 months after OMB approval
Year 3 reports submitted to CDC	33 months after OMB approval

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

No exemption is sought. The display of the OMB expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification included in this request.