

Contact Investigation Outcome Reporting Forms

Request for OMB Approval of a New Data Collection

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Supporting Statement A

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A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) is requesting a three year OMB approval for a new data collection, titled “Contact Investigation Outcome Reporting Forms.”

Background

This data collection supports the need for CDC Quarantine staff to evaluate its contact tracing investigative protocols and assists in determining if adequate information on each contact was provided to those responsible for contacting passengers believed to have been exposed to a communicable disease during travel. Section 361 of the Public Health Service (PHS) Act (42 USC 264) (Attachment A) authorizes the Secretary of Health and Human Services to make and enforce regulations necessary to prevent the introduction, transmission or spread of communicable diseases from foreign countries into the United States. Under its delegated authority, the Division of Global Migration and Quarantine (DGMQ) works to fulfill this responsibility through a variety of activities, including the operation of Quarantine Stations at ports of entry and administration of foreign and interstate quarantine regulations; 42 CFR Parts 71 and 70, respectively. The regulations require conveyances to immediately report an “ill person” or any death to the Quarantine Station prior to arrival in the United States.

When an illness or death suggestive of a communicable disease is reported during travel, Quarantine Officers respond to carry out an onsite public health assessment and collect pertinent information using “*Illness Response and Investigation Forms*”, 0920-0821. Based on the assessment of an ill/deceased person, the public health response may differ depending on the suspected communicable disease. One such response is determining that passengers need to be notified if exposed to the communicable disease during travel. This notification of passengers is critical to preventing the spread of communicable disease because it allows for timely implementation of public health measures needed to mitigate or stop further spread of disease.

The responsibility for contacting exposed passengers typically falls with state or local health departments or with maritime operators, if travel occurred on a ship. The extent of the contact investigation that determines which passengers are believed to have been exposed to a communicable disease is based on CDC investigative protocols. CDC is also responsible for providing state and local public health authorities with adequate contact information, such as phone numbers and address, to facilitate successful notification of the exposed passengers. The success of preventing the spread of a communicable disease is due in large part to the effectiveness of the CDC’s investigative protocols and the provision of contact information. Without systematic feedback

indicating the outcome of the notification and contact investigation from state and local health departments or from maritime conveyance operators, CDC's ability to control the spread of communicable disease through implementing effective investigative protocols is hampered.

Privacy Impact Assessment

This data is being collected to meet the needs of CDC in working with its partners in international, federal, state, and local agencies and organizations to fulfill their mission to reduce morbidity and mortality among immigrants, refugees, travelers, expatriates, and other globally mobile populations.

Highly sensitive information is being collected that would affect a respondent's privacy if there was a breach of confidentiality. However, stringent safeguards are in place to ensure the privacy of information collected including authorized users, physical safeguards, and procedural safeguards. Authorized users: A database security package is implemented on CDC's computer systems to control unauthorized access to the system. Attempts to gain access by unauthorized individuals are automatically recorded and reviewed on a regular basis. Access is granted to only a limited number of physicians, scientists, statisticians, and designated support staff of CDC or its contractors as authorized by the system manager to accomplish the stated purposes for which the data in this system have been collected. Physical safeguards: Access to the CDC facility where the mainframe computer is located is controlled by a cardkey system. Access to the computer room is controlled by a cardkey and security code (numeric code) system. Access to the data entry area is also controlled by a cardkey system. Guard service in buildings provides personnel screening of visitors. The computer room is protected by an automatic sprinkler system, numerous automatic sensors, and a proper mix of portable fire extinguishers is located throughout the computer room. Computer files are backed up on a routine basis. Hard copy records are stored in locked cabinets at CDC headquarters and CDC Quarantine Stations which are located in a secure area of the airport. Procedural safeguards: Protections for computerized records 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. Finally, 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.

Overview of the Data Collection System

CDC's Division of Global Migration and Quarantine has developed contact investigation outcome reporting forms for the different types of investigations. The forms are used to collect information on the outcome of contact investigations so that CDC can evaluate its investigative protocols and determine if adequate information on each contact was provided to those responsible for contacting passengers believed to have been exposed to a communicable disease during travel. These forms include 1) Optional TB Air/Land Contact Investigation Outcome Reporting, 2) Optional Measles, Mumps, or Rubella Air/Land Contact Investigation Outcome Reporting, 3) Optional General Air/Land Contact Investigation Outcome Reporting Form, 4) Optional TB Maritime Contact Investigation Outcome Reporting Form, 5) Optional Measles, Mumps or Rubella Maritime Contact Investigation Outcome Reporting Form, 6) Optional General Maritime Contact Investigation Outcome Reporting Form. The differences between the forms (Attachment B-F) reflect the specific questions unique to the communicable disease of public health concern. These forms provide the means for systematically communicating to CDC information already in the possession of the state and local public health authorities responsible for conducting the investigation. Any method of collecting information is determined by those conducting the contact investigation.

Air/Land: Each of the three forms (Optional TB Air/Land Contact Investigation Outcome Reporting, Optional Measles, Mumps, or Rubella Air/Land Contact Investigation Outcome Reporting, Optional General Air/Land Contact Investigation Outcome Reporting Form) is constructed in a three-layered approach with a series of 'stops' based on the completeness of the contact investigation performed. If the user answers "Yes" at the end of each layer, they would be directed to continue answering questions. If they answer "No", they would be directed to stop and the form would be considered complete.

The first layer asks if the contact was able to be notified. If they were not able to be notified, the form asks why they were not able to be reached (ex. incorrect locating information, contact had returned to their home country) and then the user would stop here. If they were notified, the form has additional questions regarding the method(s) used to successfully notify the contact (ex. telephone, email, and emergency contact) and then the user would continue on.

The second layer of the form asks if the contact was interviewed. If they were not, then the user would stop here after indicating why the interview did not occur. If they were interviewed, additional questions would be asked regarding disease and vaccination history, exposure information, interventions received, etc.

The third layer asks if the contact experienced relevant symptoms during and/or outside the disease-specific incubation period (MMR and General) or if the person was screened (for TB). If the passenger did not experience symptoms or was not screened, the user would stop here. If they did experience symptoms or were screened, the user would be

asked to continue onto the next set of questions.

Maritime: Each of the three forms (Optional TB Maritime Contact Investigation Outcome Reporting Form Optional Measles, Mumps or Rubella Maritime Contact Investigation Outcome Reporting Form, Optional General Maritime Contact Investigation Outcome Reporting Form) is constructed in a two-layered approach with a series of ‘stops’ based on the completeness of the contact investigation performed. If the user answers “Yes” at the end of each layer, they would be directed to continue answering questions. If they answer “No”, they would be directed to stop and the form would be considered complete. The first layer of the form asks if the contact was interviewed. If they were not, then the user would stop here. If they were interviewed, additional questions would be asked regarding disease and vaccination history, exposure information, interventions received, etc. The second layer of the form asks if the contact experienced relevant symptoms during and/or outside the disease-specific incubation period (MMR and General) or if the person was screened (for TB). If the passenger did not experience symptoms or was not screened, then the user would stop here. If they did experience symptoms or were screened, the user would be asked to continue onto the next set of questions.

Data collected from state and local health departments or maritime operators will be maintained by CDC in accordance with the CDC records retention schedule: *Communicable Disease Case Study Files (NC1-90-83-2, Item 1)*.

Items of Information to be Collected

These forms include the following information in identifiable form; medical information, date of birth, gender, country of birth, and country of residence. This is not new information but rather data compiled from existing sources. The forms provide a systematic approach for relaying information pertinent to communicating the outcome of each investigation.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

This data collection does not involve web-based collection methods. Health departments or maritime operators will forward the completed forms via secure fax or email to CDC. Only authorized CDC staff will have access to any personal identifying information or other medical information. The privacy policy and/or rules of conduct will be provided upon staff’s request of a data set. The system is not directed to children under 13 years of age.

2. Purpose and Use of Information Collection

The information collected on the forms enables Quarantine staff to fully understand the extent of disease spread and transmission during travel and to inform the development and/or refinement of investigative protocols, aimed at reducing the spread of communicable disease.

The purpose of the contact investigation outcome reporting forms is to systematically collect information, thereby enabling Quarantine officers to assess, detect and respond efficiently and accurately to communicable disease threats of potential public health importance at ports of entry. The information collected is also necessary for public health surveillance (tracking) and follow-up purposes. The forms collect the following categories of information: demographics, pertinent clinical and medical history, and epidemiologic and travel history.

This information enables Quarantine Station personnel to assist conveyances and border agents in the public health management of ill persons at U.S. ports and plan the appropriate response. This data is then entered into the Quarantine Activities Reporting System (QARS), a secure web-based, data-management system used by all Quarantine Stations to record information about the daily activities of Quarantine Station staff.

QARS is a secure intranet system implemented in June 2005 to track the number of illnesses and deaths reported to Quarantine Stations that occurred on conveyances and land border crossings entering the United States. In addition, QARS is used to store information on Quarantine Station activities such as: emergency preparedness and partnership activities, interaction with public health and other port partners, medical paperwork processing for aliens and immigrants, the importation of nonhuman primates and other animals, and drug releases (botulism and diphtheria anti-toxins and malaria treatment).

Privacy Impact Assessment

The purpose of the contact investigation is to stop the spread of disease. The purpose of the forms is to inform CDC if existing protocols need to be refined.

Highly sensitive information is being collected that would affect a respondent's privacy if there were a breach of confidentiality. However, stringent safeguards are in place to ensure a respondent's privacy including authorized users, physical safeguards, and procedural safeguards. Authorized users: A database security package is implemented on CDC's computer systems to control unauthorized access to the system. Attempts to gain access by unauthorized individuals are automatically recorded and reviewed on a regular basis. Access is granted to only a limited number of physicians, scientists, statisticians, and designated support staff of CDC or its contractors as authorized by the system manager to accomplish the stated purposes for which the data in this system have been collected. Physical safeguards: Access to the CDC facility where the mainframe computer is located is controlled by a cardkey system. Access to the computer room is controlled by a cardkey and security code (numeric code) system. Access to the data entry area is also controlled by a cardkey system. Guard service in buildings provides personnel screening of visitors. The computer room is protected by an automatic sprinkler system, numerous automatic sensors are installed, and a proper mix of portable fire extinguishers is located throughout the computer room. Computer files are backed up on a routine basis. Hard copy records are stored in locked cabinets at CDC

headquarters and CDC Quarantine Stations which are located in a secure area of the airport. Procedural safeguards: Protections for computerized records 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 medical containing Privacy Act information. Finally, 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.

3. Use of Improved Information Technology and Burden Reduction

The information needed to complete the illness forms is collected by either state or local health departments or maritime conveyance operators. CDC has future plans to distribute the forms in an electronically fillable format so that information can be directly inputted and either email or faxed. Currently, there is no web-based system for transmission of the outcome data. Facsimile or secure email will be used by the states to send the Outcome Reporting Forms to CDC.

4. Efforts to Identify Duplication and Use of Similar Information

As noted previously, CDC has the regulatory authority for performing quarantine-related activities at U.S. ports of entry (42 Part 71). One such activity is providing pertinent passenger information to state and local health departments and maritime operators with the passenger contact information so that state public health officials or maritime operators can notify who may have been exposed to communicable disease. CDC is the only agency that provides this information, and the health department of jurisdiction or maritime operator is the only entity that conducts the contact investigations. In addition, CDC works in collaboration with its international, federal, state, and local partners to ensure all contact investigations due to a communicable disease exposure during travel are done in a coordinated manner. There is no duplication of data collected for the purpose of notifying CDC of the outcome of contact investigation.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this data collection. The respondents are state and local health departments and maritime, e.g., cruise ship operators.

6. Consequences of Collecting the Information Less Frequently

The frequency of data collection is determined by the frequency that an illness or death of public health interest on a conveyance is reported to a Quarantine Station at a port of entry. Control of communicable diseases of public health significance is dependent on rapid identification and immediate response when identified. If data are not collected immediately, CDC will not know if locator information provided was adequate. There are no legal obstacles to reducing the burden.

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

Frequency of data collection is inconsistent with the guidelines, as discussed in Section 6. The frequency of data collection is determined by the frequency that an illness or death of public health interest on a conveyance is reported to a Quarantine Station at a port of entry; this could occur more often than quarterly.

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 on December 22, 2010, vol. 75, No. 245, pp.8057-80508 (See Attachment H), No comments were received from the public.

B. CDC did not consult with outside persons on the development of these forms. The forms represent data that is already captured by state and local health departments and maritime operators. Relay of this information to CDC is done on a voluntary basis. The forms are tools to facilitate transfer of this information to CDC.

9. Explanation of Any Payment or Gift to Respondents

No monetary incentives or gifts are provided to respondent

10. Assurance of Confidentiality Provided to Respondents

CDC will assure the confidentiality of respondents based on procedures implemented in accordance with the Privacy Act. These forms are maintained as a system of records under the Privacy Act system notice 0920-0171, "Quarantine and Traveler Related Activities, Including Records for Contact Tracing Investigation and Notification under 42 CFR Parts 70 and 71, published in the Federal Register, Vol. 72, No. 238, December 13, 2007, pp. 70867-70872. Stringent safeguards are in place to ensure a respondent's privacy including authorized users, physical safeguards, and procedural safeguards.

Privacy Impact Assessment Information

A. This submission has been reviewed by CDC/ICRO who has determined that the Privacy Act does apply. The applicable System of Records Notice is "Quarantine and Traveler Related Activities, Including Records for Contact Tracing Investigation and

Notification under 42 CFR Parts 70 and 71, published in the Federal Register, Vol. 72, No. 238, December 13, 2007, pp. 70867-70872. The information collected from travelers will be kept confidential, and will not be disclosed to anyone unless necessary to carry out their regulatory responsibilities or as otherwise required by law.

B. Highly sensitive information is being collected that would affect a respondent's privacy if there were a breach of confidentiality. However, stringent safeguards are in place to ensure a respondent's privacy including authorized users, physical safeguards, and procedural safeguards. Authorized users: A database security package is implemented on CDC's computer systems to control unauthorized access to the system. Attempts to gain access by unauthorized individuals are automatically recorded and reviewed on a regular basis. Access is granted to only a limited number of physicians, scientists, statisticians, and designated support staff of CDC or its contractors as authorized by the system manager to accomplish the stated purposes for which the data in this system have been collected. Physical safeguards: Access to the CDC facility where the mainframe computer is located is controlled by a cardkey system. Access to the computer room is controlled by a cardkey and security code (numeric code) system. Access to the data entry area is also controlled by a cardkey system. Guard service in buildings provides personnel screening of visitors. The computer room is protected by an automatic sprinkler system, numerous automatic sensors are installed, and a proper mix of portable fire extinguishers is located throughout the computer room. Computer files are backed up on a routine basis. Hard copy records are stored in locked cabinets at CDC headquarters and CDC Quarantine Stations which are located in a secure area of the airport. Procedural safeguards: Protections for computerized records 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 medical containing Privacy Act information. Finally, 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.

C. Respondent consent: Respondents to this data collection are from state and local health departments and maritime conveyance operators. CDC is not collecting data directly from the individual; therefore, no consent or script to conduct such an interview is needed.

D. Respondents are state and local health departments and maritime conveyance operators. Respondents are informed about the intended use of the information

collection when CDC provides the respondents with passenger contact information needed to conduct the investigation. The submission of outcome reports from the health departments/maritime operators to CDC is completely voluntary. Data will be safeguarded in a secure manner.

11. Justification for Sensitive Questions

These forms collect three types of data: 1) Epidemiologic data such as travel itinerary, clinical signs and symptoms, exposure to ill people or animals, history of illness are essential to accurately determining the public health risk; 2) Demographic data such as age, race, sex, and geographic location are routinely collected as part of standard public health surveillance; and 3) Clinical information (symptom development, medical evaluation, lab testing, etc.) All of these data elements are essential to efficiently detect a public health threat and rapidly implement appropriate public health control measures to prevent the introduction and spread of communicable disease in the U.S.

12. Estimates of Annualized Burden Hours and Costs

A. Estimate of Annualized Burden Hours

Based on the actual number of contact investigations conducted in 2009, DGMQ estimates that the number of contacts will be approximately 3347 yearly. The estimated time for state or local health departments or maritime operators to complete the forms is approximately five minutes. The amount of time depends on whether the health departments or maritime operator was able to contact the individual believed to have been exposed to a communicable disease. If contact was made, this estimate of time is based on the time it would take to relay the pertinent information they have collected to the CDC standardized forms. The total burden hours would therefore be approximately 280 hours if an outcome form was submitted for each contact.

A.1 Estimate of Annualized Burden Hours and Costs

| Type of Respondent | Form Name | Number of Respondents | Number of Responses per Respondent | Average Burden per Response (in hours) | Total Burden Hours |
|-------------------------------------|--|-----------------------|------------------------------------|--|--------------------|
| State/local health department staff | Optional TB Air /Land Contact Investigation Outcome Reporting Form | 2154 | 1 | 5/60 | 180 |
| Maritime | Optional TB | 190 | 1 | 5/60 | 16 |

| | | | | | |
|-------------------------------------|---|-----|---|------|-----|
| Operators | Maritime Contact Investigation Outcome Reporting Form | | | | |
| State/local health department staff | Optional Measles, Mumps or Rubella Air /Land Contact Investigation Outcome Reporting Form | 367 | 1 | 5/60 | 31 |
| Maritime Operators | Optional Measles, Mumps or Rubella Maritime Contact Investigation Outcome Reporting Form | 140 | 1 | 5/60 | 12 |
| State/local health department staff | Optional General Air/Land Contact Investigation Outcome Reporting Form | 456 | 1 | 5/60 | 38 |
| Maritime Operators | Optional General Maritime Contact Investigation Outcome Reporting Form | 40 | 1 | 5/60 | 3 |
| Total | | | | | 280 |

B. To estimate annualized burden cost, we have taken the average wage or median income of a public health officer, which is \$29.44 per hour (according to the U.S. Department of Labor Statistics. Assuming an hourly respondent labor wage of \$29.44 for the general public (www.bls.gov/news.release/empsit.t17.htm) the estimated annual cost to respondents would total \$8243.20.

B.1 Estimate of Annualized Burden Cost

| Form | Total Burden Hours | Hourly Wage Rate | Total Respondent Costs |
|---|--------------------|------------------|------------------------|
| Optional TB Air /Land Contact Investigation Outcome Reporting Form | 180 | \$29.44 | 5,299.20 |
| Optional TB Maritime Contact Investigation Outcome Reporting Form | 16 | \$29.44 | \$471.04 |
| Optional Measles, Mumps or Rubella Air /Land Contact Investigation Outcome Reporting Form | 31 | \$29.44 | \$912.64 |
| Optional Measles, Mumps or Rubella Maritime Contact Investigation Outcome Reporting Form | 12 | \$29.44 | \$353.28 |
| Optional General Air/Land Contact Investigation Outcome Reporting Form | 38 | \$29.44 | \$1,118.72 |
| Optional General Maritime Contact Investigation Outcome Reporting Form | 3 | \$29.44 | \$88.32 |
| Total | | | \$8243.20 |

13. Estimates of Other Total Annual cost burden to Respondents or Record Keepers

There is no other total annual cost burden to respondents or recordkeepers.

14. Annualized Cost to the Government

The annual cost to the federal government is estimated at \$8211.31. This estimate represents the amount of time for the state or local health department staff as well our maritime partners to complete the forms.

Breakdown of costs:

Investigations:

| | |
|------------------------|-----------|
| Contact Investigations | 3347 |
| Time to respond | 5 minutes |
| Hourly rate | \$29.44 |

Total annual costs: \$8211.31

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

These are recurring data collections, the time schedules for which are determined by the frequency in which there is exposure to a communicable disease that results in a contact investigation. Both daily and incident specific reports are generated for CDC staff using QARS data. In addition, Quarantine staff plan to use the data, aggregated to protect the privacy of any individually identifiable information, to provide the public, partners, and other stakeholders information about contact investigation and to evaluate and improve CDC's investigative protocols.

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

CDC requests an exemption to the expiration date displayed on the contact investigation outcome reporting forms (Attachments B). The information collected on these forms is routine and will not change except to update the expiration each time the package is renewed. The forms will be distributed to each Quarantine Station for use by Quarantine Station staff.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.