

Emergency Submission to Supplement OMB Control Number 0920-0821 in the context of Screening Travelers for Ebola Risk.

Supporting Statement A

Program Contact

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Supporting Statement

A. Justification

1. Circumstances Making the Collection of Information Necessary

Background

The Centers for Disease Control and Prevention (CDC) has been tasked to engage in active surveillance of travelers arriving at U.S. airports from countries currently affected by the Ebola outbreak. CDC's response requires revising multiple CDC Paperwork Reduction Act clearances. This emergency request focuses specifically on supplemental forms and burden that will eventually be merged into OMB 0920-0821: Quarantine Station Illness Response Forms: Airline, Maritime, and Land/Border Crossing (expiring 8/31/2015), after the required public comment period. These forms are designed to work in concert with forms recently approved under OMB 0920-0009 and OMB 0920-0900. Above what is already approved in OMB 0920-0821, the total number of respondents and burden requested is 55,380 and 13,845, respectively.

This emergency package covers the following:

1. The addition of one form, United States Traveler Health Declaration (Attachment A1 English, A2 French). An increase of 54,750 additional respondents and 13,687 hours of respondent burden is requested for 0920-0821 as a result of adding this form. CDC is also including a job aid for Department of Homeland Security personnel (DHS) that will instruct them on how to proceed through the United States Traveler Health Declaration (Attachment B). CDC requests approval to have both hard copy of the United States Traveler Health Declaration (English and French) and electronic (English only) versions of this form. The electronic form will be created and processed in the following way:
 - o The form will be re-created as a fillable PDF and data will be entered by DHS personnel on a DHS laptop
 - o PDFs will be transferred by encrypted flash drive to DHS server
 - o Batch transfer of PDFs to CDC via secure file transfer protocol
 - o Data will be mapped to a CDC database to allow upload
 - o If traveler is referred to CDC for a public health evaluation, the United States Travel Health Declaration will be printed and handed to a CDC staff member
2. The modification of the Ebola Risk Assessment For Travelers From Ebola Outbreak-Affected Countries form (Attachment C) that was approved by OMB through a non-substantive change on 9/18/2014. The modifications include:
 - Inclusion of PII so that the form can be included as part of the medical declaration accompanying any public health order, as well as be part of the individual's screening record,

- Inclusion of Yes, No, or Unknown to document the respondents' answers to questions concerning possible exposures,
 - Free text fields to allow for a description of any Yes answer to an exposure,
 - An updated description of an Ebola case and exposure from Ebola subject matter experts,
 - A simplification and consolidation of the description and instructions for the use of personal protective equipment (PPE),
 - Re-write of Question #1 to be more specific concerning high risk exposure,
 - Specifying that the risk should have occurred within the last 21 days, and to obtain the date of exposure,
 - For CDC staff to complete, the addition of a section to document exposure assessment summary, document who performed the assessment, document final disposition of the traveler, as well as include a field to document that a CDC medical officer was consulted during the assessment, and
 - A re-ordering of instructions for the person conducting the assessment.
- A change in burden is associated with this modification, because the purpose of the form has broadened. While this improved form will still be used to evaluate travelers who are reported to CDC as ill prior to arrival, according to CDC regulations at 24 Code of Federal Regulations 71.21, this form will also now be used to conduct part of a public health evaluation as a portion of the entry screening process, and will be included as part of the medical declaration for any public health order that is appropriate. CDC estimates that each use of this form will now request 15 minutes of respondent burden, instead of three minutes.
 - The addition of burden is due to the use of the Ebola Risk Assessment For Travelers From Ebola Outbreak-Affected Countries in the entry screening process. CDC is requesting an additional 630 respondents and 158 hours of burden associated with this change.

2. Purpose and Use of Information Collection

This request that would provide CDC with the tools and appropriate burden to conduct entry screening of individuals coming to the United States from countries affected by the current Ebola outbreak.

The primary change to what has already been approved under OMB No 0920-0821 is the requested addition of an information collection tool so that CDC can, on one form, very quickly screen an individual for symptoms consistent with Ebola, assess exposure risk, collect contact information, and record a temperature. This United States Traveler Health Declaration form is designed for rapid use and contains questions that are limited in scope so as not to subject travelers to unnecessarily onerous and intrusive and not unduly obstruct the flow of travel. Additionally, the United States Traveler Health Declaration, while developed by CDC, will be implemented by DHS at international airports. This form is designed to be used by DHS with basic training.

The United States Traveler Health Declaration will be administered to every traveler arriving at a U.S. airport from an affected country. DHS will assist CDC by completing the United States Traveler Health Declaration and temperature screening based on responses from the traveler and the use of a non-contact thermometer.

If a traveler answers in the affirmative to experiencing any of the specified symptoms or exposures, appears visibly ill, or has a fever, the risk threshold for a further public health evaluation is met. DHS will then contact CDC who will use the revised Ebola Risk Assessment For Travelers From Ebola Outbreak-Affected Countries form to conduct a detailed medical evaluation to determine if further intervention is necessary.

CDC also has approved Illness and Death Investigation forms under 0821-0920 to collect additional information from travelers, if needed.

While cooperation with CDC during this proposed risk assessment is voluntary, if an individual refuses to provide the requested information, or is not truthful about the information provided during screening of an illness investigation, CDC may, if it is reasonably believed that the individual is infected with or has been exposed to Ebola, quarantine, isolate, or place the individual under surveillance under 42 CFR 71.32 and 71.33.

3. Use of Improved Information Technology and Burden Reduction

Department of Homeland Security, Customs and Border Protection (DHS/CBP) requested that there be an option for electronic capture of the information from the United States Traveler Health Declaration. To facilitate this request, CDC and DHS/CBP have developed the following process:

- o The United States Travel Health Declaration will be re-created as a fillable PDF and data will be entered on a DHS laptop
- o PDFs will be transferred by encrypted flash drive to DHS server
- o Batch transfer of PDFs to CDC via secure file transfer protocol
- o Data will be mapped to a CDC database to allow upload
- o If traveler is referred to CDC for a public health evaluation, the United States Travel Health Declaration will be printed and handed to a CDC staff member

4. Efforts to Identify Duplication and Use of Similar Information

There is no duplication. This work is being done in collaboration with the U.S. Customs and Border Patrol, Department of Homeland Security.

5. Impact on Small Businesses or Other Small Entities

None

6. Consequences of Collecting the Information Less Frequently

If CDC does not collect this information, there is an increased risk of ill passengers coming in contact with the general public.

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

None

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

A. OMB has waived the 60 day public comment period.

B. CDC consulted with the Department of Homeland Security in the development of this information collection.

9. Explanations of Any Payment or Gift to Respondents

No monetary incentives or gifts are provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

This information collection request has been reviewed by the CDC Information Collection Review Office (ICRO). The ICRO has determined that the Privacy Act does apply to some aspects of this information collection request. The applicable System of Records Notice is 09-20-0171.

Information submitted will be entered into a computer system for analysis and later retrieved if necessary. Data containing personal identifiers and source documents will be retained until the event prompting the collection of data has concluded in accordance with DGMQ's records retention schedule. Data not containing personal identifiers will be retained indefinitely for statistical and historical documentation purposes. Electronic media will be protected by adequate physical, administrative, and procedural safeguards to ensure the security of the data. Access will be restricted to agency employees with a bona fide "need to know" in order to carry out the duties of their positions or to accomplish the purposes for which the data were collected. When information is deleted, a special "certified" process will be used to completely overwrite tapes on the mainframe or overwriting (not merely deleting) microcomputer files. Source documents, printouts and thumb drives will be safeguarded by storing them in locked cabinets in locked offices when not in use.

10.1 Privacy Impact Assessment Information

Privacy Impact Assessment Information

1. Respondents to this data collection will be informed whether or not providing the data described in this supporting statement is mandatory or voluntary.
2. Respondents indicate their consent by verbally agreeing to participate in the screening program.

3. Highly sensitive information is being collected and would affect a respondent's privacy if there were a breach of confidentiality. This information is collected under the Privacy Act system of records notice 09200171, "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. However, stringent safeguards are in place to ensure a respondent's privacy including restriction of access to 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. 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 and use 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, the CDC Project Director, contract officers and project officers oversee compliance with these requirements, and CDC employees and contractors are required to be trained on the Privacy Act and receive information security awareness training at least annually.

4. This data collection are subject to the Privacy Act. The existing applicable Systems of Records Notice for this revision is 09-20-0171.

11. Justification for Sensitive Questions

This information collection requests certain personally identifying information of both imports and travelers. Some personally identifying information will be collected during the proposed risk assessments in order to identify ill travelers. Some travelers might find these questions sensitive in nature, but this information is necessary to prevent the

introduction, transmission, or spread of communicable diseases from foreign countries into the United States.

12. Estimates of Annualized Burden Hours and Costs

Below are the estimates of the Annualized Burden Hours that are not already included in the OMB No. 0920-0821. CDC estimates an additional 55380 respondents and 13,845 burden hours above what is already approved.

Approximately 99% of this additional burden is associated with DHS employees assisting CDC in administering the CDC-developed United States Travel Health Declaration instrument. The remaining one percent is associated with CDC staff performing the public health evaluation using the Ebola Risk Assessment For Travelers From Ebola Outbreak-Affected Countries and already approved Illness and Death Investigation tools.

This estimate is based on the following assumptions and estimates:

- Based on aviation data from Data in. Data out., LLC, CDC assumes there will be approximately 150 travelers from the affected region who are coming to the United States each day who will be screened using the United States Travel Health Declaration. On an annual basis, this equates to 54,750 responses and 13,687 burden hours for the use of the United States Travel Health Declaration.
 - o Of these 54,750 annual arrivals, approximately 9125 per year will arrive from Guinea and may require a French translation of the United States Travel Health Declaration. CDC estimates that the total burden for French speaking respondents will be 2281 out of the 13,687 hours of additional burden requested in this emergency clearance.
- A small subset of this group will be referred by DHS to CDC based on their responses to the United States Travel Health Declaration. CDC estimates that there will be two travelers per day, on average, that require a public health assessment using the Ebola Risk Assessment for Travelers from Outbreak-affected Countries, and other Illness and Death Investigation forms if necessary. This equates to 630 responses and an additional 158 hours for the use of the revised Ebola Risk Assessment for Travelers from Outbreak-affected Countries form.

12 A. Estimates of Annualized Burden Hours

Form	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in minutes)	Total Burden Hours
Ebola Risk Assessment for Travelers from Outbreak-affected Countries	630	1	15/60	158
United States Travel Health Declaration	45625	1	15/60	11,406

(English: Hard Copy and Electronic)				
United States Travel Health Declaration (French, Hard Copy)	9125	1	15/60	2281
Total	55,380			13845

Estimates of Annualized Cost Burden 0920-0821 Quarantine Station Illness Response Forms: Airline, Maritime, and Land/Border Crossing. Wages for travelers were gathered from 00-0000 All Occupations (http://www.bls.gov/oes/current/oes_nat.htm#00-0000). The estimated additional cost is \$309,159.

12 B. Estimates of Annualized Cost

Form	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Ebola Risk Assessment for Travelers from Outbreak-affected Countries	158	\$22.33	\$3,528
United States Travel Health Declaration (English: Hard Copy and Electronic)	11406	\$22.33	\$254, 696
United States Travel Health Declaration (French, Hard Copy)	2281	\$22.33	\$50,935
Total	13845		\$309,159

14. Plans for Tabulation and Publication and Project Time Schedule

CDC and CPB may report aggregate totals of number of people screened and number of positives publicly, as appropriate.

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

Display of the expiration date is appropriate. No exemption is requested.

15. Exceptions for Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

List of Attachments

Attachment A1- United States Travel Health Declaration – English

Attachment A2 - United States Travel Health Declaration – French

Attachment B – DHS Job Aid

Attachment C - Ebola Risk Assessment For Travelers From Ebola Outbreak-Affected Countries