

Nonmaterial/non-substantive change to Emergency Submission to Supplement OMB Control Number 0920-0821 in the context of Screening Travelers for Ebola Risk (OMB Control No. 0920-1031) Expiration date 4/30/2015

Program Contact

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Circumstances of Change Request for OMB 0920-1031

CDC requests approval for a nonmaterial/non-substantive change to OMB Control No. 0920-1031 Emergency Submission to Supplement OMB Control Number 0920-0821 in the context of Screening Travelers for Ebola Risk (expiration 4/31/2015).

Since October 11th, 2014 the Centers for Disease Control and Prevention (CDC), in coordination with the Department of Homeland Security (DHS), has been screening travelers arriving at certain U.S. ports of entry from countries with widespread transmission of Ebola. The objective of this screening is to identify travelers who may be sick with Ebola or may have had an exposure to Ebola when they arrive in the United States, and ensure that these travelers are directed to appropriate care and monitoring, if needed, which will also help protect the health of all Americans.

CDC has identified specific elements in the United States Traveler Health Declaration (Attachment A1a English hard copy, Attachment A1b English electronic portal, Attachment A1c English fillable PDF, Attachment A2 French, and Attachment A3 Arabic) and Ebola Risk Assessment For Travelers From Ebola Outbreak-Affected Countries form (Attachment B1 English and B2 French) that need to be modified in order to more quickly and effectively assess the risk for Ebola in travelers to the United States from affected countries, and better align disposition of passengers into the risk categories outlined in CDC's revised Interim U.S. Guidance for Monitoring and Movement of Persons with Potential Ebola Virus Exposure (available here: <http://www.cdc.gov/vhf/ebola/exposure/monitoring-and-movement-of-persons-with-exposure.html>).

Additional administrative changes are requested to the United States Traveler Health Declaration and Ebola Risk Assessment For Travelers From Ebola Outbreak-Affected Countries form that do not have an impact on respondents, but instead focus on refining the screening process so that it is more efficient for both the screeners and the travelers. The changes are also intended to provide operational refinements to improve processing of information and linking the forms to individual travelers.

Also, with several cases identified in Mali, CDC is adding additional burden to accommodate a larger number of travelers to the United States from that country who will undergo public health screening.

Finally, CDC is making a correction to the estimate of burden outlined in approved OMB Control No. 0920-1031. The original estimate included a number of travelers for 12 months of arrivals from the affected countries. The revised estimate is for six months only.

The total burden requested for this change is 8,261.

Description of Changes

1) This is a request to modify two information collection tools that CDC and DHS are currently using to screen travelers who are coming to the United States from countries with widespread transmission of Ebola: the United States Traveler Health Declaration and the Ebola Risk Assessment for Travelers from Outbreak-affected Countries. The changes to each form are as follows.

Regarding the United States Traveler Health, CDC and our partners have identified certain changes that would make this form more useful in assessing risk for infection or exposure to Ebola, and easier to use by CDC's federal and state and local partners. Only the first two changes listed in this section have an impact on the respondent, and the marginal increase in burden is negligible, requiring at most a few

seconds of time. These changes will be made to the hard copy, fillable PDF, and electronic portal version of the United States Travel Health Declaration.

- CDC received a request from a state health department for the addition of a departure date field to the United States Traveler Health Declaration. While some trips from the affected countries may be a few connecting flights over a couple of days, some travelers may spend several days in other countries prior to arriving and being screened in the United States. Having this field will assist in accurately determining how many days an individual should be monitored after screening at the U.S. ports of entry.
- CDC is also requesting the a change to a question that currently asks whether or not the person being screened lived in the same household or had contact with someone with Ebola. The question is being changed, and will now ask if the person lived in the same household or had contact with someone with Ebola, *or with someone who was very sick or died*. CDC believes this modification is important to add this question because someone may not know if the individual who was very sick or died was a confirmed case of Ebola. This question will enable the United States Traveler Health Declaration to be more sensitive to potential Ebola exposures.
- On the health declaration, question E has been modified to capture other potential high risk exposures associated with preparing dead bodies or attendance at funerals. A CDC anthropologist recently studied funeral rites in Sierra Leone and provided information about rituals that could result in exposures to water used to wash dead bodies or the cloths used to wrap the bodies. These rituals would be considered high risk exposures that would not have been captured by the questions as previously worded. With the revision, all travelers who were around a dead body or attended a funeral in a country with widespread transmission will additionally be sent to Tertiary Screening where additional information about the potential exposure will be obtained using the Ebola Risk Assessment For Travelers From Ebola Outbreak-Affected Countries form.
- CDC is requesting that in the French version of the United States Traveler Health Declaration, the instructions be in English (Attachment A2). This is because the instructions are followed by CBP personnel, not the traveler. CDC is also requesting the addition of an Arabic version of the health declaration, for the small numbers of Arabic speakers arriving from the region (Attachment A3). This will not add burden to the change request, but will result in a rearranging of the burden hours. CDC estimates that there will be approximately 150 travelers with a need for an Arabic form, with an estimated burden of 38 hours. CDC is also requesting the addition of a field to indicate primary language of the traveler being screened, which CBP will mark to allow state and local health departments to determine if an interpreter is needed for follow-up of certain travelers. This will result in no added burden to the respondent.
- Finally, CDC is re-ordering and adding the “Care Kit” field to the disposition section located at the bottom of the United States Traveler Health Declaration. In addition, CDC is adding administrative fields to the top right hand corner of the form to document the Care ID kit number and the cell phone number associated with the kit. While these changes have no impact on the respondent, this will enable CDC and CBP to improve the documentation, linkages between forms and travelers, processing of the outcome of the responses to the United States Traveler Health Declaration, and allow for improve follow-up of individuals who meet the risk threshold for active monitoring by public health authorities.

Concerning the Ebola Risk Assessment For Travelers From Ebola Outbreak-Affected Countries, CDC has determined that a small number of changes will greatly increase the utility of the form while making it easier to use and process. In general, the impact to respondents based on these changes should be negligible, as only two changes in this section request additional information and the majority of the changes are intended as operational refinements.

- CDC is adding a new question two so that CDC can discover whether a healthcare worker provided care in any setting, not just an Ebola Treatment Center. As described in a recent MMWR article (Ebola Virus Disease Cases Among Health Care Workers Not Working in Ebola Treatment Units — Liberia, June–August, 2014, available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm63e1114a3.htm?s_cid=mm63e1114a3_w), healthcare workers in Guinea, Liberia and Sierra Leone who did not work in Ebola Treatment Units have become infected due to not recognizing that a patient was infected with Ebola. Therefore, all healthcare workers who provided direct patient care in the previous 21 days will be considered to be in the some risk category.
- In question number three on the risk assessment form, CDC is requesting the addition of one sub-question that asks if healthcare workers provided care or other services in a location where there was a known Ebola infection of other healthcare workers. This question is being added to enable CDC during screening to make a more comprehensive risk assessment in the event that breaches in personal protective equipment cannot be concretely identified on an individual basis. Currently the process involves the following:
 - Every traveler from the countries with widespread transmission of Ebola is identified by Customs and Border Protection (Primary Screening) and receives screening using the United States Traveler Health Declaration (Secondary Screening). 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 (Tertiary Screening).
 - As described for US healthcare workers (HCW) in CDC's Monitoring and Movement Guidance (<http://www.cdc.gov/vhf/ebola/exposure/monitoring-and-movement-of-persons-with-exposure.html>), HCW who took care of Ebola patients in a facility where another HCW became infected with Ebola with no recognized breach in infection control are considered exposed in the high risk category. The reason for this is that we would no longer be assured that all infection control procedures were correctly followed. The same might apply to HCW in a country with widespread transmission, although circumstances there are less clear cut due to the potential for infection unrelated to the hospital, such as in the community. However, CDC staff will obtain descriptive information to attempt to identify such situations where additional movement restrictions for HCW might be warranted due to a possible unrecognized high risk exposure.
- CDC is also adding the specific mention of observers, e.g. journalists, in question number three to the categories of individuals who may have entered a location where care for Ebola patients is being provided. In some cases, these individuals are at increased risk for exposure and infection and should be identified during screening.

- CDC is modifying question five to add contact with the water used to wash dead bodies or the cloth that covered a dead body. As described above, a CDC anthropologist recently studied funeral rites in Sierra Leone and provided information about rituals that could result in exposures to water used to wash dead bodies or the cloths used to wrap the bodies. These rituals would be considered high risk exposures that would not have been captured by the questions as previously worded. With the revision, all travelers who were around a dead body or attended a funeral in a country with widespread transmission will additionally be sent to Tertiary Screening where additional information about the potential exposure will be obtained using the Ebola Risk Assessment For Travelers From Ebola Outbreak-Affected Countries form.
- CDC is modifying certain questions to ensure that the risk assessment process during screening aligns with the categories of exposure risk identified in the revised Interim U.S. Guidance for Monitoring and Movement of Persons with Potential Ebola Virus Exposure. This will ensure that when the assessment is completed, CDC can reference the interim guidance and provide the individual with the appropriate information, public health follow-up, or other public health intervention, as necessary. CDC is also adding an additional field for a second temperature check, in case the medical evaluator feels it is necessary. This could be the case when there is a borderline fever or a temperature reading that appears to be inaccurate. To confirm or rule out a fever, a repeat temperature may be taken with an oral thermometer. Also if a period of observation was needed during further medical evaluation, a temperature maybe retaken.
- CDC has revised the instructions and added certain fields to assist public health professionals who are performing the screening. The instructions are clearer on how to proceed through the form and include more specific information concerning who at CDC headquarters should be contacted in case further assistance is needed. The data fields that have been added are those, such as countries visited and whether or not a state or local health department has been notified. These questions do not impact the respondent, but make the form more usable and useful in making sure that links to state and local health departments have been made, if necessary. Finally, a CDC anthropologist also described burial workers in “full PPE” who were wearing open shoes. Therefore, boots/shoe covers have been added to the list of appropriate PPE in the risk assessment form.
- Finally, CDC requests the addition of a French of the Ebola Risk Assessment For Travelers From Ebola Outbreak-Affected Countries form (Attachment B2). This should make it easier to conduct the medical evaluation for those travelers with limited English Proficiency. For this form, as with the health declaration, the instructions will be in English, as the screeners’ and medical evaluators’ operational language will primarily be English. CDC estimates, based on the number of travelers from Guinea, the number respondents to the French version of the risk assessment form will be 61, with a burden of 15 hours. The estimates for Mali are below.

While cooperation with CDC during this proposed risk assessment is voluntary, if an individual refused to provide the requested information, or is not truthful about the information provided during 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.

2) CDC is requesting a correction to the burden and cost totals provided in the emergency clearance, as the estimates provided were for a full 12 months instead six. As outlined in the original emergency

clearance, there are approximately 54,750 travelers from the affected countries arriving to the United States on an annual basis. CDC estimates that six months of arrivals is approximately half of this total, equal to 27,375 arriving travelers. Each of these arrivals will respond to an English, French, or Arabic version of the travel health declaration. Of this 27,375 travelers, approximately between two and three per day will require a more thorough medical evaluation provided by answering the questions in the Ebola Risk Assessment For Travelers From Ebola Outbreak-Affected Countries form. This is a total of 414 respondents in the six months of approval granted by an emergency clearance. The breakdown of language specific burden for each information collection tool is found in the table below. The reduction in total burden associated with this correction is 6,909 hours.

3) Given recent cases in Mali, CDC is requesting sufficient burden to screen the approximately 5250 travelers from that country who come to the United States in a six month time frame. As Mali is a francophone country, CDC is increasing the burden associated with the French versions of the health declaration and risk assessment form. The additional burden associated with the health declaration is 1312 hours. The additional burden associated with the risk assessment is 13 hours.

Burden

Estimates of Annualized Burden Hours for 6 months: The following modifications are included in the burden table.

- CDC has estimated the number of travelers and associated burden for the French version of the Ebola Risk Assessment for Travelers from Outbreak-affected Countries by using same proportion of French speak travelers that will use the French version of the United States Traveler Health Declaration.
- Due to cases in Mali, CDC is estimating an additional 1312 hours and 5250 respondents to the French version of the health declaration and an additional 13 burden hours and 49 respondents associated with the French version of the risk assessment.
- CDC is estimating that 150 Arabic speakers will respond to the Arabic version of the United States Traveler Health Declaration. This number has been subtracted from the number respondents to the English health declaration, so the total number of respondents to the health declaration has not changed.
- The correction from 12 months of respondents for the screening forms to six months has resulted in a decrease of 6,909 hours. The revised total burden is 8,261 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 (English)	304	1	15/60	76
Ebola Risk Assessment for Travelers from Outbreak-affected	110	1	15/60	28

Countries (French)				
United States Travel Health Declaration (English: hard copy, fillable PDF and electronic portal)	22,663	1	15/60	5,666
United States Travel Health Declaration (French, Hard Copy)	9813	1	15/60	2453
United States Travel Health Declaration (Arabic: Hard Copy)	150	1	15/60	38
Total	33,040			8,261

Estimates of Annualized Cost Burden for 6 months:

- The decrease in respondent costs due to the correction in burden estimates for the health declaration and the risk assessment form is \$154,277. The revised total cost is \$184,468

Form	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Ebola Risk Assessment for Travelers from Outbreak-affected Countries (English)	76	\$22.33	\$1697
Ebola Risk Assessment for Travelers from Outbreak-affected Countries (French)	28	\$22.33	\$625
United States Travel Health Declaration (English: hard copy, fillable PDF, and electronic portal)	5666	\$22.33	\$126,522
United States Travel Health	2453	\$22.33	\$54,775

Declaration (French, Hard Copy)			
United States Travel Health Declaration (Arabic, Hard Copy)	38	\$22.33	\$849
Total	8,261		\$ 184,468

Wages for travelers were gathered from 00-0000 All Occupations (http://www.bls.gov/oes/current/oes_nat.htm#00-0000).

Privacy Impact Assessment

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. While cooperation with CDC during this proposed risk assessment is voluntary, if an individual refused to provide the requested information, or is not truthful about the information provided during 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. 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 is 09-20-0171, Quarantine and Traveler Related Activities, Including Records for Contact Tracing Investigation and Notification under 42 CFR Parts 70 and 71.