Restrictions on Interstate Travel of Persons (42 CFR Part 70) (OMB Control No. 0920-0488) Request for Revision 04/29/2016

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#### Restriction on Travel of Persons (42 CFR Part 70) (OMB Control No. 0920-0488)

- The goal of this information collection is to ensure that CDC can collect data related to communicable disease or deaths that occur aboard conveyances during interstate travel within the United States, as authorized under 42 Code of Federal Regulations part 70.
- The intended use of the information is to ensure that CDC can assess and respond to reports of communicable disease or death that occur on conveyances engaged in interstate travel, and assist state and local health authorities if an illness or death occurs that poses a risk to public health.
- As required by regulation, all instances of communicable disease characterized by certain signs and symptoms must be reported to the local health authority with jurisdiction over the arrival port. CDC has accepted reports to CDC as fulfilling this requirement. CDC also requests reports of all deaths occurring during domestic flights.
- There is no subpopulation being studied. The universe of respondents for required reports of communicable disease and requested reports of death is any master of any vessel or person in charge of any conveyance engaged in U.S. interstate traffic.
- Data will be analyzed to ensure compliance with regulations;

This is a request for a revision of the currently approved Information Collection Request (ICR), OMB Control Number 0920-0488, expiring March 31, 2016. CDC is requesting approval for three years. This ICR includes a program change that involves removing the III Person Travel Permit and Master of Vessel or Conveyance Illness Report forms, and related copies, from the list of information collections.

CDC initially developed travel permits to align with text in the regulations that provided for this authority; however, the permits were never used. In current practice, CDC does not process applications for travel permits and does not ask for copies of permits from state health authorities using the Restriction On Travel Of Persons Multipurpose Application Form Under the Provisions of 42 CFR Part 70 (aka Ill Person Travel Permit). The process for limiting travel is not amenable to a standardized form, because, in general, CDC discovers that an ill person needs to travel from state health departments and makes decisions about travel in collaboration with the states and the individual. CDC does not receive an application from an ill person to travel. Because CDC never has nor will use the permits approved in previous versions of this information collection request, CDC is requesting the removal of the following information collections:

 42 CFR 70.3, Application to the State of destination for a permit, Copy of material submitted by applicant and permit issued by State health authority (Attending physician),

- Copy of material submitted by applicant and permit issued by State health authority (State health authority)
- 42 CFR 70.5, Application for a permit to move from State to State while in the communicable period (Attending physician)
- Application for a permit to move from State to State while in the communicable period (Traveler)

Reports of communicable disease or death from domestic conveyances are almost always submitted electronically to meet requirements of 42 CFR 70.4, so the current hard copy Master of Vessel or Conveyance Illness Report has been rendered obsolete. In addition, CDC has issued guidance (August 2014, http://www.cdc.gov/quarantine/pdf/airlines-tool.pdf) stating that reports to CDC, instead of local health authorities, regarding domestic reports of communicable disease or death on board conveyances meet the requirements of the regulation; therefore, information collections related to copies sent to state health departments are no longer necessary. The only remaining information collection under 42 CFR 70.4 is *Report by the master of a vessel or person in charge of conveyance of the incidence of a communicable disease occurring while in interstate travel*. This is an electronic submission, there is no hard copy requirement.

#### A. Justification

#### 1. Circumstances Making the Collection of Information Necessary

Section 361 of the Public Health Service Act (42 USC 264) (Attachment 1A) authorizes the Secretary of the Department 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, or from one State or possession into any other State or possession. Regulations pertaining to preventing the importation and spread of communicable diseases from foreign countries (42 CFR part 71 Attachment 1B) are administered by the Centers for Disease Control and Prevention (CDC). Regulations pertaining to interstate control of communicable diseases (42 CFR part 70) (Attachment 1C) are also administered by CDC.

Regulations found at 42 CFR part 70.4 require that the master of a vessel or a person in charge of a conveyance engaged in interstate traffic, on which a suspected case of communicable disease develops shall notify the local health authority at the next port of call, station, or stop, and take such measures to prevent the spread of the disease as the local health authority directs. CDC has interpreted "communicable disease" in a manner consistent with the definition of "ill person" found in 42 CFR part 71.1, which is a person who:

(1) Has a temperature of 100 °F. (or 38°C.) or greater, accompanied by a rash, glandular swelling, or jaundice, or which has persisted for more than 48 hours; or
(2) Has diarrhea, defined as the occurrence in a 24-hour period of three or more loose stools or of a greater than normal (for the person) amount of loose stools.

In addition to these signs and symptoms of disease, CDC has requested, in close alignment with standards set by the International Civil Aviation Organization (ICAO), that the following signs and symptoms of disease be reported to CDC:

- Persistent cough
- Persistent vomiting
- Difficulty breathing
- Headache with stiff neck
- Decreased consciousness
- Unexplained bleeding

CDC has stated via agency guidance that reports made directly to CDC Headquarters or to the CDC Quarantine Station with jurisdiction for the arrival port, generally an airport, satisfy the reporting requirement in 42 CFR part 70.4.

# 2. Purpose and Use of Information Collection

Control of disease transmission within the United States is largely considered to be the province of State and local health authorities, with Federal assistance being sought by those authorities on a cooperative basis, without application of Federal regulations. The regulations at 42 CFR Part 70 were developed to facilitate Federal action in the event of large outbreaks requiring a coordinated effort involving several States, or in the event in inadequate local control. While it is not known whether, or to what extent, situations may arise in which these regulations would be invoked, contingency planning for domestic emergency preparedness is not uncommon. If a domestic emergency occurs, the reporting and record keeping requirements contained in the regulations will be used by CDC to carry out quarantine responsibilities as required by law, specifically, to prevent the spread of communicable diseases from one State or possession into any other State or possession.

The data collected under 70.4 is also a critical part of CDC's routine and emergency response operations. It involves the collection of reports of illnesses that occur aboard domestic flights or maritime voyages within the U.S. For routine reports of illness aboard domestic voyages airplane captains will continue to report electronically via Air Traffic Control and the Domestic Events Network. Masters of maritime vessels engaged in interstate travel may report via email or other electronic method.

The reporting of required and requested signs and symptoms of disease outlined above, as well as any death, is the minimum necessary to meet statutory and regulatory obligations, and is consistent with ICAO standards for aircraft. (Available here: (http://www.icao.int/MID/Documents/2013/capsca-id3/ICAOHealthRelatedSARPsandguidelines.pdf).

# 3. Use of Improved Information Technology and Burden Reduction

There are no standard forms associated with this information collection. Reporting requirements imposed by the regulations have been reduced and streamlined by reliance upon State and local health departments to manage most situations occurring within their jurisdictions. If submission of information under these regulations becomes necessary, all information may be submitted in the most expeditious manner practical. At this time, all reporting of a communicable disease or death is accomplished electronically, e.g. via Air Traffic Control or via the airlines' points of contact (e.g., Operations Center, Flight Control, Airline Station Manager.)

Reporting for domestic flights should be consistent with International Civil Aviation Organization, which are as follows:

For aircraft outside U.S. airspace or for U.S. destination

Reports of communicable disease or death should be made in one of the two following ways:

# 1. Air Traffic Control (ATC)

[This reporting option complies with International Civil Aviation Organization (ICAO) reporting requirement, ICAO document 4444 and Annex 9, Ch. 8, 8.15.] ATC will notify CDC's Emergency Operations Center (EOC) through the Domestic Events Network; the EOC will notify the appropriate CDC Quarantine Station and the local health department of jurisdiction. Quarantine staff will communicate with the airline's designated point of contact to obtain necessary information about the death or ill traveler. Also, quarantine station will provide update to DEN via EOC about the response.

OR

# **Optional for U.S. flights [Meets U.S. federal regulations for reporting to CDC]**

2. Airline's point of contact (e.g., Operations Center, Flight Control, Airline Station Manager)

Instruct the airline's point of contact to notify CDC by contacting the:

- **CDC Quarantine Station** at or closest to the airport where the flight is arriving:
  - www.cdc.gov/quarantine/QuarantineStationContactListFull.html OR
- **CDC EOC (770.488.7100)**, who will then notify the appropriate CDC Quarantine Station.

Reports from other types of conveyances engaged in interstate travel may be made to state and local health departments, or the CDC's EOC.

# 4. Efforts to Identify Duplication and Use of Similar Information

These regulations have been in existence for many years, either under the administration of the Food and Drug Administration or the Centers for Disease Control and Prevention (since 2000). There is no duplication of this information collection.

# 5. Impact on Small Businesses or Other Small Entities

While some aviation and other travel companies may be considered small businesses, CDC anticipates that the vast majority of the burden will rest with larger passenger airline companies. In all cases, the information requested has been kept to the absolute minimum in order to minimize the public burden and for domestic flights is generally consistent with reporting procedures and requirements put forward by ICAO.

#### 6. Consequences of Collecting the Information Less Frequently

Information will only be collected when a death or suspected communicable disease occurs on an interstate voyage. Further reduction of required reporting would prevent CDC from meeting its legislative mandate, thereby endangering the public's health.

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

This request fully complies with the regulation 5 CFR 1320.5. Information regarding the incidence of disease or of a potential vector of disease must be reported on a real-time basis if it is to be used to prevent the importation and spread of disease into the United States. Depending on the situation, reporting may be verbal over radio or other electronic means, or written with no specific form specified. There is no format specified as part of this information collection.

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

A. A 60-day Federal Register Notice (Attachment 2) was published in the *Federal Register* on September 8, 2015 Vol. 80, No. 173, page 53801. No public comments were received.

B. There have been no consultations with persons outside of CDC on this specific information collection request. CDC has, in the past, coordinated with the Department of Transportation on how these illness reports are made through the Domestic Events Network. Included in this coordination is a memorandum of agreement with the Federal Aviation Administration concerning the communication of illnesses and other public health risks that occur on board aircraft (Attachment 3). CDC discussed this ICR over email with points of contact in the Federal Aviation Administration. Those points of contact are:

Justin Kinney Justin.Kinney@faa.gov

<mark>Michael Hughes</mark> Michal.Huges@faa.gov

CDC also regularly discusses procedures with airlines for reporting illness and death on board flights that operate within the United States. CDC has had previous discussions with air industry regarding the alignment of illness and death reporting for both domestic and international flights. Airlines now have the same protocols for reporting illness and death aboard both domestic and international flights. This includes guidance, as cited above, as to the types of signs and symptoms of disease that CDC requires and recommends be reported to public health authorities. CDC's goal is to ensure that communicable disease and death is reported to public health authorities as soon as is practicable without unduly affecting airline or other travel company operations.

# 9. Explanation of Any Payment or Gift to Respondents

No payment or gift will be made to any respondent.

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

This information collection request has been reviewed by the National Center for Emerging and Zoonotic Diseases (NCEZID). NCEZID has determined that the Privacy Act does apply to this information collection request. The applicable System of Records Notice is 09-20-0171 Quarantine and Traveler Related Activities, including Records for Contact Tracing Investigations.

Information submitted will be entered into a computer system called the Quarantine Activity Reporting System (QARS) for analysis and later retrieval if necessary. 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. Source documents, printouts and thumb drives will be safeguarded by storing them in locked cabinets in locked offices when not in use.

Further information concerning the protection of privacy can be found in the attached Privacy Impact Assessment (Attachment 4).

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

The protocols and tools included in this information collection request have been reviewed and approved by NCEZID's Human Subjects Advisor, who determined that this project does not meet the definition of research under 45 CFR 46.102(d). IRB review is not required (Attachment 5 CDC Non-research Determination Letter).

If a death or case of communicable disease is reported to CDC, the reporting and record keeping requirements contained in the regulations will be used by CDC to carry out quarantine responsibilities as required by law, specifically, to prevent the spread of communicable diseases from one State or possession into any other State or possession. Obtaining personally identifiable information, such as name, address, contact information, and travel document number, may be necessary during follow-up to the initial report of illness. The information concerning illnesses or deaths would only be collected when it is required, and is the minimum necessary to meet statutory obligations.

# 12. Estimates of Annualized Burden Hours and Costs

A. For reports of death or communicable disease made by master of a vessel or person in charge of a conveyance engaged in interstate traffic, the requested burden is approximately 23 hours. This total is estimated from 200 domestic reports of death or communicable disease a year, with an average burden of 7 minutes per report. This totals 23 hours. There is no standard form for reporting to CDC or the health departments.

Type of	Form Name	Number of	Number of	Average	Total burden
Respondent		respondents	responses	burden per	(in hours)
			per	response	
			respondent	(in hours)	
Master of a	42 CFR 70.4	200	1	7/60	23
vessel or	Report by the				
person in	master of a vessel				
charge of a	or person in				
conveyance	charge of				
	conveyance of the				
	incidence of a				
	communicable				
	disease occurring				
	while in interstate				
	travel				
Total					23

Estimated Annualized Burden Hours

B. The cost to respondents was calculated using the May 2014 National Occupational Employment and Wage Estimates United States data from the Bureau of Labor Statistics (<u>http://www.bls.gov/oes/current/oes\_nat.htm</u>).

#### Estimated Annualized Burden Costs

Estimated Finiadaized Barden 605t5				
Type of	Form Name	Total	Hourly	Total
Respondent		Burden	Wage Rate	Respondent
		Hours		Cost
Master of	42 CFR 70.4 Report by	23	\$50.60	\$1,164
vessel or	the master of a vessel			
person in	or person in charge of			
charge of	conveyance of the			
conveyance	incidence of a			
	communicable disease			
	occurring while in			
	interstate travel			
	Total			\$1,164

Respondents for this information collection include airline maritime conveyance operators, importers/filers, and the general public. Average wages for each category of

respondent were calculated using occupation and wage statistics from the Bureau of Labor Statistics.

 For conveyance operators (air and maritime), an average of 53-2011 Airline Pilots, Copilots, and Flight Engineers and 53-5021 Captains, Mates, and Pilots of Water Vessels is used. This yields an average of \$50.60 per hour. (53-5021 Captains, Mates, and Pilots of Water Vessels: <u>http://www.bls.gov/oes/current/oes535021.htm</u>. 53-2011 Airline Pilots, Copilots, and Flight Engineers: <u>http://www.bls.gov/oes/current/oes532011.htm</u>)

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

None

# 14. Annualized Cost to the Government

For each report of illness in travelers covered by 42 CFR part 70, Quarantine staff collect and review the information to determine whether a public health response is necessary. Their actions are determined by the statutory and regulatory requirements for each report, and the time required to appropriately respond varies. The amount of time to respond depends on the specifics of the report, requiring action such as filing and/or data entry to conducting an investigation involving multiple staff.

CDC estimates the yearly cost for this information collection request as a function of the staff time required to provide only the initial collection and review of the information provided by the respondents, the pay level of the average CDC staff member reviewing the data, as well as the IT costs associated with the QARS system.

CDC is providing an estimate for staff cost that includes all of the estimated 200 reports of illness or death under the current 42 CFR 70.4. While some may indeed go to the state or local health department, CDC anticipates most will come to CDC directly, which CDC has stated meets the requirements under the regulations. The staff hours used for this estimation are composed of the total number of estimated reports of death or illness multiplied by 84 minutes; 84 minutes is the average time required for CDC to do the initial review and processing of the illness or death report. This total is then multiplied by a GS 12 CDC-staff member in the Atlanta locality.

	Time in hours required to review and process initial incoming report	Average hourly wage of staff reviewing data (GS12 Atlanta locality adjustment)	Total Estimated Yearly Cost
Electronic reports of communicable	200 reports x 84 minutes/report =	\$35.14	\$ 9,839
	1		
disease or death	280 hours		

There are also CDC system and personnel costs associated with the use, development, and maintenance of QARS. These costs include the IT costs and associated staffing

costs. The QARS related costs dedicated only to domestic reports of communicable disease or death cannot be separated from the total QARS system costs; therefore, the total QARS costs are presented here. These costs are as follows:

QARS System Costs	\$199,669
Staff Costs (Atlanta locality adjustment):	\$111,281
1xGS-12 and 1xGS-9(75%)	
Total	\$310,950

CDC does not have access to any state or local health department system costs, so they are not accounted for in this estimate.

The estimated annualized cost to the Federal Government is \$320,789.

# 15. Explanation of Program Changes or Adjustments

This is a request for a revision of the currently approved Information Collection Request (ICR), OMB Control Number 0920-0488, expiring March 31, 2016. This ICR includes a program change that involves removing the Ill Person Travel Permit and Master of Vessel or Conveyance Illness Report forms from the list of information collections. This change is a result of reviewing current operations and logistics with regard to: 1) the issuance of travel restrictions, and 2) illness or death reports from domestic conveyances.

- The travel permits were originally developed to align with the authorities currently outlined in 42 CFR 70.3 and 70.5. However, the permits were never used, because the way in which CDC and state and local health authorities coordinate in travel restrictions is not amendable to the use of a standard permit and does not involve an identical collection of fact or opinion. Each case is highly complex, with a variety of factors to be considered before a travel restriction is put in place or not. Because in n current practice CDC does not process applications for travel permits using the Restriction On Travel Of Persons Multipurpose Application Form Under the Provisions of 42 CFR Part 70 (aka Ill Person Travel Permit), CDC is requesting the removal of the following information collections from this Supporting Statement:
  - 42 CFR 70.3, Application to the State of destination for a permit, Copy of material submitted by applicant and permit issued by State health authority (Attending physician),
  - Copy of material submitted by applicant and permit issued by State health authority (State health authority) are being removed.
  - **0 42** CFR 70.5, Application for a permit to move from State to State while in the communicable period (Attending physician)
  - O Application for a permit to move from State to State while in the communicable period (Traveler) are also being removed.
- Reports of communicable disease or death from domestic conveyances are almost always submitted electronically to meet requirements of 42 CFF 70.4, so the current hard copy Master of Vessel or Conveyance Illness Report, which was constructed to be used by masters of vessels to comply with 42 CFR 70.4, has been rendered obsolete. In addition, CDC has issued guidance stating that reports to CDC, instead of local health authorities, regarding domestic reports of

communicable disease or death on board conveyances meet the requirements of the regulation; therefore, information collections related to copies of the report sent by masters of vessels to state health departments are no longer necessary. The only remaining information collection under 42 CFR 70.4 is *Report by the master of a vessel or person in charge of conveyance of the incidence of a communicable disease occurring while in interstate travel*.

CDC is also requesting an adjustment to the burden associated with reports of communicable disease or death from domestic conveyances. CDC is reducing the burden from 15 minutes per report to 7 minutes. This is due to the facilitation of reporting using electronic means, i.e. Air Traffic Control and the Domestic Events Network for domestic flights. Extra time associated with completing the hard copy Master of Vessel or Conveyance Illness Report is no longer required.

The resulting change in burden is a reduction of 3678 hours.

This ICR also includes an adjustment to wages based on 2014 data from the Bureau of Labor Statistics for respondent burden.

# 16. Plans for Tabulation and Publication and Project Time Schedule

Data are not collected for statistical purposes, but only to meet the legislative mandate as implemented in 42 CFR Part 70.

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

Display of the expiration date is not inappropriate. No exemption is requested.

# 18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

# Attachments

Attachment 1A: Section 361 of the Public Health Service Act (42 USC 264) Attachment 1B: 42 CFR Part 71 Attachment 1C: 42 CFR Part 70 Attachment 2: Attachment 2: 60 day Federal Register Notice Attachment 3: CDC FAA Memorandum of Agreement Attachment 4: Privacy Impact Assessment Attachment 5: CDC Non-research determination