

Report of Illness or Death: Interstate Travel of Persons (42 CFR part 70)

**OMB Control No. 0920-0488
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Request for Revision**

**Supporting Statement A
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**Report of Illness or Death: Interstate Travel of Persons
(42 CFR part 70)
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- 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 May 31, 2019. CDC is requesting approval for three years.

CDC is requesting a change of title from “Restriction on Travel of Persons (42 CFR Part 70)” to “Report of Illness or Death: Interstate Travel of Persons (42 CFR Part 70)”. The current information collection does not involve travel permits or refers to restrictions on travel, so the title has been changed to more accurately describe the content of the information collection request.

In 2017, CDC finalized the Control of Communicable Disease regulations (42 CFR 70 and 71), which included a new provision, 70.11 Report of death or illness onboard aircraft operated by an airline, that clarified how air conveyances should report illness or death that occur during travel. With this new provision, CDC divided the total anticipated reporting burden between 70.11 and 70.4 in the accompanying Paperwork Reduction Act section of the rule, assuming that aircraft would report most cases of ill people and deaths to CDC, with a some airline and other conveyances reporting still to local public health authorities. This results in two rows in section A12, but with no additional burden.

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.

Additionally, in 2017, CDC added section 70.11 Report of death or illness onboard aircraft operated by an airline, which states:

(a) The pilot in command of an aircraft operated by an airline who is conducting a commercial passenger flight in interstate traffic under a regular schedule shall report as soon as practicable to the Director the occurrence onboard of any deaths or the presence of ill persons among passengers or crew and take such measures as the Director may direct to prevent the potential spread of the communicable disease, provided that such measures do not affect the airworthiness of the aircraft or the safety of flight operations.

(b) The pilot in command of an aircraft operated by an airline who reports in accordance with paragraph (a) of this section shall be deemed to satisfy the reporting obligation under 42 CFR 70.4.

For the purposes of these two regulations, ill person means an individual who:

(1) Has a fever (a measured temperature of 100.4 °F [38 °C] or greater, or feels warm to the touch, or gives a history of feeling feverish) accompanied by one or more of the following: Skin rash, difficulty breathing, persistent cough, decreased consciousness or confusion of recent onset, new unexplained bruising or bleeding (without previous injury), persistent diarrhea, persistent vomiting (other than air sickness), headache with stiff neck, appears obviously unwell; or

(2) Has a fever that has persisted for more than 48 hours; or

(3) Has symptoms or other indications of communicable disease, as the CDC may announce through posting of a notice in the Federal Register.

There is no additional burden anticipated as a result of this new provision, as the burden has been allocated between the 70.4 and 70.11 regulations.

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 of 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 and 70.11 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:

- o **CDC Quarantine Station** at or closest to the airport where the flight is arriving:
www.cdc.gov/quarantine/QuarantineStationContactListFull.html **OR**
- o **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 ill person is identified during an interstate voyage. Further reduction of required reporting would prevent CDC from meeting its regulatory 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 August 21, 2018, Vol. 83, No. 162, page 42300. 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). The reporting required in 70.11 was part of rulemaking finalized in 2017, which went through notice and public comment.

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 ill person 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.

Cover sheets (Attachments 6 and 7) are included with this submission.

Estimated Annualized Burden Hours

Type of respondent	Form name	No. of respondents	No. of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Pilot in command	42 CFR 70.11 Report of death or illness onboard aircraft operated by airline	190	1	7/60	22
Master of vessel or person	42 CFR 70.4 Report by the master of a	10	1	7/60	1

Type of respondent	Form name	No. of respondents	No. of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
in charge of conveyance	vessel or person in charge of conveyance of the incidence of a communicable disease occurring while in interstate travel				
Total		200			23

B. The cost to respondents was calculated using the May 2017 National Occupational Employment and Wage Estimates United States data from the Bureau of Labor Statistics (http://www.bls.gov/oes/current/oes_nat.htm).

Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Pilot in command	42 CFR 70.11 Report of death or illness onboard aircraft operated by airline	22	\$77.54	\$1,706
Master of vessel or person in charge of conveyance	42 CFR 70.4 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	1	\$58.24	\$58
	Total	23		\$1,764

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 pilots in command, 53-2011 Airline Pilots, Copilots, and Flight Engineers (<http://www.bls.gov/oes/current/oes532011.htm>) was used, with an average hourly wage of \$77.54

- 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 \$58.24 per hour. (53-5021 Captains, Mates, and Pilots of Water Vessels: <http://www.bls.gov/oes/current/oes535021.htm>. 53-2011 Airline Pilots, Copilots, and Flight Engineers: <http://www.bls.gov/oes/current/oes532011.htm>)

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 and 70.11. 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 90 minutes; 90 minutes is the approximate 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 disease or death	200 reports x 90 minutes/report = 280 hours	\$36.92	\$ 11,076

There are also CDC system and personnel costs associated with the use, development, and maintenance of QARS. These costs include the IT staffing costs and associated SME 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	\$185,000
Staff Costs (Atlanta locality adjustment): 1xGS-12 and 1xGS-9(75%)	\$116,911
Total	\$301,911

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 \$312,987.

15. Explanation of Program Changes or Adjustments

CDC is requesting a change of title from “Restriction on Travel of Persons (42 CFR Part 70)” to “Report of Illness or Death Interstate Travel of Persons (42 CFR Part 70)”. The current information collection does not involve the Travel Permit or refer to restrictions on travel, so the title has been changed to more accurately describe the content of the information collection request.

In 2017, CDC finalized the Control of Communicable Disease regulations (42 CFR 70 and 71), which included a new provision, 70.11 Report of death or illness onboard aircraft operated by an airline, that clarified how air conveyances should report illness or death that occur during travel.

With this new provision, CDC divided the total anticipated reporting burden between 70.11 and 70.4 in the accompanying Paperwork Reduction Act section of the rule, assuming that aircraft would report most cases of ill people and deaths to CDC, with some airlines and other conveyances reporting still to local public health authorities.

This results in two rows in the burden table in section A12, but with no additional burden.

The Passenger Locator Form (PLF) is covered under OMB control number 0920-1181. It was previously included in 0920-0134.

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: 60 day Federal Register Notice

Attachment 3: CDC FAA Memorandum of Agreement

Attachment 4: Privacy Impact Assessment

Attachment 5: CDC Non-research determination

Attachment 6: 42 CFR 70.11 - Report of death or illness onboard aircraft operated by airline

Attachment 7: 42 CFR 70.4 - 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