

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### 42 CFR Parts 70 and 71

[CDC Docket No. CDC–2016–0068]

RIN 0920–AA63

#### Control of Communicable Diseases

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Final rule.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS), is issuing this final rule (FR) to amend its regulations governing its domestic (interstate) and foreign quarantine regulations to best protect the public health of the United States. These amendments have been made to aid public health responses to outbreaks of new or re-emerging communicable diseases and to accord due process to individuals subject to Federal public health orders. In response to public comment received, the updated provisions in this final rule clarify various safeguards to prevent the importation and spread of communicable diseases affecting human health into the United States and interstate.

**DATES:** This rule is effective February 21, 2017.

**FOR FURTHER INFORMATION CONTACT:** Director, Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–E03, Atlanta, GA 30329, or email [dgmqpolicyoffice@cdc.gov](mailto:dgmqpolicyoffice@cdc.gov).

**SUPPLEMENTARY INFORMATION:** Based on public comment received to the Notice of Proposed Rulemaking (NPRM) (81 FR 54230) this final rule, among other things: Withdraws a provision regarding “Agreements” as proposed in the NPRM, requires CDC to issue a federal order within 72 hours after apprehending an individual, increases the threshold for those who may be considered “indigent” to 200% of the applicable poverty guideline, adds a definition for “Secretary,” adds a requirement for CDC to provide legal counsel for isolated or quarantined individuals qualifying as indigent who request a medical review, modifies the definition of “non-invasive,” includes “known or possible exposure” in the list of information that may be collected during a public health risk assessment, and strengthens due process protections by ensuring that CDC will arrange for translation or interpretation services for

public health orders and medical reviews as needed. In implementing quarantine, isolation, or other public health measures under this Final Rule, HHS/CDC will seek to use the least restrictive means necessary to prevent the spread of communicable disease.

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#### I. Executive Summary

##### A. Purpose of the Action

HHS/CDC has statutory authority (42 U.S.C. 264, 265) to promulgate regulations that protect U.S. public health from communicable diseases, including quarantinable communicable diseases as specified in an Executive Order of the President. *See* Executive Order 13295 (April 4, 2003), as amended by Executive Order 13375 (April 1, 2005) and Executive Order 13674 (July 31, 2014). The need for this rulemaking was reinforced during HHS/CDC’s response to the largest outbreak of Ebola virus disease (Ebola) on record, followed by the recent outbreak of Middle East Respiratory Syndrome (MERS), both quarantinable communicable diseases, and repeated outbreaks and responses to measles, a non-quarantinable communicable disease of public health concern. This

final rule will enhance HHS/CDC's ability to prevent the introduction, transmission, and spread of communicable diseases into the United States and interstate by clarifying and providing greater transparency regarding its response capabilities and practices.

#### B. Summary of Major Provisions

Both the domestic and foreign portions of this regulation include new proposed public health definitions; new regulatory language implementing HHS/CDC's activities concerning non-invasive public health prevention measures (*i.e.*, traveler health screening) at U.S. ports of entry and other U.S. locations (*i.e.*, railway stations, bus terminals); and provisions affording due process to persons served with a Federal public health order (*e.g.*, isolation, quarantine), including requiring that HHS/CDC explain the reasons for issuing the order, administrative processes for appealing the order, and a mandatory reassessment of the order.

The domestic portion of this final rule includes a requirement that commercial passenger flights report deaths or illnesses to the CDC. It also includes a provision requiring that individuals apply for a travel permit if they are under a Federal quarantine, isolation, or conditional release order (unless the specific travel is authorized by the Federal conditional release order) or if a State or local public health department requests CDC assistance in enforcing a State or local quarantine or isolation order. Additionally, the domestic portion of this final rule includes new regulatory language clarifying when an individual who is moving between U.S. states is "reasonably believed to be infected" with a quarantinable communicable disease in a "qualifying stage." These determinations are made when the CDC considers the need to apprehend or examine an individual for potential infection with a quarantinable communicable disease. The foreign portion of this final rule includes new regulatory authority permitting the CDC Director to prohibit the importation of animals or products that pose a threat to public health.

HHS/CDC has also changed the text of the regulation to reflect modern terminology, technology, and plain language used by private industry, public health partners, and the public. The final rule also authorizes public health monitoring through electronic or internet-based means of communication for individuals under a Federal conditional release order who are reasonably believed to be exposed to or

infected with a quarantinable communicable disease. This would include communication through email and webcam application tools. Finally, while neither modifying nor authorizing additional criminal penalties for violations of quarantine rules and regulations, this final rule updates regulatory language to align with existing criminal penalties set forth in statute.

#### C. Summary of Costs and Benefits

The regulatory impact analysis quantitatively addresses the costs and benefits associated with this final rule. The economic impact analysis of this final rule is subdivided into two sections.

The first analysis summarizes the economic impact of changes to 42 CFR 70.1, 42 CFR 71.1/71.4/71.5 for which the primary costs for submitting passenger and crew information to HHS/CDC are incurred by airlines and vessel operators and the primary benefit is improved public health responsiveness to assess and offer post-exposure prophylaxis to travelers potentially exposed to communicable diseases of public health concern. The most likely estimates of annual costs to airlines, vessel operators, the United States government, and public health departments are low (\$32,622, range \$10,959 to \$430,839) because the final rule primarily codifies existing practice or improves alignment between existing regulatory text and the International Civil Aviation Organization (ICAO)'s guidelines for symptoms to report. The cost estimates in this final rule are based on (1) an anticipated small increase in the number of illness reports delivered by airlines and processed by HHS/CDC and (2) increased costs for airlines and vessel operators to comply with HHS/CDC orders for traveler and crew contact data, to the extent that such information is readily available and already maintained, and not already transmitted to the U.S. Customs and Border Protection (CBP). The cost estimate also includes an increase in costs for public health departments to contact more exposed travelers due to the availability of improved contact data.

The best estimate of the annual quantified benefits of the final rule are \$110,045 (range \$26,337 to \$297,393) and mostly result from increased efficiencies for HHS/CDC and State and local public health departments to conduct contact investigations among travelers on an aircraft exposed to communicable diseases of public health concern, especially for measles and tuberculosis. To the extent that improved responsiveness of airlines to

HHS/CDC traveler data orders may result from the implementation of the provisions in this final rule, HHS/CDC may become better able to respond to infectious diseases threats and (1) reduce case-loads during infectious disease outbreaks, (2) reduce public anxiety during disease outbreaks, (3) mitigate economic impacts on businesses as a consequence of reduced public anxiety associated with quarantinable communicable disease outbreaks initiated by international travelers (such as have been observed during outbreak of severe acute respiratory syndrome in Canada or Middle East respiratory syndrome in South Korea), and (4) reduce the amount of personnel labor time to conduct large-scale contact investigations in response to a new infectious disease or one with larger scale public health and medical consequences like Ebola.

The second analysis in this final rule is of a number of provisions that aim to improve transparency of how HHS/CDC uses its regulatory authorities to protect public health. HHS/CDC believes that improving the quality of its regulations by providing clearer explanations of its policies and procedures is an important public benefit. However, HHS/CDC is not able to attach a dollar value to this added benefit in a significant way.

## II. Public Participation

On August 15, 2016, HHS/CDC published a notice of proposed rulemaking (NPRM) (81 FR 54299) to amend 42 CFR part 70 (interstate) and 42 CFR part 71 (foreign) quarantine regulations. The public was invited to comment on these amendments. The comment period ended October 14, 2016. In the NPRM, HHS/CDC specifically requested public comment on the following:

- Whether the use of the standard definition of "indigent" is an appropriate threshold to determine whether an individual cannot afford representation and therefore should be appointed a medical representative at the government's expense and whether the public believes that there may be non-indigent individuals, as defined in the NPRM, who may have difficulty affording a representative;

- The definition of *public health emergency* and its utility in identifying communicable diseases that "would be likely to cause a public health emergency if transmitted to other individuals" under 42 U.S.C. 264(d)(2)(B);

- Requirements relating to travelers under a Federal order of isolation, quarantine, or conditional release; specifically, on whether stakeholders

have concerns regarding the requirement imposed on conveyance operators to not “knowingly” transport individuals under a Federal order and the feasibility of this requirement and the application of this provision to individuals under State/local order as well as individuals traveling entirely within a State.

- Public health prevention measures and whether the public has any concerns regarding the mandatory health screening of passengers using non-invasive means as defined in the proposal or the collection of personal information from screened individuals for the purposes of contact tracing;
- Payment for care and treatment, and whether there are any concerns that all third party payments be exhausted prior to the Federal reimbursement of medical care or treatment for individuals placed under a Federal order for quarantine, isolation, or conditional surveillance;
- The application of requirements relating to issuance of a Federal order for quarantine, isolation or conditional release as it applies to groups and whether this provision sufficiently informs the public of the important details concerning circumstances during which HHS/CDC would issue to groups or individuals Federal orders for quarantine, isolation, and conditional release and the duration and conditions of such orders;
- Whether 72 hours is the necessary amount of time to conduct a reassessment after a Federal order is first issued, or if the reassessment should take place earlier or later;
- Whether or not the public sees a role for the Federal government to ensure that basic living conditions, amenities, and standards are satisfactory when placing individuals under Federal orders;
- Whether the definition of “non-invasive” aligns with common perceptions of what constitutes non-invasive procedures that may be conducted outside of a traditional clinical setting;
- Whether the penalties proposed, and the circumstances under which such penalties may be imposed, were clearly explained;
- The applicability of the December 13, 2007 system of records notice (SORN) to the activities proposed (72 FR 70867), and whether the SORN sufficiently addresses the public’s concerns related to maintenance and protection of the data elements proposed;
- The request for a passenger and crew manifest within 24 hours and whether the provision grants operators

of airlines sufficient time for operators to respond to manifests orders;

- The likelihood that the passenger and crew data elements requested are already collected and maintained by airline operators for transmission to CDC;
- Any industry concerns regarding whether proposed section 71.63 sufficiently details the circumstances under which HHS/CDC may impose an embargo on the importation of animals, articles, or things, including how such an embargo would be implemented, as well as any concerns regarding coordination with other Federal agencies.

The public comment period for the proposed rule ended on October 14, 2016 and HHS/CDC received 15,800 comments from individuals, stakeholders, and groups. A summary of those comments and responses to those comments are found at Section IV, below.

## II. Background

### A. Legal Authority

The primary legal authorities supporting this rulemaking are sections 361 and 362<sup>1</sup> of the Public Health Service Act (42 U.S.C. 264, 265). HHS/CDC also believes that the following Public Health Service Act sections are relevant with respect to this rulemaking: section 311 (42 U.S.C. 243), section 321 (42 U.S.C. 248), section 322 (42 U.S.C. 249), section 365 (42 U.S.C. 268), and sections 367–69 (42 U.S.C. 270–72). A detailed explanation of these legal authorities was provided in the NPRM published at 81 FR 54230 (Aug. 15, 2016).

### B. Regulatory History

On August 15, 2016, HHS/CDC published a Notice of Proposed Rulemaking to update 42 CFR 70 (domestic) and 42 CFR 71 (foreign) quarantine regulations. These amendments were proposed to aid public health responses to outbreaks of communicable disease, such as the largest outbreak of Ebola virus disease (Ebola) on record, Middle East Respiratory Syndrome (MERS), both quarantinable communicable diseases, and repeated outbreaks of measles in the United States, a non-quarantinable communicable disease of public health concern. (81 FR 54299). Communicable diseases of public health concern are those diseases that because of their

<sup>1</sup> Section 3 of Executive Order 13295 (April 4, 2003) states that the functions of the President under sections 362 and 364(a) of the Public Health Service Act (42 U.S.C. 265 and 267(a)) are assigned to the HHS Secretary.

potential for spread, particularly during travel, may require a public health intervention. The provisions contained within the proposal were designed to enhance HHS/CDC’s ability to prevent the further importation and spread of communicable diseases into the United States and interstate by clarifying HHS/CDC’s response capabilities, practices, and making them more transparent.

## III. Summary of the Final Rule

Upon consideration of public comment, the following is a section-by-section summary of the changes from the proposed text that HHS/CDC made to parts 70 and 71:

### A. General References to “CDC” and “Director” in Parts 70 and 71

Throughout the regulatory text in parts 70 and 71, references to “CDC” or “HHS/CDC” have been replaced with “Director.” This is in keeping with the common practice that federal agencies act through employees and officials to whom the authority involved has been delegated. *Director* is currently defined in sections 70.1 and 71.1 to mean “the Director, Centers for Disease Control and Prevention, Department of Health and Human Services, or another authorized representative as approved by the CDC Director or the Secretary of HHS.” Where it is necessary to exclude CDC employees or officials from undertaking certain functions this has been indicated by use of parenthesis, e.g., “Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order).” This is a stylistic change from the NPRM, but does not result in a substantive change in the final rule.

### B. Definitions (Sections 70.1 and 71.1(b))

- The definition of *Agreements* has been removed.
- The definition of *Electronic or internet-based monitoring* has been modified to include “communication through” these means and “audio” conference.
- The definition of *Indigent* has been modified to increase the threshold to 200% of the applicable poverty guidelines.
- The definition of *Ill person* under section 71.1 has been modified to include a person who “Has a fever that has persisted for more than 48 hours” or “Has acute gastroenteritis, which means either diarrhea, defined as three or more episodes of loose stools in a 24-hour period or what is above normal for the individual, or vomiting accompanied by one or more of the following: One or more episodes of loose stools in a 24-

hour period, abdominal cramps, headache, muscle aches, or fever (temperature of 100.4 °F [38°C] or greater)." This language was quoted verbatim in the preamble of the NPRM at 81 FR 54305 but was inadvertently omitted from the proposed regulatory text.

- The definition of *Medical Examination* has been modified to indicate that the health worker conducting the assessment must be "licensed."

- The definition of *Medical Representative* has been changed to *Representatives* and now includes for an indigent individual the additional appointment of "an attorney who is knowledgeable of public health practices" if the indigent individual requests a medical review.

- The definition of *Non-invasive* has been modified to: (1) Replace "physical examination" with "visual examination;" (2) specify that the individual performing the assessment must be a "public health worker (*i.e.*, an individual with education and training in the field of public health)"; and (3) remove "auscultation, external palpation, external measurement of blood pressure."

- A definition for *Secretary* has been added. *Secretary* means the Secretary of Health and Human Services (HHS) or any other officer or employee of that Department to whom the authority involved has been delegated. We note that while the NPRM did not propose this definition, the NPRM referenced the *Secretary* in defining *Public Health Emergency*. Thus, HHS/CDC considers it useful to also define the term *Secretary*.

#### C. Apprehension and Detention of Persons With Quarantinable Communicable Diseases (Section 70.6)

This provision is has been finalized as proposed, with the exception that references to CDC have been replaced with Director throughout this section. HHS/CDC has also added a requirement that the Director arrange for adequate food and water, appropriate accommodation, appropriate medical treatment, and means of necessary communication, for individuals who are apprehended or held in quarantine or isolation. Similar language has been added to an analogous provision at Section 71.33(a).

#### D. Medical Examinations (Sections 70.12 and 71.36)

These provisions are finalized as proposed, with the exception that references to CDC have been replaced with Director throughout this section. HHS/CDC has also added a requirement

that the Director, as part of the Federal order, advise the individual that the medical examination shall be conducted by an authorized and licensed health worker with prior informed consent.

#### E. Requirements Relating to the Issuance of a Federal Order for Quarantine, Isolation, or Conditional Release (§§ 70.14 and 71.37)

Paragraphs (a)(5) and (a)(4) of these provisions have been modified, respectively, to require that the Federal order include an explanation that the Federal order will be reassessed no later than 72 hours after it has been served and an explanation of the right to request a medical review, present witnesses and testimony at the medical review, and to be represented at the medical review by either an advocate (*e.g.*, an attorney, family member, or physician) at the individual's own expense, or, if indigent, to have representatives appointed at the government's expense. Paragraph (b) of these provisions has been modified to require that a Federal public health order be served within 72 hours of an individual's apprehension. Paragraph (c) has been modified to require that the Director arrange for translation or interpretation services of the Federal order as needed. References to CDC have been replaced with Director throughout this section.

#### F. Mandatory Reassessment of a Federal Order for Quarantine, Isolation, or Conditional Release (§§ 70.15 and 71.38)

These provisions have been modified to include paragraph (g) which states that the Director shall arrange for translation or interpretation services of the Federal order as needed. References to CDC have been replaced with Director throughout this section.

#### G. Medical Review of a Federal Order for Quarantine, Isolation, or Conditional Release (§§ 70.16 and 71.39)

Paragraph (f) of these provisions has been modified to reference "Representatives," consistent with the change in definition. Paragraph (f) of these provisions has also been modified to remove, "and cannot afford a medical representative" because this language is duplicative and unnecessary if the individual has already qualified as indigent. Paragraph (k) of these provisions has been modified to state: "The medical review shall be conducted by telephone, audio or video conference, or through other means that the medical reviewer determines in his/her discretion are practicable for allowing the individual under

quarantine, isolation, or conditional release to participate in the medical review." These provisions have also been modified to include paragraph (q) which states that the Director shall arrange for translation or interpretation services as needed for purposes of this section. References to CDC have been replaced with Director throughout this section.

#### H. Administrative Records Relating to a Federal Order for Quarantine, Isolation, or Conditional Release (§§ 70.17 and 71.29)

These sections have been modified to remove paragraphs (5) regarding agreements between CDC and the individual.

#### I. Payment for Care and Treatment (§§ 70.13 and 71.30)

These provisions have been finalized as proposed, with the exception that references to CDC have been replaced with Director throughout this section.

#### J. Agreements (§§ 70.18 and 71.40)

These provisions have been removed.

#### K. Penalties (§§ 70.18 and 71.2)

The content of these provisions has been finalized as proposed. Proposed § 70.19 *Penalties* has been moved to § 70.18, since proposed § 70.18 *Agreements* has been removed from this final rule.

#### L. Public Health Prevention Measures To Detect Communicable Disease (§§ 70.10 and 71.20)

Paragraph (b) has been modified to include "known or possible exposure" information to the list of information that may be collected. References to CDC have been replaced with Director throughout this section.

#### M. Requirements Relating to Travelers Under a Federal Order of Isolation, Quarantine, or Conditional Release (Section 70.5)

Paragraph (a), (a)(4), (b)(1), (b)(2), and (c) of this provision have been modified to remove "agreements." Paragraph (d) has been modified to add "to individuals traveling entirely intrastate and to conveyances that may transport such individuals." The language in paragraph (d) was discussed in the NPRM at 81 FR 54243 and public comment concerning intrastate application of this provision was explicitly solicited. The language, however, was inadvertently omitted from the regulatory text. References to CDC have also been replaced with Director throughout this section. In response to public comments, HHS/CDC

has included a requirement that the Director respond to a request for a travel permit within five (5) business days and to an appeal under this section within three (3) business days. Public comments concerning this provision are addressed below.

*N. Report of Death or Illness Onboard Aircraft Operated by an Airline (§ 70.11)*

This provision has been finalized as proposed, with the exception that references to CDC have been replaced with Director throughout this section.

*O. Requirements Relating to Transmission of Airline and Vessel Passenger, Crew, and Flight and Voyage Information for Public Health Purposes (§ 71.4 and 71.5)*

These provisions have been finalized as proposed, with the exception that the title has been modified to remove references to collection and storage of information to more accurately reflect the requirements under this section and references to CDC have been replaced with Director throughout this section.

*P. Suspension of Entry of Animals, Articles, or Things From Designated Foreign Countries and Places Into the United States (§ 71.63)*

This provision has been finalized as proposed with the exception that references to CDC have been replaced with Director throughout this section.

*Q. Report of Death or Illness (§ 71.21)*

The title of this provision has been finalized as proposed, to remove the word "Radio."

**V. Overview of Public Comments to the 2016 NPRM**

On August 15, 2016 HHS/CDC published a Notice of Proposed Rulemaking proposing to amend the current interstate (domestic) and foreign quarantine regulations for the control of communicable diseases. The NPRM included a 60-day public comment period and during this time, HHS/CDC received 15,800 comments from individuals, groups, organizations, industry, and unions. Comments were both in support of and in opposition to the regulation. Many public comments expressed concern that these updated regulations sought to compel medical treatment or vaccination without patient consent. One association stated its strong objection "to the coercive imposition of treatment, including vaccination, without the genuine consent of the patient."

HHS/CDC begins this section by stating that these regulations do not compel vaccination or involuntary

medical treatment. In keeping with current practice, HHS/CDC will continue to recommend care and treatment, including post-exposure prophylaxis when indicated, to individuals who are either sick with or at risk of disease following exposure to a communicable disease of public health concern.

HHS/CDC also received comments relating to immigration policy and regulations, issues of citizenship, border security, religion, personal testimony regarding adverse vaccine events, and requests to apply these regulations only to individuals who are not citizens of the United States. These comments are beyond the scope of this final rule and have not been included in this discussion. However, HHS/CDC notes that it will continue to apply communicable disease control and prevention measures uniformly to all individuals in the United States, regardless of citizenship, religion, race, or country of residency.

HHS/CDC also received public comment regarding disinsection (*i.e.*, measures to control or kill insect vectors of disease) and fumigation procedures, citing HHS/CDC's statutory authorities relating to inspection, fumigation, and pest extermination. We note that while HHS/CDC maintains regulations at 42 CFR 70.2 and 71.32(b) implementing this statutory authority, such comments are outside of the scope of this final rule, which did not include proposed changes to these regulatory provisions.

The following is a discussion of public comments received that are applicable and within the scope of the regulation. Topics including: Accountability, Administrative Records, Agreements, Apprehension, Authority (including Scope), Conditional Release, Constitutional Issues (including Amendments, Court Cases, and Habeas Corpus), Data Collection, Definitions, Detention, Due Process, Economic Impact, Electronic Monitoring, Exposure, Informed Consent, Least Restrictive Means, Minors, Medical Assessments, Examination, Notice, Penalties, Privacy, Qualifying Stage, Quarantine, Quarantinable Communicable Diseases List, and others are discussed.

A summary of comments and a response to those comments are found below, organized by general and specific comments that apply to both parts 70 and 71, comments that only apply to part 70 (interstate), and comments that only apply to part 71 (foreign).

*A. Provisions Applicable to Both Parts 70 and 71*

a. General Comments

Since posting the proposed regulation on August 15, 2016, HHS/CDC received 15,800 public comments. HHS/CDC received several comments from individuals, groups, or industry requesting to extend the 60-day comment period. In light of the number of comments submitted, HHS/CDC has determined that a 60-day comment period was both fair and sufficient to adequately inform the public of the contents of this rulemaking, allow the public to carefully consider the rulemaking, and receive informed public feedback. Thus, HHS/CDC declines to reopen the comment period.

Several commenters requested that HHS/CDC withdraw the NPRM in its entirety. A non-profit organization stated that the "NPRM would be, if adopted, a direct and onerous infringement of the personal liberties of Americans and an unnecessary aggressive method of assisting in the control of communicable disease." Another commenter said that the "NPRM is premature." HHS/CDC disagrees and declines to withdraw the proposal in its entirety because it contains important measures that will aid the public health response to prevent the introduction, transmission, and spread of communicable diseases into and within the United States. Moreover, in the spirit of transparency, these measures, which are largely current practice, are being published and codified to make the public aware of their use.

HHS/CDC received a comment from a partnership of public health legal scholars and organizations stating that it should promulgate a separate rule guaranteeing humane conditions of confinement. HHS/CDC disagrees that such a separate rule is needed and believes that the current final rule adequately addresses these concerns, as discussed in detail below.

HHS/CDC received a comment that the proposed rule does not comply with Executive Order 12866 because there is no public need for the rule and it did not adequately assess the costs and benefits of the rule, including the alternative of not regulating. HHS/CDC disagrees. As discussed in detail below, this rule describes the public health measures that may be used in response to outbreaks of communicable diseases, such as the recent largest recorded outbreak of Ebola. The economic impact analysis has been clarified to more clearly differentiate quarantinable and non-quarantinable diseases. The

economic impact analysis also examines the costs and benefits of the Final Rule measured against current practices (*i.e.*, a status quo baseline). Both the costs and benefits of this Final Rule are small because the provisions set forth are primarily a codification of current practices, based on existing regulatory authorities.

A public health research center commented that there is no evidence that measures employed at points of entry were effective during the response to the 2014–2016 Ebola outbreak and that HHS/CDC is attempting to codify these ineffective practices for use in future disease outbreaks. They further noted that despite greater than 99% complete monitoring, zero cases of Ebola were detected among those monitored. HHS/CDC appreciates this comment and recognizes the challenges presented by measuring the benefits of prevention in public health.

HHS/CDC disagrees that the measures employed in response to the 2014–16 Ebola outbreak were ineffective and that it is seeking to codify ineffective measures. HHS/CDC considers more than 99% complete monitoring a successful effort in State and Federal cooperation in response to an unprecedented outbreak of Ebola. Second, rather than the number of cases detected, HHS/CDC considers the key metrics of effectiveness to be the number of people who were able to continue to travel safely without fear of disease spread and the ability to facilitate rapid isolation and evaluation of the approximately 1400 individuals who developed illness compatible with Ebola during the 21-day monitoring period. Finally, we note that this commenter limited his or her statement to HHS/CDC measures put into place at U.S. ports of entry during the Ebola response.

The enhanced public health risk assessment protocol put into place at U.S. ports of entry in response to the Ebola outbreak was one part of a layered risk mitigation program to prevent the importation and spread of Ebola within the United States, which included exit screening in the affected countries as recommended by the World Health Organization (WHO) (see Statement on the 1st meeting of the International Health Regulations [IHR] Emergency Committee on the 2014 Ebola outbreak in West Africa 8/8/2014) and a reliance on air industry partners for detection and reporting of potentially ill travelers prior to arrival.

The enhanced entry risk assessment process was instituted after an individual infected with Ebola entered the United States and transmitted the

disease. This case demonstrated that the processes then in place to prevent departure of individuals exposed to or infected with Ebola in affected West African countries could not detect persons who were exposed but were unaware of or denied such exposure and were potentially incubating the infection. To further reduce the risk of introduction and spread, HHS/CDC recommended monitoring of all potentially exposed individuals by a public health authority through the 21-day risk period after potential exposure, rather than relying on previously recommended self-monitoring. Monitoring was viewed as the least restrictive alternative to widespread quarantine and travel bans demanded by some members of the public that would ultimately have hampered the response efforts in West Africa and domestically. HHS/CDC, along with its Federal and State partners, implemented an entry process by which individuals identified as having recently traveled to, from, or through an affected country entered through five ports of entry where public health staff and partners were stationed, submitted accurate and complete contact information, were checked for symptoms, and were provided answers to Ebola risk assessment questions.

This was done for several reasons:

- To ensure that any individual entering the United States who could have been exposed to or infected with Ebola in a country experiencing an Ebola outbreak was identified and reported to the State and local health department of final destination so that, if the individual became ill, State or local health departments could rapidly notify healthcare providers prior to the individual's arriving at a hospital. This process was designed specifically to prevent unknowing individuals from exposing others such as occurred in Texas when a patient exposed two healthcare workers.

- While HHS/CDC acknowledges that a public health worker may be unlikely to encounter someone with symptoms at the moment of entry because of the 21-day incubation period, individuals coming from the outbreak countries frequently traveled for well over 24 hours and in many cases had itineraries that involved interstate movement within the United States. The odds of developing symptoms during that travel, and potential onward travel, were considered non-trivial, and public health measures to detect symptoms upon entry were considered warranted given the serious morbidity and costs associated with Ebola.

- The risk assessment at the limited ports of entry provided an important opportunity for HHS/CDC to stratify the risk of developing Ebola for every individual who entered from the affected countries. It allowed HHS/CDC to work with State and local health departments in implementing the least restrictive means of monitoring individuals for development of symptoms. HHS/CDC notes that there were no Federal quarantine orders issued because of the availability of monitoring options provided by State and local authorities under the *Interim U.S. Guidance for Monitoring and Movement of Persons with Potential Ebola Virus Exposure*.

- The encounter also provided an opportunity to provide travelers with educational materials, orientate them to the monitoring program (Check and Report Ebola (CARE)), and facilitate reporting of the traveler's health status to State and local health departments.

The enhanced entry risk assessment and monitoring process described above was developed in response to the epidemiological profile of Ebola and the complexities of a 21-day incubation period. However, in the event of an outbreak of a different communicable disease requiring enhanced assessment or monitoring of travelers (whether quarantinable or non-quarantinable), HHS/CDC, in concert with Federal and State partners, may implement a different system of risk assessment and monitoring. HHS/CDC would tailor the program in accordance with the scientific evidence of the situation and the utility and feasibility of the program given the availability of resources.

The same public health research center commented that employing non-evidence-based measures is contrary to the United States' international legal agreements, specifically mentioning the public health measures implemented during the response to Ebola as they pertain to the International Health Regulations (IHR 2005). The commenter further stated that given the absence of evidence to support the use of travel monitoring and quarantine, HHS/CDC should proceed cautiously before employing these measures in the future.

Having addressed the commenter's concern regarding the evidence of the effectiveness of public health measures at ports of entry above, HHS/CDC concurs with the commenter that the use of quarantine and travel restrictions, in the absence of evidence of their utility, is detrimental to efforts to combat the spread of communicable disease. However, HHS/CDC disagrees that it used non-evidence based measures in contravention of the IHR.

To the contrary, HHS/CDC used the best available science and risk assessment procedures in designing a port of entry risk assessment and management program that took into account available resources, circumstances in the countries with Ebola outbreaks, and principles of least restrictive means to successfully ensure that measures to ban travel between the United States and the affected countries were unnecessary. These measures would have negatively impacted the efforts to combat Ebola in the region and would have had dramatic negative implications for travelers and industry.

Furthermore, the measures did not unduly affect travel or trade beyond the voluntary changes made by industry and travelers. HHS/CDC believes that CDC's entry risk assessment and management program was appropriate, commensurate with the risk, and consistent with the following WHO recommendation: "[Member] States should be prepared to detect, investigate, and manage Ebola cases; this should include assured access to a qualified diagnostic laboratory for Ebola and, where appropriate, the capacity to manage travelers originating from known Ebola-infected areas who arrive at international airports or major land crossing points with unexplained febrile illness." *WHO Statement on the 1st meeting of the IHR Emergency Committee on the 2014 Ebola outbreak in West Africa* (Aug. 8, 2014). Travelers were assessed for risk on an individual basis upon entry; and any individual who met the pre-defined symptom threshold (based on exposure level) was medically evaluated and referred to care as needed. No Federal quarantine orders were issued for the duration of the response because HHS/CDC in coordination with State and local public health authorities was able to tailor its interventions to allow onward travel.

Future outbreaks may necessitate a different combination of public health measures at ports of entry. In those circumstances, HHS/CDC will use the best available science to assess the risk of importation and spread within the United States.

One commenter suggested that if HHS/CDC were to apply the "Precautionary Principle," it would not promulgate these regulations. HHS/CDC notes first that the "precautionary principle," often described as the avoidance of harm when there is scientific uncertainty about risks, originated in environmental contexts and remains largely associated with environmental issues. Invoking the precautionary principle in an environmental context, for instance,

places the onus on those considering a potentially harmful action, such as drilling or mining near a watershed, to prove its safety in advance. The principle may be used by policy makers to justify discretionary decisions in situations where there is the possibility of harm from making a certain decision (e.g. taking a particular course of action) when extensive scientific knowledge on the matter is lacking.

HHS/CDC disagrees that this regulation will have harmful effect or that these measures lack a scientific basis for protecting public health. In fact, as described above regarding the response efforts to the 2014–2016 Ebola response, HHS/CDC has successfully employed the measures outlined in this regulation for many years. Again, the provisions outlined through this regulation are not new practices, nor new authorities, but a codification of HHS/CDC practice to protect public health.

One commenter suggested that education on healthy practices would be more effective than regulatory provisions. Another commenter stated that our immune systems would ward off communicable disease if we encourage clean water, adequate shelter, effective sewage treatment, and nutritious food. HHS/CDC agrees that these necessities are important to public health, and we rely on health communication often to educate the public on how to protect themselves and others from certain communicable diseases. For example, HHS/CDC routinely advises people with seasonal influenza to stay home from work and school, to cover their coughs and sneezes, and to wash their hands. HHS/CDC also works with State, local, and airport authorities in posting health education materials for the public. However, in certain circumstances, when a communicable disease poses a severe health threat to others, additional measures may be needed to protect the public's health. This is particularly important in situations when the infectious individual has disregarded public health recommendations by, for example, refusing to take prescribed medications to treat infectious tuberculosis or traveling while infectious. In such situations, it may be necessary to use public health authorities to require the individual to remain in isolation or to prevent travel to protect the public's health.

HHS/CDC received a few comments suggesting that publication of the NPRM in the **Federal Register** was not sufficient to inform the public of these proposed updates. One comment questioned why the proposed

regulations were not more widely disseminated through media outlets. In response, HHS/CDC notes that Federal courts have long recognized that publication in the **Federal Register** is legally sufficient for giving affected persons notice of proposed rulemaking. *See Federal Crop Ins. Corp. v. Merrill*, 332 U.S. 380, 385 (1947) ("Congress has provided that the appearance of rules and regulations in the **Federal Register** gives legal notice of their contents."). The **Federal Register**, within the National Archives and Records Administration, is the official publication for all Federal agency rules, proposed rules, and notices of Federal agencies and organizations, as well as for Executive Orders and certain other presidential documents. Individuals interested in obtaining more information regarding HHS/CDC's regulatory processes, including input provided by persons and organizations, may examine the regulatory docket or submit a request through the Freedom of Information Act.

HHS/CDC received a comment stating that HHS/CDC should, by regulation, provide sufficient public health justification for screening practices to support its proposed public health prevention measures at ports of entry. While HHS/CDC agrees that it should provide sufficient public health justification for large-scale screening practices, HHS/CDC disagrees that this justification should be formalized in regulations. During the 2014–2016 Ebola epidemic, HHS/CDC issued *Interim U.S. Guidance for Monitoring and Movement of Persons with Potential Ebola Virus Exposure* to assist HHS/CDC staff and public health partners engaged in the response. The guidance provided public health authorities and partners with recommendations for monitoring people potentially exposed to Ebola and for evaluating their intended travel, including the application of movement restrictions when necessary. From August 2014–December 2015, the guidance was accessed online approximately 334,000 times, with more than 88,000 views during the first 4 days after the October 2014 update that added recommendations for active monitoring and clarified travel and movement restriction recommendations. Updates to the guidance to accommodate new information and changes in the outbreak situation continued through 2015. The guidance was retired on February 19, 2016, when more than 45 days had passed since Guinea was declared free of Ebola virus transmission, signaling widespread human-to-human transmission in the



affected countries was at an end. Formalizing this guidance in regulation would have deprived HHS/CDC of the needed flexibility to respond to public health events as they occurred, would have proved administratively burdensome and unnecessary, and would have potentially delayed prevention measures therefore resulting in a less effective response. HHS/CDC will consider the need for similar guidance during future outbreaks taking into account the extent of the outbreak and the risk of importation and spread of disease into the United States.

HHS/CDC received several comments suggesting that the proposed regulations were not written in plain language and were therefore difficult to understand. One commenter also noted errors in the document such as hyperlinks, references, and footnotes. This commenter also reviewed the NPRM for inconsistencies, conflicts, missing definitions, misleading language, and ambiguities. HHS/CDC thanks these commenters for the input. We have developed communication materials and published them to our Web site to help facilitate the review and comprehension of these documents. Interested persons should see <http://www.cdc.gov/quarantine/notice-proposed-rulemaking-control-communicable-diseases.html>.

One commenter opposed the rule because of a perceived negative social impact upon individuals placed under a public health order. We respond that one compelling reason for the publication of this final rule is to make the public aware of these measures so that the words, purposes, and meanings of “quarantine” and “isolation” become more familiar and less likely to cause public anxiety and stigmatization.

HHS/CDC received comments suggesting that, to best prevent the introduction of communicable diseases into the U.S., individuals who travel to or originate in countries with high risk of communicable disease should not be allowed to enter (or return to) the United States. On March 27, 2015, HHS/CDC published a Notice in the **Federal Register** titled *Criteria for Recommending Federal Travel Restrictions for Public Health Purposes, Including for Viral Hemorrhagic Fevers*. See 80 FR 16400 (Mar. 27, 2015). The Notice describes the tools the Federal government has to ensure that people who pose a public health risk do not board flights or enter the United States without a public health evaluation. See 80 FR 16400 (Mar. 27, 2015). It is the policy of HHS/CDC to work with the Department of State, and any other relevant Federal and State agencies to

ensure infected U.S. citizens seeking to return to the U.S. do so in a manner that does not place the public at risk.

A few commenters expressed concern, as parents or guardians, about their rights with respect to children or minors. Specifically, these commenters wondered whether children/minors would be separated from parents/guardians during a public health risk assessment. HHS/CDC thanks the commenters for these questions and appreciates the opportunity to respond. In response, HHS/CDC notes that these regulations do not limit the rights that parents or guardians may have over minor children, including the right to make medical decisions. Notwithstanding, children are included in the definition of “individuals” as used in these regulations and thus minor children may be subject to apprehension, detention, examination, and conditional release for quarantinable communicable diseases to the same extent as adults. In such rare circumstances, HHS/CDC will work with the child’s parent or guardian to ensure that the rights accorded to any individual subject to Federal isolation or quarantine, such as the opportunity for an administrative medical review, are adequately protected.

In addition, and in keeping with standard public health practice, parents or guardians while in the presence of infected minor children may be required to adhere to infection control precautions for their own protection. Such protections may include wearing personal protective equipment (such as a mask) while in close proximity to the child/minor to avoid further transmission of the illness. In extremely rare circumstances, such as a child infected with Ebola, the risk may be too great to allow a parent to remain with a child; however, every effort will be made to facilitate communication between a parent and a minor child through the least restrictive means, for example, through the use of technology.

One commenter asked about HHS/CDC obtaining the consent of a parent or legal guardian prior to the medical examination, quarantine, or treatment of minors. We respond that HHS/CDC will adhere to all applicable laws regarding the medical examination or treatment of minors. If minors are traveling unaccompanied by a parent or legal guardian and are believed to be infected with or exposed to a quarantinable communicable disease, HHS/CDC will use its best efforts to contact a parent or guardian to obtain consent prior to medical examination. In addition, HHS/CDC will not restrict a minor’s ability to communicate with family or legal

counsel hired by the minor’s parent or legal guardian. As explained further below, HHS/CDC will appoint representatives, including a medical representative and an attorney, if the individual (including a minor’s parent or legal guardian) is indigent and requests a medical review. HHS/CDC clarifies, however, that the public health measures included in this final rule, including apprehension, examination, quarantine, and isolation, do not require a parent or legal guardian’s consent as a prerequisite to their application. However, in response to concerns about informed consent, HHS/CDC has added regulatory language requiring that the Director advise the individual that if a medical examination is required as part of a Federal order that the examination will be conducted by an authorized and licensed health worker with prior informed consent.

#### b. Scope and Authority

HHS/CDC received comments from the public questioning whether HHS/CDC is a part of the Federal government and has the authority to propose and promulgate regulations, or whether the Agency is a private entity. The “Communicable Disease Center” became part of the U.S. Public Health Service on July 1, 1946 and is an Agency within the U.S. Department of Health and Human Services. For more information on the history of CDC, please see <http://www.cdc.gov/museum/timeline/index.html>.

HHS/CDC received numerous comments from the public seeking clarity on the scope of authority the Agency has to take actions described in this regulation. Specifically, HHS/CDC received comments questioning whether the authority to detain an individual may be exercised by a Federal agency of government, instead of the U.S. President or Congress. Several commenters specifically questioned whether the wording of the regulation was too “general” and expressed concern over its potential for abuse. A public health organization recommended that HHS/CDC’s authority should be limited only to those diseases listed by Executive Order as quarantinable communicable diseases. An association suggested that the proposed rule would vastly increase the authority of HHS/CDC. One individual stated that this regulation is an attempt by HHS/CDC to evade Congress. One organization speculated that HHS/CDC plans to request that the list of quarantinable communicable diseases be expanded “to include measles and other vaccine targeted diseases for the purpose of



apprehending and quarantining travelers entering the US or traveling between States, who have not been vaccinated with MMR (measles-mumps-rubella vaccine) and other Federally recommended vaccines.”

In response, HHS/CDC first notes that it cannot—and will not—act beyond the scope of authority granted by Congress in statute; HHS/CDC offers the following clarifications. Under section 361(a) of the Public Health Service Act (42 U.S.C. 264(a)), the HHS Secretary is authorized to make and enforce regulations as in the Secretary’s judgment are necessary to prevent the introduction, transmission, or spread of all communicable diseases from foreign countries into the States or possessions of the United States and from one State or possession into any other State or possession. Under section 361(b)(42 U.S.C. 264(b)), the authority to issue regulations authorizing the apprehension, examination, detention, and conditional release of individuals is limited to those communicable diseases specified in an Executive Order of the President, *i.e.*, “quarantinable communicable diseases.” The authority for carrying out these regulations has been delegated from the HHS Secretary to the CDC Director, who in turn delegated these authorities to HHS/CDC’s Division of Global Migration & Quarantine (DGMQ). These quarantinable communicable diseases are currently limited to cholera, diphtheria, infectious tuberculosis (TB), plague, smallpox, yellow fever, and viral hemorrhagic fevers (such as Marburg, Ebola, Lassa fever, and Crimean-Congo), severe acute respiratory syndromes, and influenza caused by novel or re-emergent influenza viruses that are causing or have the potential to cause a pandemic. *See* Executive Order 13295 (April 4, 2003), as amended by Executive Order 13375 (April 1, 2005) and Executive Order 13674 (July 31, 2014). Changes to the list of quarantinable communicable diseases are beyond the scope of this regulation. And again, we reemphasize that HHS/CDC does not intend, through these regulations, to mandate vaccination or compulsory medical treatment of individuals.

One commenter supported the international proposals (part 71), but urged HHS/CDC to remove the domestic portion (part 70) of this regulation. We disagree. HHS/CDC’s authorities apply to all travelers in the United States, regardless of citizenship or residency, and are intended to complement State authorities within their jurisdictions by providing a mechanism to prevent importation of communicable disease

from other countries as well as spread of communicable disease between States and between States and territories. Thus, HHS/CDC’s and States’ authorities together create a comprehensive system to protect the public from communicable disease threats including in situations such as interstate travel when a single State’s authorities may be inadequate to address the communicable disease threat.

Several commenters suggested that HHS/CDC has the authority to unilaterally change or update the list of quarantinable communicable diseases. Other commenters requested that the list be narrowed to only those diseases with a “high mortality rate.” HHS/CDC reemphasizes that, as prescribed by statute, the list of quarantinable communicable diseases may only be changed by Executive Order of the President and that such suggestions are beyond the scope of this final rule.

HHS/CDC received several comments on the Agency’s accountability system, encouraging that a “strong system of checks and balances” should be in place for this regulation to be implemented. HHS/CDC agrees that there should be accountability and oversight regarding the agency’s activities. We note that these regulations do not affect the ability of Congress to conduct its oversight activities or affect the jurisdiction of federal courts to review federal agency actions under the Administrative Procedure Act (5 U.S.C. 704).

HHS/CDC received a comment that there is no court supervision of HHS/CDC activities. We disagree. These regulations do not affect the jurisdiction of the Federal courts or the statutory rights of individuals to obtain judicial review of CDC’s actions and decisions through appropriate mechanisms such as the habeas corpus statute (28 U.S.C. 2241) or the Administrative Procedure Act (5 U.S.C. 704).

Some commenters questioned the need for HHS/CDC to use its authorities if the threat of death is minimal compared with the size of the population, listing illnesses such as chickenpox, pertussis, Zika, the common cold and flu, and leprosy. One organization suggested that, through the language of the NPRM, HHS/CDC was “equating” non-quarantinable diseases with quarantinable diseases. Another commenter suggested that HHS/CDC’s authority to act should be based on the mortality of the illness, rather than whether or not it appears on the list of quarantinable communicable diseases. HHS/CDC thanks the commenters for

consideration of the proposal as well as the input provided.

First, we note that HHS/CDC only has authority to quarantine or isolate individuals who have illnesses that are listed by Executive Order of the President as quarantinable communicable diseases. HHS/CDC does not have the ability or authority to unilaterally modify the list of quarantinable communicable diseases. Second, because HHS/CDC also has statutory authority to prevent the “introduction, transmission, and spread” of communicable diseases, HHS/CDC may take actions other than quarantine or isolation to protect the public’s health. These other actions may include contact tracing investigations to notify individuals to seek proper treatment if they have been exposed to a communicable disease, even if the disease is not listed by Executive Order as quarantinable. HHS/CDC does not seek to compel vaccination or medical treatment. In keeping with current practice, HHS/CDC recommends certain vaccines for post-exposure prophylaxis and individuals may choose to follow these recommendations as they deem appropriate.

Other commenters questioned why diseases such as Ebola, measles, and Zika—three very different diseases with three very different effects on individuals—are used to support the same regulatory provisions. One organization quoted the NPRM, citing correctly that while measles is not a quarantinable communicable disease, it was used in the NPRM to support the need for this updated regulation. HHS/CDC welcomes the opportunity to provide further clarification.

The proposed rule provides HHS/CDC with a number of options for public health interventions based on a public health risk assessment of the communicable disease in question and the situation at hand. These interventions could include conducting a contact investigation on an airplane or vessel if a person with a serious communicable disease was known to have traveled on the airplane or vessel. These contact investigations are similar to those conducted by health departments in community settings. In addition to these interventions, for the nine communicable diseases currently designated by Executive Order as quarantinable communicable diseases, HHS/CDC may apprehend, detain, examine, quarantine, isolate, or conditionally release individuals for purposes of preventing communicable disease spread. Ebola and infectious tuberculosis are examples of quarantinable communicable diseases.

HHS/CDC also provides the public with recommendations to address other communicable diseases of public health concern. Zika is a good example of a disease of public health concern because of the ways it can be spread, e.g., through mosquitoes, sexual transmission, and maternal-fetal transmission. Therefore, HHS/CDC has recommended avoiding mosquito bites, protecting against sexual transmission, and for pregnant women to avoid travel to areas where Zika is spreading. Another example is seasonal influenza, which is very contagious but also very common; therefore, HHS/CDC makes recommendations for people sick with flu-like symptoms to stay home from work or school and take basic precautions such as covering their coughs and sneezes and washing their hands. In all situations, HHS/CDC considers how common and severe the communicable disease is, how it is transmitted, and what interventions are available and appropriate before making recommendations or taking action to protect the health of the public.

One commenter questioned why HHS/CDC was not able to currently control all communicable diseases, specifically leprosy. While HHS/CDC works regularly and continuously with other Federal, State, local and tribal health departments to eliminate the introduction, transmission and spread of all communicable disease, outbreaks can and do still occur. HHS/CDC staff have experienced first-hand the impact of globalization on public health. The rapid speed and tremendous volume of international and transcontinental travel, commerce, and human migration enable microbial threats to disperse worldwide in 24 hours—less time than the incubation period of most communicable diseases. These and other forces intrinsic to modern technology and ways of life favor the emergence of new communicable diseases and the reemergence or increased transmission of known communicable diseases.

HHS/CDC received many comments regarding measles and the need to apply public health measures to prevent the transmission and spread of the disease. We note also that while measles may be transmissible during travel, it is not one of the quarantinable communicable diseases listed by Executive Order of the President. Therefore, while HHS/CDC may recommend post-exposure prophylaxis, or other ways to manage and prevent spread, we do not have the authority to apprehend, examine, detain, or conditionally release individuals who may have measles, nor those who may have been exposed. See

80 FR 16,400 (Mar. 27, 2015)(describing air travel restrictions that may be applicable to a passenger who would represent a threat to public health).

HHS/CDC believes that requesting that DHS restrict the air travel of persons with measles is warranted because measles is a serious and highly contagious communicable disease that would pose a public health threat during travel. People exposed to measles who are not immune to the infection and have not been vaccinated following the exposure are advised to delay their travel voluntarily until they are no longer at risk of becoming infectious.

A number of commenters suggested that the proposed regulations are unconstitutional or in violation of the “Nuremberg Code,” the United Nations Educational, Scientific and Cultural Organization (UNESCO), the Universal Declaration on Bioethics and Human Rights, the Geneva Convention, human rights in general, and/or civil liberties in general because they ostensibly authorize compulsory medical treatment without informed consent. Commenters also cited numerous Supreme Court cases purportedly in support of these claims, such as *Mills v. Rogers*, 457 U.S. 291 (1982), (curtailing the involuntary administration of anti-psychotic drugs to mental patients); *Vacco v. Quill*, 521 U.S. 793 (1997) (constitutionality of an assisted suicide ban); *Washington v. Harper*, 494 U.S. 210 (1990) (involuntary administration of anti-psychotic drugs to prison inmates); *Sell v. United States*, 539 U.S. 166 (2003)(upholding certain strict due process protections before any involuntary administration of anti-psychotic drugs to incarcerated prisoners can be made); and *Canterbury v. Spence*, 409 U.S. 1064 (1972)(duty of doctors to obtain informed consent). HHS/CDC disagrees and re-asserts that this final rule does not authorize compulsory medical treatment, including compulsory vaccination, without informed consent.

These regulations do not violate or take away any recognized rights guaranteed by the U.S. Constitution or applicable international agreements. While HHS/CDC has successfully responded to outbreaks of communicable diseases, such as Ebola, these regulations will improve HHS/CDC’s future ability to prevent the introduction, transmission, and spread of communicable diseases, through such mechanisms as improved reporting of illnesses and public health prevention measures at airports. While many of these activities have been carried out in the past through internal operating

procedures, these regulations improve the public’s awareness and understanding of HHS/CDC’s activities to protect the public’s health.

One commenter expressed concerns about religious exemptions for mandatory vaccination or treatment. In response, HHS/CDC notes that these regulations do not authorize compulsory vaccinations or medical treatment. While HHS/CDC will implement these regulations in a manner consistent with respecting the religious rights of individuals, religion is not a basis for exempting individuals from the provisions of these regulations, including those provisions relating to quarantine and isolation.

One commenter raised similar concerns that the regulations may lead to apprehensions based on factors unrelated to public health such as wearing of religious garb or reading of certain newspapers. HHS/CDC agrees that public health actions should not be taken based on factors unrelated to protecting the public’s health and these regulations do not authorize such actions. Additionally, these regulations strike the appropriate balance between individual liberties and public health protection.

Several commenters questioned whether quarantine and isolation may be carried out consistent with the Fourth Amendment to the U.S. Constitution. One commenter also suggested that implementation of public health prevention measures at airports would lead to “unreasonable searches and seizures” under the Fourth Amendment. HHS/CDC disagrees with these assertions. The Fourth Amendment protects the rights of persons to be free in their persons, houses, papers, and effects, against unreasonable government searches and seizures. HHS/CDC notes that at ports of entry, routine apprehensions and examinations related to quarantine and isolation may fall under the border-search doctrine, which provides that, in general, searches conducted by CBP officers at the border are not subject to the requirements of first establishing probable cause or obtaining a warrant. See *United States v. Roberts*, 274 F.3d 1007, 1011 (5th Cir. 2001); see also *United States v. Bravo*, 295 F.3d 1002, 1006 (9th Cir. 2002) (noting that only in circumstances involving extended detentions or intrusive medical examinations have courts required that border searches be premised upon reasonable suspicion). Similarly, apprehensions and examination of persons traveling interstate under this rule are authorized under the special-needs doctrine articulated by the

Supreme Court in *Skinner v. Railway Labor Executives' Ass'n*, 489 U.S. 602 (1989) because of the “special need” in preventing communicable disease spread. Furthermore, to the extent that “probable cause,” rather than “special needs,” would be the applicable Fourth Amendment standard, HHS/CDC contends that meeting the requirements of 42 U.S.C. 264 satisfies this standard. See *Villanova v. Abrams*, 972 F.2d 792, 795 (7th Cir.1992)(noting that probable cause for emergency civil commitment exists where “there are reasonable grounds for believing that the person seized is subject to the governing legal standard.”). HHS/CDC further acknowledges that any searches and seizures of individuals must be reasonable under the circumstances. HHS/CDC reiterates that this final rule does not authorize compulsory medical treatment, including vaccination, without informed consent.

HHS/CDC received a comment citing *Missouri v. McNeely*, where the U.S. Supreme Court ruled that police must generally obtain a warrant before subjecting a drunken-driving suspect to a blood test, and that the natural metabolism of blood alcohol does not establish a *per se* exigency that would justify a blood draw without consent. In response, HHS/CDC notes that courts have recognized that while the requirements for probable cause and a warrant generally apply in a criminal context, these standards do not apply when the government is conducting a non-law enforcement related activity. See *Nat'l Treasury Employees Union v. Von Raab*, 489 U.S. 665 (1989) (reaffirming the general principle that a government search may be conducted without probable cause and a warrant when there is a special governmental need, beyond the normal need for law enforcement). HHS/CDC reiterates that the special-needs doctrine articulated by the Supreme Court in *Skinner v. Railway Labor Executives' Ass'n*, 489 U.S. 602 (1989) provides the appropriate legal standard under the Fourth Amendment for apprehensions and detentions under this final rule.

Several commenters also questioned whether the regulations are consistent with the requirements of the Fifth and Sixth Amendments to the U.S. Constitution. We note at the outset that the Sixth Amendment only applies to criminal proceedings and thus would be inapplicable to isolation and quarantine decisions which are public health protection measures unrelated to the normal needs of law enforcement. Furthermore, HHS/CDC asserts that this final rule is consistent with the requirements of due process embodied

in the Fifth Amendment to the U.S. Constitution. Specifically, procedural safeguards contained in the final rule include: (1) A requirement for written orders of quarantine, isolation, or conditional release, including translation or interpretation services as needed; (2) mandatory review of the Federal order after the first 72 hours; (3) notifying individuals through the written order of their right to request a medical review; (4) an opportunity at the medical review for the detained individual to be heard through an attorney or other advocate hired at their own expense, present experts or other witnesses, submit documentary or other evidence; and confront and cross-examine any government witnesses; (5) a decision-maker independent of those who authorized the original isolation, quarantine, or conditional release; (6) a written statement by the fact-finder of the evidence relied upon and the reasons for the decision; (7) appointment of representatives, including a medical representative and an attorney, if the individual is indigent and requests a medical review; and (8) timely notice of the preceding rights. See *Vitek v. Jones*, 445 U.S. 480 (1980); *Mathews v. Eldridge*, 424 U.S. 319 (1976).

HHS/CDC also received a comment that quarantine violates the guarantees of substantive due process under the 5th Amendment to the U.S. Constitution. HHS/CDC disagrees. In addition to a guarantee of fair procedures, the U.S. Supreme Court has interpreted the Fifth Amendment's Due Process Clause as containing a substantive component barring certain arbitrary, wrongful government actions regardless of the fairness of the procedures used to implement them. See *Zinermon v. Burch*, 494 U.S. 113, 125 (1990). HHS/CDC notes that the quarantine of individuals who have been exposed to a communicable disease, but are not yet capable of transmission is a well-known and accepted public health strategy of long standing. See *Jacobson v. Massachusetts*, 197 U.S. 11, 25 (1905) (recognizing the power of States to issue “quarantine laws and health laws of every description”); *Compagnie Francaise de Navigation a Vapeur v. State Bd. of Health, Louisiana*, 186 U.S. 380, 396 (1902) (discussing the 1893 Federal quarantine statute). The restrictions on individuals authorized under this regulation are justified by the benefits to the public health.

HHS/CDC received a comment that quarantine and isolation are State police powers that should not be exercised at the Federal level. While HHS/CDC acknowledges that the States have

primary authority for quarantine and isolation within their borders, the Federal government has an important and longstanding role in preventing communicable disease spread at ports of entry and interstate. This authority is reflected in 42 U.S.C. 264 and consistent with principles of Federalism.

HHS/CDC received one comment stating that it should conduct a Federalism analysis because implementing the rule will require working with State health officials and resources. Under Executive Order 13132, a Federalism analysis is required if a rulemaking has federalism implications, would limit or preempt State or local law, or imposes substantial direct compliance costs on State or local governments. Under such circumstances, a Federal agency must consult with State and local officials. Federalism implications is defined as having substantial direct effects on State or local governments, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Under 42 U.S.C. 264(e), Federal public health regulations do not preempt State or local public health regulations, except in the event of a conflict with the exercise of Federal authority. Other than to restate this statutory provision, this rulemaking does not alter the relationship between the Federal government and State/local governments as set forth in 42 U.S.C. 264. While HHS/CDC acknowledges that portions of this rule may involve HHS/CDC “working with State health officials” to better coordinate public health responses, the rule is consistent with 42 U.S.C. 264(e) and there are no provisions that impose direct compliance costs on State and local governments. The longstanding provision on preemption in the event of a conflict with Federal authority (42 CFR 70.2) is left unchanged by this rulemaking. Therefore, HHS/CDC believes that the rule does not warrant additional consultation under Executive Order 13132.

HHS/CDC received several questions asking who would be responsible for the enforcement of these regulations. One commenter questioned whether HHS/CDC would use “militarized police or create [an] armed Federal police force to carry out these actions.” As explained elsewhere, in keeping with current practice and existing law, law enforcement support for quarantine or isolation orders will generally be provided by U.S. Customs and Border Protection, U.S. Coast Guard, or other Federal law enforcement programs, but

HHS/CDC may also accept voluntary State and local assistance in enforcing its Federal orders. HHS/CDC will also continue to enforce its regulations in a manner consistent with the Fourth Amendment and other provisions of the U.S. Constitution.

### c. Definitions

#### Agreements

HHS/CDC received many comments on the definition of *Agreement*, largely expressing confusion and concern that such agreements would not be truly voluntary. The intent of this provision was to provide HHS/CDC with an additional tool to facilitate cooperation from individuals in regard to recommended public health actions. In response to public comments, however, HHS/CDC has withdrawn this definition and will not issue the proposed provisions on “Agreements.”

#### Airline

HHS/CDC did not receive public comment on the proposed definition of *Airline*. However, consistent with HHS/CDC’s intent that this definition apply to common air carriers, to improve clarity, we have removed the phrase “including scheduled or public charter passenger operations operating in air commerce within the United States” and removed the reference to 49 U.S.C. 40102(a)(3).

#### Apprehension

HHS/CDC received many comments on the proposed definition and provision regarding *Apprehension*; a discussion of these comments is in the section below titled, “Apprehension and Detention of Persons with Quarantinable Communicable Diseases.” The definition is finalized as proposed.

#### Commander

HHS/CDC did not receive public comment on the proposed definition of *Commander*. Therefore, this definition is finalized as proposed.

#### Communicable Stage

HHS/CDC received a comment seeking clarity regarding the definition of *Communicable Stage*. The commenter stated that the definition for *communicable stage* may unnecessarily restrict social distancing powers because it appears limited to human-to-human transmission and does not include human transmission via an intermediate vector, such as mosquitoes or flea bites. HHS/CDC disagrees. The definition of *communicable stage* includes transmission of an infectious agent either “directly or indirectly from

an infected individual to another individual.” Thus, HHS/CDC clarifies that indirect transmission of an infectious agent may include transmission via an insect vector as described by the commenter. This definition is finalized as proposed.

#### Conditional Release

HHS/CDC received many comments on the proposed definition and provision regarding *Conditional Release*; a substantive discussion of these comments is presented in the section below titled *Requirements Relating to Issuance of a Federal Order for Quarantine, Isolation, or Conditional Release*.

HHS/CDC is modifying the definition of *Conditional Release* under section 70.1 to remove the cross-reference to the definition of surveillance as that term appears in current section 71.1. The definition of *Conditional Release* under section 70.1 tracks the definition of surveillance under section 71.1 and means “the temporary supervision by a public health official (or designee) of an individual or group, who may have been exposed to a quarantinable communicable disease to determine the risk of disease spread and includes public health supervision through in-person visits, telephone, or through electronic or internet-based monitoring.” HHS/CDC is making this change to improve clarity and remove the need for the public to cross-reference the definition of surveillance to understand the definition of *Conditional Release* as used in section 70.1.

This definition of *Conditional Release* under section 71.1 is finalized as proposed.

#### Contaminated Environment

HHS/CDC did not receive public comment on the proposed definition of *Contaminated Environment*. Therefore, this definition is finalized as proposed.

#### Conveyance

HHS/CDC did not receive public comment on the proposed definition of *Conveyance*. Therefore, this definition is finalized as proposed.

#### Electronic or Internet-Based Monitoring

HHS/CDC received many comments on the proposed definition and provision regarding *Electronic or Internet-based monitoring*. We have modified this definition as follows: “mechanisms or technologies allowing for the temporary public health supervision of an individual under conditional release and may include *communication through* electronic mail,

SMS texts, video or audio conference, webcam technologies, integrated voice-response systems, or entry of information into a web-based forum; wearable tracking technologies; and other mechanisms or technologies as determined by the Director or supervising State or local health authority.”

Several commenters expressed privacy concerns because conditional release of exposed or ill individuals may be accomplished over the internet or through electronic monitoring. Other commenters expressed concerns about privacy, having misunderstood the proposed rule as authorizing HHS/CDC to conduct invasive surveillance of personal communications such as emails, text messages, and telephone calls. Commenters also expressed concerns related to the use of webcams and wearable tracking technologies as an option for monitoring of exposed people. One association viewed this proposed provision as an expansion of CDC’s “electronic monitoring of personal information, under the guise of protecting the public against rare, isolated outbreaks of disease.”

HHS/CDC appreciates the opportunity to address these concerns. CDC’s intent was to describe mechanisms that HHS/CDC or other public health authorities can use to communicate with individuals for the purpose of conducting monitoring following exposure to a quarantinable communicable disease. These mechanisms are intended as alternatives to in-person interviews because of the inconvenience and logistical problems that may arise when meeting in-person.

During the 2014–2016 Ebola response, HHS/CDC recommended “active monitoring” defined as daily communication between public health authorities and the individuals being monitored. HHS/CDC did not specify how this communication should occur, and health departments used a variety of electronic technologies for this purpose including those listed in the regulation. HHS/CDC also recommended “direct active monitoring” for people with certain higher levels of exposure. This involved having a public health official check in with the person through direct observation rather than relying on phone calls or electronic communications. Webcams were used by some health departments as an alternative to in-person visits to observe the person taking his or her temperature. The webcam was only operational during this scheduled public health “visit.” The use of webcams proved convenient for both

the health departments and the people being monitored, especially if the people lived in remote areas. Webcams are also used routinely by health departments for “directly observed therapy” for diseases like tuberculosis (TB), in order to watch patients take their TB medications. HHS/CDC has clarified the regulatory text to state that these technologies will be used for communicating with the individual and not as a means of monitoring the individual’s personal communications.

One commenter asked whether HHS/CDC would “assist with payment for internet services” if webcam communications was required. In keeping with current practice, if an individual does not have access to internet services, HHS/CDC may use alternative methods to assist with communication, such as the issuance of a cellular phone. Some organizations also expressed concerns about the use of technologies such as cellular phones or wearable tracking technologies for the purpose of electronic monitoring. HHS/CDC acknowledges that the use of wearable tracking technology may be necessary in rare situations when a person does not comply with the required monitoring or when it is necessary to know the physical whereabouts of the person to ensure that they are not in a public place. While HHS/CDC acknowledges that public health surveillance of ill or exposed individuals through electronic monitoring may raise some privacy concerns, HHS/CDC believes that protecting the public’s health outweighs these concerns.

HHS/CDC is committed to protecting the privacy of personally identifiable information collected and maintained under the Privacy Act of 1974. As detailed in the preamble of the proposed rule, on December 13, 2007, HHS/CDC published a notice of a new system of records under the Privacy Act of 1974 for its conduct of activities under this final rule (72 FR 70867). HHS/CDC accepted public comment on its proposed new system of records at that time. As required under the Privacy Act, HHS/CDC described in its notice the proposed system of records, the purpose for the collection of the system data, the proposed routine uses (*i.e.*, disclosures of system data that are compatible to the purpose for the data collection), the benefits and need for the routine use of this data, our agency’s policies, procedures, and restrictions on the routine use disclosure of this information, and, most importantly, our safeguards to prevent its unauthorized use.

Under this system of records, CDC will only release data collected under this rule and subject to the Privacy Act to authorized users as legally permitted. HHS/CDC will take precautionary measures including implementing the necessary administrative, technical and physical controls to minimize the risks of unauthorized access to medical and other private records. In addition, HHS/CDC will make disclosures from the system only with the consent of the subject individual or, in accordance with the routine uses published at 72 FR 70867, or as allowed under an exception to the Privacy Act. Furthermore, HHS/CDC will apply the protections of the SORN to all travelers regardless of citizenship or nationality. Finally, such records will be stored and maintained in keeping with the official Records Control Schedule as set forth by the National Archives and Records Administration. For more information, please see <https://www.archives.gov/records-mgmt/rcs>.

#### Ill Person

We have modified the definition of *Ill person* under 71.1 to include a person who “(b)(2) Has a fever that has persisted for more than 48 hours; or (b)(3) Has acute gastroenteritis, which means either diarrhea, defined as three or more episodes of loose stools in a 24-hour period or what is above normal for the individual, or vomiting accompanied by one or more of the following: One or more episodes of loose stools in a 24-hour period, abdominal cramps, headache, muscle aches, or fever (temperature of 100.4 °F [38 °C] or greater).” This language was quoted verbatim in the preamble of the NPRM at 81 FR 54305 but was inadvertently omitted from the proposed regulatory text.

HHS/CDC received comments regarding the updated definition of *Ill person* which flight crews use to report to the CDC occurrences of illnesses in passengers or crew during travel. Specifically, commenters expressed concern that “non-medical personnel” such as flight attendants would report such observations; others questioned whether the definition is too broad and may result in over-reporting of non-threatening illnesses; others worried that it could lead to unnecessary apprehensions of individuals. One commenter claimed to be “chemical sensitive,” and worried that he or she may be penalized for having a reaction from sitting next to someone on a plane wearing a “strong fragrance.” HHS/CDC thanks the commenters for considering the proposal and providing feedback.

HHS/CDC clarifies that the purpose of the *ill person* definition is to align with current global and accepted detection and reporting practices so that onboard deaths and illnesses are reported by airlines and, where necessary, investigated by HHS/CDC. We note that the *ill person* definition in this final rule is consistent with the internationally recognized and accepted illness reporting guidelines published by the International Civil Aviation Organization (ICAO). This practice is not new, but has been used successfully for many years by aircraft and vessel crews to assist public health officials in preventing further transmission and spread of communicable disease.

HHS/CDC also does not intend to apprehend individuals based solely on their meeting the definition of an *ill person*. The purpose of an illness report is to allow trained HHS/CDC public health and medical officers to determine whether an illness occurring onboard a flight or voyage necessitates a public health response. In contrast, an apprehension of an individual is based on a variety of criteria in addition to an illness report including: Clinical manifestations, contact or suspected contact with infected individuals, host susceptibility, travel to affected countries or places, or other evidence of exposure to or infection with a quarantinable communicable disease. Thus, HHS/CDC disagrees that the *ill person* definition will lead to unnecessary apprehensions of individuals.

Several commenters noted that the symptoms listed in HHS/CDC’s definition of an *ill person* are common symptoms of many non-threatening conditions, and thus questioned their inclusion in the definition. HHS/CDC appreciates the opportunity to respond to these concerns. The symptoms listed in HHS/CDC’s *ill person* definition are provided for airlines and vessels to report to HHS/CDC so that HHS/CDC can make a public health risk assessment; *the symptoms alone would not result in issuance of a public health order*. In making such an assessment, HHS/CDC medical and public health officers consider the symptoms as well as the medical history of the person and any possible exposures that could indicate that the person may be infected with a quarantinable communicable disease.

A few commenters stated that the definition of *ill person* appears to expand the scope of HHS/CDC’s authority beyond the list of quarantinable communicable diseases specified through an Executive Order of the President. HHS/CDC disagrees. The

purpose of the ill person definition is to help facilitate the identification, particularly by flight crews, of communicable diseases of public health concern. Thus, HHS/CDC has defined *ill person* in such a way that the term may be understood by non-medically trained crewmembers. While the reporting of an ill person onboard a flight may trigger a public health evaluation by a trained quarantine officer in consultation with an HHS/CDC medical officer, such reporting does not expand the basis upon which an ill person may be subject to apprehension, detention, or conditional release. As noted by the commenter, such public health actions are limited to those quarantinable communicable diseases specified through an Executive Order of the President (e.g., cholera, diphtheria, infectious tuberculosis, yellow fever, viral hemorrhagic fevers, Severe Acute Respiratory Syndromes, and pandemic influenza).

A public health association suggested that any changes to the list of signs and symptoms within the definition of *ill person* should be made available for public comment. HHS/CDC assumes this comment is in reference to section (3) of the definition which provides for reporting of “symptoms or other indications of communicable disease, as the HHS/CDC may announce through posting of a notice in the **Federal Register**.” HHS/CDC appreciates the opportunity to clarify the purpose of this section. Section (3) of the *ill person* definition is intended to apply only to new, emerging, and imminent threats to public health. We expect it will only be relied on in emergency situations where a quick response is required to protect the public. Other circumstances, where the list of signs and symptoms may change due to evolving science or technology, will be made available for public comment, through a similar process as this rulemaking—Notices in the **Federal Register**—and may also request input from the public.

A number of commenters noted that symptoms listed in HHS/CDC’s definition of an *ill person* are common symptoms of many conditions, particularly “appears obviously unwell” which many commenters requested be removed from the definition. HHS/CDC appreciates the opportunity to clarify that, with the exception of acute gastroenteritis on vessels, HHS/CDC only requires reporting of an ill traveler on an aircraft or vessel if fever “accompanied by one or more of the following” other symptoms listed are present. Therefore, as an example, headache alone would not be sufficient to require reporting, but rather fever

plus headache, fever plus cough, fever plus persistent vomiting, fever plus persistent diarrhea, etc. These symptoms combined with fever are frequently seen in communicable diseases that could pose a public health risk to others during travel. Because a person with fever who also appears obviously unwell could have a serious communicable disease, HHS/CDC feels it is appropriate to retain this symptom, and further notes that its inclusion better aligns with Note 1 to the guidelines set forth by the International Civil Aviation Organization in paragraph 8.15 of Annex 9 to the Convention on International Civil Aviation.

One public health organization commented that the definition of *ill person* was broad and would be better issued through agency guidance rather than a rule. In response, HHS/CDC notes that the existing regulation contains an outdated and overly narrow definition of *ill person* that does not reflect current knowledge of communicable diseases, and that the reporting of ill travelers has been managed through a combination of regulation and agency guidance. This combination of “required” and “requested” reporting has proven confusing to some airline and vessel employees and this rule seeks to mitigate such confusion by including all relevant symptom clusters in the rule. Further, HHS/CDC notes that the change in the *ill person* definition better aligns with guidelines set forth by the International Civil Aviation Organization and is supported in comments received from the airline industry.

One public health organization commented on the different definitions of *ill person* for aircraft and vessels and recommended that the definitions be combined and not depend on the mode of transport. In response, HHS/CDC wishes to point out three crucial differences between aircraft and vessels which HHS/CDC feels justify the different definitions. One difference, additionally noted by the commenting organization, is the difference in time that a traveler spends on an aircraft and a vessel which makes the time frame (24 hours) specified in the definition of acute gastroenteritis for vessels relevant and minimizes the reporting of travelers with a single episode of loose stool that subsequently resolves, a common occurrence. The second is the high risk of spread of gastrointestinal infections onboard vessels that is unlikely to occur on aircraft; for this reason, reporting of diarrheal illnesses on aircraft includes the presence of fever which is more likely to indicate a serious

communicable disease, whereas the definition on vessels includes diarrheal illness without fever to allow for the reporting of viral gastrointestinal illnesses that typically do not cause fever but have been known to cause large outbreaks on cruise vessels. The third difference is the presence onboard cruise vessels of medical facilities capable of making a diagnosis of pneumonia which allows the inclusion of pneumonia in the vessel definition. In all other respects, the definitions are the same. HHS/CDC adds that combining the definitions would be confusing to industry professionals responsible for conducting this reporting.

One public health organization provided a recommendation to modify the description of the “rash” component in the definition of ill person to ensure that the term fully encompassed the range of potential skin rash symptoms. The organization’s recommendation for revisions was as follows: “The individual has areas on the skin that are red or purple, flat or bumps; with multiple red bumps; red, flat spots; or blister-like bumps filled with fluid or pus that are intact, draining, or partly crusted over; or dry and scaling patches. The rash may be discrete or run together, and may include one area of the body, such as the face, or more than one area.”

HHS/CDC responds that it will not change the regulatory text of the ill person definition with this language because we are concerned that this might add too much complexity to the regulatory definition. However, consistent with the regulatory definition of “ill person,” HHS/CDC will update its reporting guidance for aircraft and vessels to include this revised description. Current guidance may be found at: <http://www.cdc.gov/quarantine/air/reporting-deaths-illness/guidance-reporting-onboard-deaths-illnesses.html>.

An air industry commenter suggested another change to the ill person definition. The proposed definition included “headache with stiff neck,” and the commenter suggested that this be modified to “severe headache of recent onset with stiff neck.” While HHS/CDC will not change the regulatory definition of ill person to accommodate this change, HHS/CDC believes this is a useful modification to make in ill person reporting guidance to aircraft and vessels.

#### Incubation Period

HHS/CDC did not receive any comments on the proposed definition of *Incubation period*. However, upon a

review of the definition, we have decided that the definition should more closely track the definition of *Precommunicable stage*. For quarantinable communicable diseases, the *Incubation period* is defined as the *Precommunicable stage* of the disease. Thus, we have determined that the two definitions should more closely align. A substantive discussion of comments received concerning the definition of *Precommunicable stage* appears below.

Accordingly, we have modified the definition of *Incubation period* to add “or, if signs and symptoms do not appear, the latest date signs and symptoms could reasonably be expected to appear.” Other aspects of this definition are finalized as proposed.

#### Indigent

HHS/CDC received comments relating to the proposed definition of *Indigent* which is used to determine whether a detained individual qualifies for appointment at government expense of representatives to assist him/her during a medical review. One comment from a public health department suggested raising the threshold for indigent status to at least 200% of the applicable poverty guideline. HHS/CDC agrees and has made this change in the final regulation.

One commenter opposed including a definition for indigents and indicated that HHS/CDC should assume all costs whenever an individual is placed into Federal isolation or quarantine. HHS/CDC disagrees that assuming such costs without regard to indigence is necessary or appropriate.

Other substantive comments relating to the appointment at government expense of representatives to assist detained indigent individuals during a medical review are discussed below.

#### Master or Operator

HHS/CDC did not receive any comments on the definition of *Master or operator*. Accordingly, this definition is finalized as proposed.

#### Medical Examination

In response to comments received regarding medical examinations under sections 70.12 and 71.36, we have modified the definition of *Medical Examination* to indicate that the health worker conducting the assessment must be “licensed.” Comments regarding sections 70.12 and 71.36 are addressed below.

HHS/CDC received a comment regarding the definition of *Medical Examination*. The commenter stated that the definition of medical examination should include a mental

health assessment because a mental health condition may impact an individual’s appreciation of his or her public health risk to others. While HHS/CDC acknowledges that a mental health assessment may be useful as part of an individual’s medical care and treatment and that such an assessment may be ordered as needed by a treating clinician, HHS/CDC declines to make such assessments a formal part of the medical examination process. Specifically, because a mental health assessment is not generally needed to diagnose or confirm the presence or extent of infection with a quarantinable communicable disease, HHS/CDC disagrees that it is necessary or appropriate to require such an assessment as part of a Federal public health order.

#### Medical Representative

HHS/CDC received several comments relating to the proposed definitions of *Medical Representative* and *Medical Reviewer* as well as the potential use of HHS/CDC employees as representatives or medical reviewers. One commenter suggested that it would be less problematic for HHS/CDC to allow and pay for outside participants to serve in these capacities. First, HHS/CDC notes that the definition of *Medical representative* has been changed to *Representatives* and revised as detailed below. HHS/CDC disagrees with this comment and notes that the definition of both *Representatives* and *Medical reviewer* would in fact allow for the appointment of non-HHS/CDC employees in these capacities as suggested by the commenter. For this reason, both *Representatives* and *Medical reviewer* are broadly defined in terms of the occupational qualifications of these individuals. HHS/CDC also does not consider it problematic to rely on internal reviewers and notes that it is not unusual, for instance, for hospitals to rely on internal decision-makers when determining whether to commit a mental health patient on an emergency basis.

HHS/CDC received a comment that the “definition of medical exemption is not apparent.” In response, HHS/CDC notes that no clarification of what is meant by “medical exemption” is provided by the commenter and that HHS/CDC did not propose adding such a definition. While these regulations do not authorize compulsory vaccination or medical treatment, there is no recognized “medical exemption” from quarantine, isolation, or conditional release and HHS/CDC declines to create one.

#### Non-Invasive

HHS/CDC received several comments concerning the definition of *Non-invasive*, including support from a public health association regarding the definition. However, several individuals disagreed with the proposed definition. In response to public comment that the definition of “non-invasive” allowed too much physical contact between the individual and public health officer, HHS/CDC has replaced “physical” with “visual” and removed “auscultation; external palpation; external measurement of blood pressure” from the definition. While HHS/CDC continues to believe that these procedures qualify as *Non-invasive* under the definition, after considering public comment and a review of standard operating procedures, HHS/CDC finds such procedures to be unlikely to be conducted during a public health risk assessment. Such procedures may be conducted at a port of entry by emergency medical service personnel as part of a medical assessment to determine the need for emergency medical care. We also modified the definition to clarify that the individual conducting the public health risk assessment will be a “public health worker.” Public health workers are individuals who have education and training in the field of public health.

One commenter mentioned that the new definition of *Non-invasive* states that the HHS/CDC could order laboratory testing under certain conditions. The commenter further asserted that forced laboratory testing, without the option of quarantine instead, is an invasive measure, and questioned how this could be in line with the concept of non-invasive. HHS/CDC responds that the definition of non-invasive applies to procedures conducted during a public health risk assessment at a port of entry and that this definition does not authorize forcible or invasive procedures to extract human biological samples for laboratory testing. Should laboratory testing be needed for a person reasonably believed to be infected with a quarantinable communicable disease, such testing would be done as part of a medical examination conducted at a healthcare facility and performed with the patient’s informed consent. HHS/CDC has added language to the regulatory text requiring that the Director advise individuals of their right to have medical testing and examination conducted by an authorized and licensed health worker and with prior informed consent. While this regulation does not authorize forcible testing,



HHS/CDC may require laboratory test results demonstrating that a symptomatic individual is no longer infectious prior to rescinding a Federal isolation order.

#### Precommunicable Stage

HHS/CDC received comments relating to the definition of *Precommunicable stage*. One commenter suggested that persons in the “precommunicable stage” of a quarantinable communicable disease pose no direct threat to the public’s health. A public health organization also stated that this definition should not apply to non-symptomatic people who have been exposed to Ebola. HHS/CDC disagrees with both comments. For instance, a patient diagnosed with multidrug-resistant or extensively drug-resistant tuberculosis who is not currently infectious, but who has not been adequately treated and is thus at high risk for relapse would be considered to be in the “precommunicable stage” of the disease and pose a direct threat to the public’s health. Similarly, an individual who is reasonably believed to have been exposed to Ebola poses a direct threat.

Several public health organizations additionally expressed concerns regarding the use of the “precommunicable stage” definition to justify quarantine of healthcare workers caring for patients with quarantinable communicable diseases such as Ebola or severe acute respiratory syndromes, including healthcare workers providing care in the United States or in other countries. One such organization further requested clarification of whether the rule provides for the needs and protection of healthcare workers who voluntarily self-quarantine while providing care for patients with the quarantinable communicable diseases noted above.

In response, HHS/CDC states that it does not recommend quarantine or occupational restrictions of healthcare workers who follow recommended infection control precautions while providing care for patients with quarantinable communicable diseases. Healthcare workers who do not follow infection control precautions or who have had unprotected exposures to patients with a quarantinable communicable disease may be subject to quarantine or occupational restrictions; these individuals would be afforded the same due process protections as other exposed individuals.

Several commenters also questioned CDC’s proposed definition for *Precommunicable stage* stating that it may result in an apprehension of an

individual who displays no symptoms of a communicable illness. In response, HHS/CDC states that it has defined *Precommunicable stage* consistent with the public health practice of quarantine. Quarantine refers to the public health practice of separating and restricting the movement of individuals who are reasonably believed to have been exposed to a communicable disease, but are not yet ill. In contrast, isolation refers to the public health practice of separating and restricting the movement of individuals who have been exposed to a communicable disease and are symptomatic from those who are not sick.

The definition of *Precommunicable stage* is finalized as proposed.

#### Public Health Emergency

HHS/CDC received several comments relating to the definition of *Public health emergency*. One commenter stated that use of the term is duplicative and unnecessary because the term is used elsewhere in the Public Health Service Act (42 U.S.C. 247d) and appears in State-based legislation based on the Model State Emergency Health Powers Act. This commenter suggested that to avoid confusion the term should be renamed “Public Health Exigency.” HHS/CDC disagrees. Section 361(d) of the Public Health Service Act (42 U.S.C. 264(d)(1)) authorizes the apprehension and examination of individuals traveling interstate who are in the “precommunicable stage” of a quarantinable communicable disease, but only if the disease “would be likely to cause a public health emergency if transmitted to other individuals.” Thus, section 361(d) is unique and differs from how the term public health emergency is used in other statutes or provisions of the Public Health Service Act because it authorizes application of specific public health measures (apprehension and examination) to specific individuals (those in the precommunicable stage of a quarantinable communicable disease), but only if the disease would be likely to cause a public health emergency. Thus, HHS/CDC considers it essential to define public health emergency because the existence of such an emergency is a necessary prerequisite to the apprehension and examination of individuals in the precommunicable stage of a quarantinable communicable disease.

This commenter also suggested that the definition of public health emergency contains an oversight because it does not mention the potential for an infectious condition being highly likely to cause “short- or

long-term disability.” HHS/CDC disagrees because the definition includes infectious diseases that are highly likely to cause “serious illness” if not properly controlled. HHS/CDC clarifies that “short- or long-term disability” caused by an infectious agent would be considered a “serious illness.”

This commenter further suggested that in addition to referencing a public health emergency declaration by the HHS Secretary, the definition should also include similar declarations by the President under the Stafford Act or under the National Emergencies Act. HHS/CDC disagrees. We note first that the definition of public health emergency is not limited to those emergencies declared by the HHS Secretary. Second, in the event of a man-made or natural disaster that also affects public health, the HHS Secretary may issue a separate declaration under the Public Health Service Act as was done in response to the terrorist attacks of September 11, 2001 and in response to Hurricane Katrina. Thus, HHS/CDC does not see a need to also reference Presidential declarations as suggested by the commenter.

This commenter also requested clarification concerning whether the World Health Organization’s (WHO) declaration of a Public Health Emergency of International Concern (PHEIC) could continue to serve as the basis for a “public health emergency” if the President or HHS Secretary disagreed with the declaration of a PHEIC on legal, epidemiologic, or policy grounds. In response, HHS/CDC notes that the scenario proposed by the commenter is unlikely, but that CDC remains a component of HHS, subject to the authority and supervision of the HHS Secretary and President of the United States.

HHS/CDC also received a comment objecting to referencing the WHO’s declaration of a Public Health Emergency of International Concern (PHEIC) in the definition of “public health emergency” because this ostensibly relinquishes U.S. sovereignty. HHS/CDC disagrees. By including references to a PHEIC, HHS/CDC is not constraining its actions or making its actions subject to the dictates of the WHO. Rather, the declaration or notification of a PHEIC is only one way for HHS/CDC to define when the precommunicable stage of a quarantinable communicable disease may be likely to cause a public health emergency if transmitted to other individuals. While HHS/CDC will give consideration to the WHO’s declaration of a PHEIC or the circumstances under which a PHEIC may be notified to the

WHO, HHS/CDC will continue to make its own independent decisions regarding when a quarantinable communicable disease may be likely to cause a public health emergency if transmitted to other individuals. Thus, HHS/CDC disagrees that referencing the WHO determination of a PHEIC results in any relinquishment of U.S. sovereignty.

The International Health Regulations are an international legal instrument that sets out the roles of WHO and State parties in identifying, responding to, and sharing information about public health emergencies of international concern. HHS/CDC believes that it would be unlikely for the United States to formally object to the WHO's declaration of a PHEIC, but that CDC remains a component of HHS, subject to the authority and supervision of the HHS Secretary and President of the United States.

Also regarding the definition of "public health emergency," one public health association expressed concern that *any* disease considered to be a public health emergency may qualify it as quarantinable. Another commenter noted that some PHEICs "most certainly do not qualify as public health emergencies" under the proposed definition. HHS/CDC appreciates the opportunity to clarify. Only those communicable diseases listed by Executive Order of the President may qualify as quarantinable communicable diseases. For example, Zika virus infection, which although the current epidemic was declared a PHEIC by WHO, is not a quarantinable communicable disease. The definition of *Public health emergency* is finalized as proposed.

#### Public Health Prevention Measures

HHS/CDC received one comment relating to the definition of *Public health prevention measures*. The commenter stated that the second use of "and other non-invasive means" should be deleted from the definition of *public health prevention measures* as redundant. HHS/CDC disagrees because "observation, questioning, review of travel documents, and records review" as cited in the definition appears to materially differ from "other non-invasive means" that may be used as a part of public health prevention measures such as temperature checks, visual observation, or visual examination of the ear, nose, or mouth. Accordingly, HHS/CDC believes that the updated definition provides greater clarity as written. Further information, including a discussion regarding comments received on these proposed

provisions, is discussed in the section below titled *Public Health Prevention Measures to Detect Communicable Disease*. The definition is finalized as proposed.

#### Qualifying Stage

HHS/CDC received several comments relating to *Qualifying stage*. Several commenters, including one public health organization, expressed concern that the definition was either too vague, too broad, or too confusing. One commenter suggested that the definition for *Qualifying stage* is confusing because it splits communicable diseases into a "precommunicable stage" and a "communicable stage" and that a communicable disease would not be on the list of Federal quarantinable communicable diseases if its spread did not already have some potential to cause a public health emergency. In response, HHS/CDC notes that the term "qualifying stage" is defined under 42 U.S.C. 264(d)(2) to include both a "precommunicable stage" and a "communicable stage" and that this definition explicitly references diseases "likely to cause a public health emergency." Thus, while HHS/CDC may clarify and explain statutory terms through regulation, it has no authority to change the language of the statute.

One public health organization recommended that HHS/CDC policy implementing the *Qualifying stage* definition acknowledge that a one-size fits all protocol is not appropriate because different diseases have different transmission patterns and the need for isolation and quarantine may differ. HHS/CDC agrees that the need for isolation and quarantine may differ based on the disease and adds that it conducts a public health risk assessment before issuing Federal public health orders. For example, HHS/CDC does not typically issue Federal public health orders for cholera, a quarantinable communicable disease as defined by Executive Order because the sanitation infrastructure in the United States makes cholera transmission unlikely. HHS/CDC further notes that it typically conducts the public health risk assessment in coordination with the State or local health department of jurisdiction before issuing a Federal public health order.

Public health organizations and other commenters cautioned against apprehending individuals or issuing public health orders when the risk of communicable disease spread during the precommunicable period is low. HHS/CDC agrees and further adds that it will typically conduct a public health risk assessment in coordination with

State and local public health officials to ensure that any restrictions imposed on an individual are commensurate with the degree of risk and using the least restrictive means available.

The definition of *Qualifying stage* is finalized as proposed.

#### Reasonably Believed To Be Infected, as Applied to Individuals

HHS/CDC received several comments regarding the definition of *Reasonably believed to be infected, as applied to an individual*. Several public health organizations expressed concern there could be undue burden placed on healthcare facilities or health departments by greatly expanding the number of individuals requiring health screening, medical examination and testing, or placed under Federal isolation of quarantine orders. HHS/CDC disagrees. This rule represents a codification of current practice and decisions regarding the need for medical examination of individuals suspected of being infected with a quarantinable communicable disease, including during an outbreak or public health emergency, will generally be based on published disease-specific case definitions for PUIs (persons under investigation) that incorporate clinical and epidemiologic factors. Furthermore, decisions regarding the issuance of Federal public health orders or medical examination for a suspected quarantinable communicable disease would typically be made in coordination with a State or local health department of jurisdiction. Therefore, HHS/CDC does not anticipate placing an undue burden on healthcare facilities or health departments as a result of these definitions.

One commenter stated that the *Reasonably believed to be infected, as applied to an individual* definition allows for apprehension, quarantine, or isolation based solely on reasonable inferences that the person was exposed somehow or in some way to infectious agents. HHS/CDC disagrees because as stated in the definition reasonable inferences may only be drawn from "specific articulable facts" that an individual has been exposed to an infectious agent such as through "contact with an infected person or an infected person's bodily fluids, a contaminated environment, or through an intermediate host or vector." Thus, HHS/CDC disagrees that this standard does not comport with standard public health practice.

HHS/CDC received a comment from a public health agency expressing concern that travel to other countries where transmission of a quarantinable

communicable disease has likely occurred would be the sole basis upon which HHS/CDC would form a reasonable belief that an individual may be infected with a quarantinable communicable disease. In response, HHS/CDC clarifies that travel to other countries was simply used as an illustrative example. The decision to place an individual into isolation or quarantine will ordinarily be based on several factors, including travel, contact with an infected person or an infected person's bodily fluids, host susceptibility, and clinical manifestations. HHS/CDC believes that this definition is clear and that no further changes are necessary.

The definition of *Reasonably believed to be infected as applied to an individual* is finalized as proposed.

#### Secretary

HHS/CDC has added a definition for *Secretary* meaning the Secretary of Health and Human Services (HHS) or any other officer or employee of that Department to whom the authority involved has been delegated. We note that while the NPRM did not propose this definition, the NPRM referenced the *Secretary* in defining *Public Health Emergency*. Thus, HHS/CDC considers it useful to also define the term *Secretary*.

After consideration of comments regarding *Definitions*, HHS/CDC has made the following changes in the final rule:

- The definition of *Agreements* has been withdrawn.
- The definition of *Conditional Release* under section 70.1 has been modified to remove the internal cross-reference to the definition of surveillance under section 71.1. The definition of *Conditional Release* under section 70.1 has been further modified to align with the definition of surveillance under section 71.1 and means “the temporary supervision by a public health official (or designee) of an individual or group, who may have been exposed to a quarantinable communicable disease to determine the risk of disease spread and includes public health supervision through in-person visits, telephone, or through electronic or internet-based monitoring.”
- The definition of *Electronic or internet-based monitoring* has been modified to indicate “communication through” such means, and include “audio” conference.
- The definition of *Incubation period* has been modified to add “or, if signs and symptoms do not appear, the latest date signs and symptoms could reasonably be expected to appear.” This

aligns the definition with the *Precommunicable stage* definition.

- The definition of *Indigent* has been modified to increase the threshold to 200% of the applicable poverty guidelines.
- The definition of *Medical Examination* has been modified to indicate that the health worker conducting the assessment must be “licensed.”
- The definition of *Medical Representative* has been changed to *Representatives* and now includes in addition to the appointment of a medical professional, the appointment of “an attorney who is knowledgeable of public health practices.”
- The definition of *Non-invasive* has been modified to (1) replace “physical examination” with “visual examination,” (2) specify that the individual performing the assessment must be a “public health worker (*i.e.*, an individual with education and training in the field of public health)” and (3) remove “auscultation, external palpation, external measurement of blood pressure.”
- A definition for *Secretary* has been added and means “the Secretary of Health and Human Services (HHS) or any other officer or employee of that Department to whom the authority involved has been delegated.”

#### d. Public Health Prevention Measures To Detect Communicable Disease

HHS/CDC received support from commenters on screening individuals entering the U.S. from parts of the world where highly infectious diseases are common. One such commenter requested to know the criteria HHS/CDC uses when deciding whether to detain an individual. Another commenter stated that travel history “should be a prerequisite for Federal orders to quarantine” and “medical exam should be a prerequisite for Federal orders to isolate.” HHS/CDC thanks these commenters and welcomes the opportunity to explain this process.

HHS/CDC's decision to detain an individual is based on several criteria, including: Clinical manifestations: Signs and symptoms consistent with those of a quarantinable communicable disease; known or suspected contact with cases, *i.e.*, patients either confirmed or suspected to be infected with a quarantinable communicable disease; epidemiologic information/evidence (travel history, exposure to animals); other documentary or physical evidence in the individual's possession, such as a physician's note documenting infection with or medication for treatment of a quarantinable disease;

and/or public health authorities having notified HHS/CDC that the individual is known or suspected to be infected with a quarantinable communicable disease and likely non-adherent with public health recommendations.

HHS/CDC has modified paragraph (b) of the provisions relating to public health prevention measures to detect communicable disease (§§ 70.10 and 71.20) to include information about “known or possible exposure,” in response to comments requesting further clarity of CDC's criteria.

One organization from the airline industry was generally supportive of 70.10 and 71.20, *public health prevention measures to detect communicable disease*, and requested that any measures, such as screening, occur prior to individuals boarding an aircraft, and preferably prior to arrival at the gate. HHS/CDC thanks these commenters for their support. In response, while an operational plan for each location has not yet been finalized, HHS/CDC expects such measures to occur prior to the boarding of an aircraft, and to the extent possible, prior to arrival at the gate. One airline organization insisted that airline operators should not be financially responsible for any costs associated with screening. HHS/CDC responds that it does not expect airlines and airline operators to assume direct costs associated with public health screening, such as providing additional personnel to conduct the screening. However, indirect costs such as missed flights of passengers who are detained may occur.

Another airline organization requested that HHS/CDC ensure wait-times in lines are not impacted by screening, and encouraged HHS/CDC to take into account the needs of all stakeholders. HHS/CDC feels strongly that in these rare circumstances, which would only occur should a threat to public health exist, preventing airline employees and other passengers from being exposed to a detained or delayed individual provides a greater benefit than the monetary loss of airfare. In keeping with current practice, HHS/CDC will work together with public health partners, carriers, and all who have equities, to ensure insofar as possible that the least restrictive and time-consuming measures are implemented. Finally, commenters requested that individuals who refuse to undergo a public health risk assessment prior to travel be denied boarding of an aircraft. In response, HHS/CDC notes that individuals may be denied boarding for public health reasons pursuant to the criteria published at 80 FR 16,400 (Mar. 27, 2015) titled *Criteria for Requesting*

*Federal Travel Restrictions for Public Health Purposes, Including for Viral Hemorrhagic Fevers.*

HHS/CDC received a comment expressing concern about conducting public health prevention measures at “other locations” besides U.S. ports of entry because the commenter found this language vague. HHS/CDC clarifies that this term is meant to include all locations where individuals may enter the United States from a foreign country (i.e., border crossings) or gather for the purposes of engaging in interstate travel (e.g., airports, seaports, railway stations, bus terminals), regardless of whether such places are formally designated as such.

One public health organization requested clarification regarding what information or event would justify triggering the screening of travelers. CDC’s response is that, while specific triggers cannot be defined at this time, screening of travelers may generally be conducted during a public health emergency if HHS/CDC determined that monitoring of potentially exposed travelers was needed to protect the public’s health.

One public health organization and many individual commenters asserted that people exposed to measles should not be “tracked” through the use of Federal public health orders. First, we reiterate that because measles is not a quarantinable communicable disease, HHS/CDC does not have the authority to issue a public health order for this illness. Second, it is not HHS/CDC’s policy to monitor people following measles exposures. Rather, HHS/CDC notifies State or local health departments regarding people in their jurisdictions who may have been exposed to measles. The State or local health departments, in turn, choose to notify people regarding their measles exposure, assess their immunity to measles and, if they are not immune, offer vaccination with MMR vaccine to prevent infection. State or local health authorities may choose to monitor people following exposures to measles based on their own criteria.

One commenter asked whether mandatory health screenings at airports would be conducted privately, whether processes would comply with HIPAA, and how data would be protected at airports. In response, HHS/CDC states that, in all situations, HHS/CDC strives to protect the privacy of individuals subject to screening, collection of information, or the issuance of Federal public health orders under HHS/CDC’s authority. While some aspects of the entry risk assessment process conducted during the 2014–2016 Ebola epidemic

were performed in areas of the airport that are not considered private, these were limited to collection of contact information, noncontact temperature measurement, observation for visible signs of illness, and superficial screening questions that did not collect sensitive information. Any more detailed public health assessment would be done in a private area.

HHS/CDC is bound by the Privacy Act to protect personally identifiable data collected and maintained in accordance with that Act. Furthermore, HHS/CDC will apply the protections of the SORN to all travelers regardless of citizenship or nationality. Personally identifiable data collected by HHS/CDC at airports are maintained in a secure database and shared only for official purposes on a need to know basis using secure methods as described in CDC’s System of Records Notice published at 72 FR 70867. HHS is also a hybrid entity under HIPAA, but only those parts of HHS that have been determined to be health care components are subject to the HIPAA Privacy Rule. CDC is generally not a health care component treated as a “covered entity” under the HIPAA Privacy Rule. However, certain specific offices of HHS, CDC, and the National Institute for Occupational Safety and Health (NIOSH) performing activities related to the World Trade Center Health Program are considered health care components of HHS and must comply with HIPAA and the Privacy Rule.

One public health organization recommended that the rulemaking specify that individuals undergoing a public health risk assessment only be asked to provide contact tracing information if the risk assessment leads to a reasonable belief that the individual may become infected. It is CDC’s policy to conduct conveyance-related contact investigations for confirmed cases of communicable diseases. In instances when confirmation cannot be obtained, HHS/CDC may investigate contacts based on reasonable belief of infection following a public health risk assessment which is typically conducted in coordination with the State or local health department of jurisdiction. Such operational details are generally defined in internal protocols. State or local authorities may conduct community-based contact investigations within their jurisdictions based on their own criteria.

After consideration of these comments, HHS/CDC has modified paragraph (b) the provisions relating to *Public Health Prevention Measures to Detect Communicable Disease* (§§ 70.10 and 71.20) to include information about

“known or possible exposure” in the list of information that may be collected.

e. Apprehension and Detention of Persons With Quarantinable Communicable Diseases

HHS/CDC received several comments relating to the “apprehension” of an individual. One public health association and a public health department suggested that HHS/CDC not use the term “apprehension” because this may create social stigma. HHS/CDC uses this term in these regulations to align with the statutory terminology used in 42 U.S.C. 264(b) which authorizes the “apprehension, detention, or conditional release” of individuals coming into a State or possession from a foreign country or possession for purposes of preventing the introduction, transmission, and spread of quarantinable diseases. Similarly, 42 U.S.C. 264(d) authorizes the “apprehension and examination” of any individual in the qualifying stage of a quarantinable communicable disease who is moving or about to move between States or constitutes a probable source of infection to individuals moving between States. While HHS/CDC can clarify and explain this term, only Congress has the authority to change statutory language. In addition to being a term specifically used in statute under 42 U.S.C. 264, HHS/CDC has determined that this term best conveys that HHS/CDC may, based on public health grounds, assume physical custody of individuals. Furthermore, using alternative terminology, may reduce public understanding and transparency regarding HHS/CDC’s legal authorities.

One commenter stated that not every social distancing technique needs to involve taking physical custody of individuals and that using more voluntary-based options would be advisable. HHS/CDC agrees that attempting to obtain voluntary compliance with public health measures is more advisable than assuming legal custody, but believes that maintaining the authority to apprehend individuals who may pose a public health risk is a necessary tool to protect the public’s health. HHS/CDC received a comment regarding the “burden of proof” for an apprehension. In response, HHS/CDC notes that the applicable standard for an apprehension of an interstate traveler is “reason to believe” that the individual is in the qualifying stage of a quarantinable communicable disease. HHS/CDC notes that *Reasonably believed to be infected as applied to an individual* is defined under this final rule.

Several commenters expressed concern that because the “apprehension” period is not explicitly time-limited, that HHS/CDC may “apprehend” an individual indefinitely without providing the individual with a written public health order or a medical review. One commenter noted that HHS/CDC used the term “generally” in the preamble of the NPRM and felt it was too vague, stating “setting a firm timeframe is vital.” A partnership of public health legal scholars and organizations stated that because HHS/CDC did not explicitly limit how long an individual could remain apprehended that such apprehensions could turn into the functional equivalent of a quarantine thus potentially raising Fourth and Fifth Amendment concerns. In response to these concerns, HHS/CDC has added language requiring that it serve an apprehended individual with a public health order within 72 hours of that individual’s apprehension.

HHS/CDC received several other comments relating to the sections authorizing the apprehension and detention of persons with quarantinable communicable diseases. A partnership of public health legal scholars and organizations suggested two public health frameworks for apprehension and detention, one for implementation during non-exigent circumstances and a second for exigent circumstances. As described, the primary distinction between the non-exigent and exigent framework, is that in the former HHS/CDC would be required to hold a due process hearing prior to the imposition of an isolation or quarantine, while in the latter HHS/CDC may briefly detain the individual prior to holding a hearing. While HHS/CDC appreciates the input provided by this partnership, HHS/CDC declines to adopt this suggestion. Importantly, unlike State and local public health authorities who have primary responsibility for the imposition of public health measures occurring within their jurisdictions, HHS/CDC acts in time-sensitive circumstances to prevent communicable disease spread, such as at ports of entry, upon the request of a State or local public health authority of jurisdiction, or when State or local control is inadequate. Furthermore, unlike State and local public health authorities who generally have broad police-power authority to protect the public’s health, HHS/CDC’s statutory authority with respect to isolation and quarantine is limited to only those small, subset of communicable diseases specified through an Executive Order of the

President as quarantinable. Accordingly, HHS/CDC does not foresee sufficient “non-exigent” circumstances where it would be necessary for it to issue a Federal isolation or quarantine order and thus declines to establish the suggested alternative framework on this basis.

The circumstances under which HHS/CDC may apprehend and detain individuals is limited by the terms of 42 U.S.C. 264. HHS/CDC may only isolate, quarantine, or conditionally release an individual if it reasonably believes that the individual is infected with a quarantinable communicable disease and the individual is either arriving into the U.S. from a foreign country, moving between States, or constitutes a probable source of infection to others who may then move between States.

Accordingly, the circumstances under which CDC is would issue a quarantine or isolation order are “exigent” because the individual constitutes a communicable disease risk and is actively engaged in travel or constitutes a source of infection to others engaged in travel. It is thus unnecessary and impractical to provide a “pre-deprivation” hearing prior to quarantining or isolating the individual because he/she if released from custody may be lost to public health follow-up and may expose others. HHS/CDC would not quarantine or isolate an arriving traveler from a foreign country where a single case of a communicable disease such as Ebola exists unless it reasonably believes that the traveler arriving into the U.S. is infected with a quarantinable communicable disease.

Commenters stated that individuals must receive notice of their suspected exposure and be permitted to speak with legal counsel or have legal counsel appointed to them. HHS/CDC agrees that individuals should be adequately notified of the basis for their detention and directs this commenter to sections 70.14 and 71.37, which detail the specific factual content that must be included in a Federal order for quarantine, isolation, or conditional release. We have also modified these sections to explicitly require that the federal order include an explanation of the right to request a medical review, present witnesses and testimony at the medical review, and to be represented at the medical review by either an advocate (e.g., family member, physician, or attorney) at the individual’s own expense, or, if indigent, to have representatives appointed at the government’s expense.

As previously stated, consistent with principles of preventing communicable disease spread, HHS/CDC will also take

measures (such as ensuring phone access) to allow apprehended individuals to have contact with family or legal counsel whom they hire at their own expense. As explained further below, HHS/CDC will also appoint representatives, including a medical representative and an attorney, if the individual is indigent and requests a medical review. Individuals who do not qualify as indigent may also choose to be represented at the medical review by an advocate (e.g., an attorney, physician, family member) and present a reasonable number of medical experts, of their own choosing and at their own expense. HHS/CDC, however, rejects as impractical the notion that indigent individuals should have representatives appointed to them *at the moment of apprehension* because most illnesses of public health concern can be ruled out based on a short interview with a quarantine officer involving an assessment of symptoms and travel history. Thus, the expected length of an apprehension will be very short and not justify the appointment of representatives.

This commenter also requested clarity on what legal recourse may be available to apprehended individuals. While HHS/CDC does not express an opinion regarding what form of legal action an aggrieved individual should pursue, we note that these regulations do not impact the constitutional or statutory rights of individuals to seek judicial redress for detention.

HHS/CDC received comments from the public regarding HHS/CDC’s authority to “arrest” individuals. One commenter stated that individuals should only be detained when a crime has been committed. One association objected to HHS/CDC’s “power to detain an individual for 72 hours and longer without any Federal court order.” Some commenters also worried that any person showing signs of a “common cold” may be held. To be clear, HHS/CDC is not a law enforcement agency, it has no legal authority to “arrest” individuals, but rather has been granted the authority by Congress to “apprehend and detain” individuals for the purposes of preventing the introduction, transmission and spread of quarantinable communicable disease as specified in an Executive Order of the President. 42 U.S.C. 264(b). This provision further provides that “regulations may provide that if upon examination any such individual is found to be infected, he may be detained for such time and in such manner as may be reasonably necessary.” 42 U.S.C. 264(d)(1). HHS/CDC strongly believes that these

authorities may be implemented in a manner consistent with the U.S. Constitution. Furthermore, during the period of apprehension, HHS/CDC will arrange for adequate food and water, appropriate accommodation, appropriate medical treatment, and means of necessary communication.

HHS/CDC received comments from the public inquiring about the criteria that HHS/CDC uses to determine whether an individual should be detained and assessed. As provided for in the regulation, HHS/CDC may apprehend, examine, isolate, and quarantine such individuals to protect the public's health. In determining whether an individual poses a threat to public health, HHS/CDC has developed and uses the following criteria: Clinical manifestations: Signs and symptoms consistent with those of a quarantinable disease; known or suspected contact with a case, *i.e.*, patients either confirmed or suspected to be infected with a quarantinable disease; epidemiologic information/evidence (travel history, exposure to animals); other documentary or physical evidence in the individual's possession, such as a physician's note documenting infection with or medication for treatment of a quarantinable communicable disease; and/or public health authorities have notified HHS/CDC that the individual is known or suspected to be infected with a quarantinable communicable disease and non-adherent with public health recommendations. This determination is typically made in consultation and coordination with State and local public health authorities, as well as the treating health care physician (when available). One public health association agreed that travel history (entering the U.S. from a country where quarantinable diseases occur) made sense for screening, but not for a quarantine or isolation order. HHS/CDC responds that the criteria listed above, as well as those within the NPRM, are examples of factors that HHS/CDC takes into consideration when determining the totality of the circumstances—not one criterion does, should, or will, decide if the individual requires a public health order.

One commenter questioned whether, regarding the list of quarantinable communicable diseases listed by Executive Order of the President, a "common cold" would qualify as a "severe acute respiratory syndrome" and therefore subject the ill individual to a public health order. In response, we note that Executive Order 13295 (April 4, 2003), as amended by Executive Order 13375 (April 1, 2005) and

Executive Order 13674 (July 31, 2014), explicitly excludes "influenza" from the definition of severe acute respiratory syndrome.

HHS/CDC received several comments from a flight attendant union relating to apprehension and detention of a flight crew. These comments include that the flight attendant's employer should be made aware of the apprehension, that HHS/CDC should limit the personal health information that is shared with the employer, that the employer should treat this information as confidential, and that those apprehended should be able to notify families and their union. In response, HHS/CDC notes that it works closely with the airline industry regarding potential occupational exposures to communicable diseases. Furthermore, HHS/CDC notes that personally identifiable health information collected and maintained under the Privacy Act will be disclosed only with the consent of the subject individual, in accordance with the routine uses published in HHS/CDC's system of records notice (72 FR 70867), or under an applicable exception to the Privacy Act. While these regulations do not mandate how employers should treat the personal health information of their employees, HHS/CDC agrees that such information should be treated as confidential. Lastly, consistent with principles of preventing communicable disease spread, HHS/CDC will allow persons detained in accordance with these regulations to communicate with family, union representatives, legal counsel whom they hire at their own expense, and others of their choosing. HHS/CDC will also appoint representatives, including a medical representative and an attorney, if the individual is indigent and requests a medical review.

One commenter asked about provisions for people detained under HHS/CDC's authority who require emergency medical care, and whether the need to conduct a public health assessment could impede such care resulting in harm to the individual. In response, HHS/CDC states that public health officers at ports of entry work closely with emergency medical service (EMS) personnel and that emergency medical care takes precedence over the public health risk assessment. When an individual suspected of being infected with a quarantinable communicable disease requires emergency care, the individual would be transported immediately by EMS to a medical facility, using appropriate infection control precautions. The public health risk assessment would be completed subsequently using information

provided by the examining health care provider in coordination with the health department of jurisdiction.

After consideration of these comments, HHS/CDC has finalized the *Apprehension and Detention of Persons With Quarantinable Communicable Diseases* (§ 70.6) provision as proposed, with the exception that Federal public health orders must be served on the individual within 72 hours of an apprehension. As further detailed below, the 72-hour period was determined based on public comment from health departments familiar with the process, as well as CDC's previous experience of the time necessary to conduct a medical examination, collect and package laboratory specimens, transport the specimens to an appropriate laboratory (when necessary), and conduct the testing.

#### f. Medical Examinations

HHS/CDC received several comments relating to medical examinations. HHS/CDC received a comment from a public health agency stating that when an individual agrees to submit to a medical examination, it may be more appropriate to medically examine the patient during the "apprehension" period. In response, HHS/CDC notes that these regulations do not prohibit voluntary compliance with public health recommendations in the absence of a public health order. Notwithstanding, HHS/CDC believes that the ability to order a medical examination as part of an order for isolation, quarantine, or conditional release is an important tool to protect the public's health. This agency also stated that the definitions of "health status" and "public health risk" should be modified to ensure that the medical examination contains the minimum requirements needed to assess the communicable disease of public health concern. In response, HHS/CDC clarifies that its sole purpose in ordering a medical examination would be to determine the presence, absence, or extent of infection with a quarantinable communicable disease. HHS/CDC notes, however, that the medical examination is conducted by clinical staff who have primary responsibility for the patient's medical care and treatment and that a medical examination would thus ordinarily include the taking of a medical history and physical examination. HHS/CDC believes that this definition is clear and that no further modifications are needed.

HHS/CDC received a comment expressing concern that an individual would not be able to choose his or her own clinical healthcare provider if

ordered to undergo a medical examination. One commenter raised concerns about the possibility of medical examinations being conducted by “unqualified” or “non-medical personnel.” In response, HHS/CDC clarifies that, in keeping with current practice, any medical evaluation required by HHS/CDC would be conducted at a healthcare facility by a licensed healthcare practitioner. Furthermore, HHS/CDC has determined that it would be impractical to allow individuals to choose their own medical examiners. HHS/CDC notes that among other considerations, it must ensure that the healthcare facility where the medical examination will be conducted has appropriate containment facilities, that necessary laboratory samples will be properly collected, and that it is HHS/CDC’s practice to coordinate closely with State and local public health authorities in the choosing of clinical healthcare providers. Accordingly, we have concluded that the public interest is best served by having HHS/CDC, in coordination with the local health authority and EMS, choose the healthcare facility where the medical examination will be conducted and not the detained individual.

One commenter expressed concern that nonmedical personnel may be allowed to make a determination of illness resulting in actions being taken based on potential misdiagnosis. HHS/CDC appreciates the opportunity to clarify this point. Decisions to issue Federal public health orders are based on the assessment of qualified and licensed physicians. These decisions are based on all available evidence, including clinical presentation, medical and exposure history, and the results of medical evaluation and laboratory testing. Treatment decisions are made by the individual’s treating physician with guidance from public health subject-matter experts.

One commenter suggested that medical examinations should be conducted only with the informed consent of the individual and should not “forcibly” be required. HHS/CDC clarifies that it may require a medical examination under 42 U.S.C. 264(d) because this section, among other things, authorizes the “apprehension and examination” of individuals reasonably believed to be infected with quarantinable communicable diseases in a qualifying stage. CDC, however, agrees that medical examinations may not be conducted “forcibly.” Furthermore, because medical examinations will typically occur in a hospital setting and be performed by clinical staff, it will be incumbent upon clinical staff to obtain

the patient’s informed consent consistent with established standards of medical practice.

Public health organizations provided several comments regarding medical examinations, including that they be performed promptly so as not to curtail liberty, include only minimal components necessary to establish the diagnosis of or rule out the quarantinable communicable disease of concern, and that specimens obtained during such examinations not be used for purposes other than diagnostic testing without informed consent. In response, HHS/CDC states that it agrees with all of these points and that CDC, in keeping with current practice, has a commitment to upholding the highest ethical standards for both medical care and research.

One public health organization asked for clarification of whether hospital staff would be involved in obtaining consent for medical examinations authorized under this rule. In response, HHS/CDC states that, while a public health order authorizes that a medical examination be conducted, should any invasive procedures be determined by the treating clinician to be necessary for diagnostic or treatment purposes, consent for such procedures should be obtained by medical staff in accordance with established standards.

One organization asked for clarification of the location where medical examinations would be conducted, including whether inpatient or ambulatory-care facilities would be included. HHS/CDC responds that it will coordinate with State or local health departments of jurisdiction concerning such operational details as the exact locations where medical examinations may be conducted.

Several public health organizations commented on whether the issuance of public health orders is needed prior to medical examination if individuals agree voluntarily to such examinations, noting that a requirement for the issuance of orders could impede or delay the medical examination and that the examination, itself, could determine whether such orders are needed. In response, HHS/CDC notes that it may choose not to exercise its authority to issue public health orders if an individual complies voluntarily with HHS/CDC’s requirements, including the requirement of a medical examination. However, HHS/CDC retains the right to issue an order requiring a medical examination should an individual not comply voluntarily. Of note, one public health organization supported the use of Federal public health orders in requiring medical examinations, stating

that such orders had been used effectively in the past to facilitate timely examination.

One public health organization requested that language be added to the rule stating that medical examinations will be performed with proper adherence to worker safety and health policies and protocols. HHS/CDC responds that such occupational health protections are beyond the scope of this regulation and are covered by regulations of the Occupational Safety and Health Administration (OSHA).

HHS/CDC received several comments from a flight attendant union relating to medical examinations. This organization stated that the regulations should mandate that an employer pay a flight attendant’s salary and per diem and that no flight attendant should incur discipline as a result of being absent from work. This organization further commented that any changes in the employer-employee relationship should be addressed through joint guidance between government and industry groups. This group also commented that “promptly” should be defined in terms of the length of time that may be needed to arrange for a medical exam and that no more than five hours would be reasonable. This group further stated that “reasonably believed” should be defined to require specific, articulable facts that a trained medical professional can articulate.

HHS/CDC responds that these regulations do not alter, define, or mandate the employer-employee relationship between flight attendants and their employers. In regard to the timeframe for arranging a medical examination, HHS/CDC rejects a specific 5-hour timeframe as too prescriptive, but agrees that the medical examination should be arranged as quickly as possible based on the circumstances of the event. HHS/CDC further notes that the definition of “reasonably believed to be infected” already requires the existence of “specific articulable facts” articulated by a public health officer. Such specific, articulable facts would, for instance, include “contact with an infected person or an infected person’s bodily fluids, a contaminated environment, or through an intermediate host or vector.”

HHS/CDC received a comment from a partnership of public health legal scholars and organizations expressing concern that the regulations do not appear to limit the invasiveness of a medical examination, so long as the examination itself is needed to diagnose or determine the presence or extent of infection with a quarantinable communicable disease. HHS/CDC



welcomes this opportunity to provide further clarifications. HHS/CDC notes that because medical examinations will occur in a hospital setting and be performed by the hospital's clinical staff, it will be incumbent upon clinical staff to obtain the patient's informed consent consistent with established standards of medical practice prior to any examination occurring and that such examinations may not be forcibly conducted. HHS/CDC has also added a requirement that the Director, as part of the Federal order, the individual that the medical examination shall be conducted by an authorized and licensed health worker with prior informed consent. Furthermore, HHS/CDC will implement this provision consistent with U.S. constitutional requirements and Articles 23 and 31 of the International Health Regulations, which requires that parties apply "the least intrusive and invasive medical examination that would achieve the public health objective."

After consideration of these comments, HHS/CDC has finalized the provisions relating to *Medical Examination* (§§ 70.12 and 71.36) as proposed, with the exception that the Director as part of the Federal order must advise the individual that the medical examination will be conducted by an authorized and licensed health worker with prior informed consent.

#### g. Requirements Relating to Issuance of a Federal Order for Quarantine, Isolation, or Conditional Release

HHS/CDC received several comments relating to the issuance of Federal orders for isolation or quarantine. A flight attendant union commented that crew lists should not be published as part of a quarantine order posted in a conspicuous location. This group further stated that quarantine orders for flight attendants should be treated differently than those applicable to passengers or other airline personnel because flight attendants are health and safety personnel trained in how to perform CPR and operate defibrillators. In response, HHS/CDC notes that if a public health order is publicly posted, the order will be written to refer to a group of individuals, such as all individuals onboard a particular affected interstate or international flight. Under such circumstances, HHS/CDC expects that all members of the group will receive individual copies of the public health order. In some circumstances, CDC anticipates that issuance of a group federal order to an individual may not be feasible—such as when the location of the individual is unknown. Thus, HHS/CDC does not

expect to publish the names of individual passengers or crew as part of a publicly posted quarantine order.

Furthermore, while HHS/CDC agrees that flight attendants provide an important public health and safety role, HHS/CDC disagrees that acknowledging this role requires the issuance of different public health orders than those issued to other affected persons.

HHS/CDC received several comments requesting the "least restrictive" means with respect to quarantine and isolation. HHS/CDC agrees and clarifies that in all situations involving quarantine, isolation, or other public health measures, it seeks to use the least restrictive means necessary to prevent spread of disease. Regarding quarantine, as an example, during the 2014–2016 Ebola epidemic, HHS/CDC recommended monitoring of potentially exposed individuals rather than quarantine. Most of these people were free to travel and move about the community, as long as they maintained daily contact with their health department. For some individuals with higher levels of exposure, HHS/CDC recommended enhanced monitoring (involving direct observation) and, in some cases restrictions on travel and being in crowded places, but did not recommend quarantine. HHS/CDC has the option of "conditional release" as a less restrictive alternative to issuance of an order of quarantine or isolation. Under a conditional release order, the person would not be confined as long as the terms of the order were followed. Should a quarantine or isolation order be deemed necessary, home quarantine or isolation would be considered as a less restrictive option to confinement in a guarded facility as long as this was determined to be safe for other household members, appropriate based on the individual's ability and willingness to follow all necessary precautions, and based on the individual's history of compliance with public health recommendations.

One public health organization requested that HHS/CDC specify the types of locations of Federal quarantine and asked clarification of whether this would occur on lands or property under Federal jurisdiction, and whether Federal or State standards would apply to an individual quarantined on lands or property not under Federal control. In response, HHS/CDC notes that operational issues such as the exact location of a quarantine and whether Federal, State, and local orders would be issued separately or concurrently would depend on individual facts and circumstances unique to each case. HHS/CDC notes, however, that it is not

unusual for the Federal government to exercise jurisdiction concurrently with State and local governments.

One public health organization noted the longstanding difficulties faced by Federal, State and local authorities in identifying suitable facilities for quarantining of large groups of people (approximately 350, representing the potential complement of travelers onboard an international flight), including the immediate availability of such facilities in the event of an emergency. HHS/CDC acknowledges these difficulties and affirms that it is actively working with Federal partners to identify suitable locations to accommodate large groups of people while under a Federal public health order.

One commenter stated, "If this is enacted . . . everyone who works with diseases . . . CDC, WHO, Labs, Drs., nurses etc. would have to be arrested as potential carriers." HHS/CDC disagrees with this assertion. HHS/CDC is not a law enforcement agency and does not have authority to arrest individuals. HHS/CDC's authority to issue Federal public health orders is limited to those diseases defined by Executive Order as quarantinable communicable diseases. Furthermore, HHS/CDC does not recommend restriction of movement for healthcare workers, laboratory workers, or others whose occupations involve working with infectious pathogens as long as the recommended infection control precautions are followed. Workers who do not take the necessary precautions or have unprotected exposures to a quarantinable communicable disease may be subject to restrictions if they meet the requirements for issuance of Federal public health orders.

Some commenters indicated that vaccination or treatment should not be "conditions" under "conditional release." HHS/CDC confirms that this final rule does not compel mandatory vaccination or medical treatment of individuals. HHS/CDC clarifies that when medically appropriate, vaccination or treatment, may be "conditions" of an individual's release from quarantine or isolation. Individuals consent to these conditions.

A public health agency commented that HHS/CDC should consider the conditions of confinement to ensure that certain minimum requirements, such as access to telephones, and reasonable accommodation of dietary restrictions, are observed. Specifically, such conditions should be considered at different stages including as part of the issuance of an order, during the mandatory reassessment, and as a part

of the medical review. In response, HHS/CDC notes that in addition to implementing these regulations consistent with U.S. constitutional requirements, CDC's implementation will also be consistent with Article 32 of the International Health Regulations which, among other things, requires that in implementing health measures under the IHR the gender, sociocultural, ethnic and religious concerns of the traveler be taken into consideration. Furthermore, Article 32 requires arranging for adequate food and water, protection for baggage and other possessions, appropriate accommodation, appropriate medical treatment, and means of necessary communication for those subject to public health orders. Furthermore, as stated in the regulations, as part of a mandatory reassessment and medical review, HHS/CDC will consider whether the least restrictive means are being used to protect the public health. HHS/CDC, however, does not believe that it is necessary for "conditions of confinement" to be formally considered as part of an administrative review because many conditions of confinement, such as availability of entertainment or other amenities, may be raised through informal means such as making one's concern known to the facility where the individual is being housed.

HHS/CDC received a comment from a public health agency noting that it should assume the responsibility of providing translation and interpretation services when issuing an order for quarantine, isolation, or conditional release, or when conducting a medical review. HHS/CDC agrees and has incorporated these changes into the regulatory text.

HHS/CDC received a comment from a partnership of public health legal scholars and organizations requesting clarification as to whether personal service will occur when a quarantine order is issued on a group basis and posted in a conspicuous location. In response, HHS/CDC notes that if a public health order is publicly posted, the order will be written to refer to a group of individuals, such as all individuals onboard a particular affected interstate or international flight. Under such circumstances, HHS/CDC expects that all members of the group will receive individual copies of the public health order, thus addressing any concerns about adequacy of notice. Because HHS/CDC, however, cannot foresee all of the circumstances that may arise in an emergency situation, HHS/CDC believes that it is appropriate for these regulations to authorize service

through posting or publication, but only when individual service is "impracticable."

After consideration of these comments, HHS/CDC has modified the provisions regarding requirements relating to *issuance of a Federal order for quarantine, isolation, or conditional release* (§§ 70.14 and 71.37). Paragraphs (a)(5) and (4) of these provisions have been modified, respectively, to require that the federal order include an explanation of the right to request a medical review, present witnesses and testimony at the medical review, and to be represented at the medical review by either an advocate (e.g., family member, physician, or attorney) at the individual's own expense, or, if indigent, to have representatives appointed at the government's expense. Paragraph (b) of these provisions has been modified to require that a Federal public health order be served within 72 hours of an individual's apprehension. A new provision, paragraph (c), has been added requiring that the Director arrange for translation and interpretation services of the Federal order as needed.

#### h. Mandatory Reassessment of a Federal Order for Quarantine, Isolation, or Conditional Release

A number of commenters were confused regarding the 72-hour period, believing this period referred to the period of apprehension pending the issuance of a Federal public health order and asked why 72 hours were needed. The 72-hour period proposed referred to the timeframe in which HHS/CDC must conduct a mandatory reassessment of the continued need for isolating or quarantining an individual following the service of a Federal public health order. However, in response to public comments HHS/CDC has also added in sections 70.14(b) and 71.37(b) a requirement that it serve the individual with a Federal public health order within 72 hours of that individual's apprehension.

Some commenters, including a public health association, supported the mandatory 72-hour reassessment provision guaranteed by these regulations. One of these commenters also suggested the time be re-evaluated periodically in the event that technology provides a way of speeding up the diagnosis process; another suggested the time frame be expanded to five days to account for weekends; one more commenter noted that circumstances may arise where an additional 72 hours may be needed; and another commenter stated that a second 72-hour reassessment should be required. HHS/

CDC is committed to performing a reassessment within 72 hours of the federal public health order being served on the individual. If, at that time, HHS/CDC determines that the order was properly issued and that a public health risk continues to exist, the order would either be continued or HHS/CDC would work with the State and local health department to transfer custody. In the event that HHS/CDC continues the order, the individual may request a medical review at that time.

A few commenters stated that the reassessment of HHS/CDC's orders should be conducted in a shorter time period than 72 hours such as within 12 hours, performed electronically and conducted by a 3rd party. While HHS/CDC appreciates the input provided by these commenters, HHS/CDC finds these suggestions impractical. Medical examination to confirm or rule out infection with a quarantinable communicable disease may require up to 72 hours to allow for laboratory testing. While some communicable diseases (typically viral infections) may be diagnosed using molecular tests such as polymerase chain reaction (PCR) that take several hours to perform, others require that the organism be cultured to make a confirmed diagnosis or to conduct antimicrobial sensitivity testing in order to provide appropriate treatment. This is typically needed for bacterial infections, such as diphtheria or plague, and may take 48–72 hours (or longer) to complete. For some infectious tuberculosis cases, laboratory confirmation may take several weeks although preliminary molecular testing may assist in conducting an assessment of risk sufficient to continue or rescind the order. Specimen transportation time may also need to be factored in as testing for certain diseases is only available at state public health laboratories or CDC.

While HHS/CDC is required by this provision to reassess the need for a Federal public health order within 72 hours, HHS/CDC will immediately release individuals from detention if at any time it receives information confirming the absence of infection with a quarantinable communicable disease. We note that while the medical assessment is intended primarily as a review of available medical records and other relevant information, these regulations do not prohibit HHS/CDC from conducting the review electronically, for instance by relying on electronic medical records. Furthermore, HHS/CDC disagrees that relying on internal decision-makers for the reassessment is inappropriate or undesirable and thus does not consider

it necessary to rely on a “3rd party.” However, the CDC official or employee conducts the reassessment will not be the same person who issued the quarantine, isolation, or conditional release order. Following the reassessment, the detained individual may also request a medical review as described in these regulations.

HHS/CDC received a comment from a public health agency requesting clarification as to whether all individuals within a group will receive individual due process when a group order is issued. This agency also questioned the feasibility of providing a mandatory reassessment and medical review for large groups. In response, HHS/CDC confirms that if a group order is issued, all individuals within that group will be accorded due process. Furthermore, HHS/CDC has provided flexibility in the regulations to allow for a mandatory reassessment of the group order and consolidation of medical reviews where appropriate.

HHS/CDC received a comment from a partnership of public health legal scholars and organizations stating that while the rule requires consideration of least restrictive means upon reassessment of an order and as part of the medical review, HHS/CDC must also consider least restrictive means prior to the issuance of a quarantine or isolation order. HHS/CDC agrees that all means short of assuming legal custody of the individual including attempting to obtain voluntary compliance with public health measures should be explored. HHS/CDC notes, however, that an isolation or quarantine order is typically issued in time-sensitive situations where because of the exigent circumstances surrounding the risk of communicable disease spread it is not immediately possible to explore all available less restrictive means, including the appropriateness of a home environment, instead of a hospital. For this reason, HHS/CDC has chosen the mandatory reassessment and medical review as the appropriate time to conduct a formal assessment of least restrictive means. To the extent that the commenters suggest that due process requires more, we disagree. *See Yin v. California*, 95 F.3d 864, 870 (9th Cir. 1996) (recognizing that in searches and seizures justified by special needs, the government does not have to use the least restrictive means to further its interests); *Stockton v. City of Freeport, Texas*, 147 F.Supp.2d 642, 647 (S.D. Tex. 2001) (recognizing that the Fourth Amendment does not require that a search or seizure be conducted through the least restrictive means, but rather that the alleged personal invasion be

reasonable under all of the circumstances).

After consideration of these comments, HHS/CDC has finalized the provisions relating to *mandatory reassessment of a Federal order for quarantine, isolation, or conditional release* (§§ 70.15 and 71.38) as proposed.

i. Medical Review of a Federal Order for Quarantine, Isolation, or Conditional Release

HHS/CDC received several comments arguing that its proposed medical review procedures are deficient. Specifically, one commenter stated that assessment procedures should be clearly communicated to all affected persons; that HHS/CDC should more clearly delineate “less restrictive alternatives;” that affected individuals should have a right to legal representation; and that access to independent judicial review is essential.

HHS/CDC agrees that it should clearly communicate review procedures to individuals subject to Federal isolation, quarantine, or conditional release. We note that sections 70.14 and 71.37 have been modified to require that the federal order authorizing isolation, quarantine, or conditional release include an explanation that the federal order will be reassessed 72 hours after it is served on the individual and of the right to request a medical review, present witnesses and testimony at the medical review, and to be represented at the medical review by either an advocate (*e.g.*, family member, physician, or attorney) at the individual’s own expense, or, if indigent, to have representatives appointed at the government’s expense. We further note that the provisions relating to medical reviews, sections 70.16 and 71.39 have been revised to include new paragraphs (q) which states that “The Director shall arrange for translation or interpretation services as needed for purposes of this section.”

Similarly, in regard to minor children or adults with a cognitive disability, HHS/CDC will work with a competent guardian to ensure that procedures are clearly communicated. In regard to less restrictive alternatives, HHS/CDC believes that it is not possible to delineate with specificity all of the less restrictive options that may be available because such determinations will inevitably be based on the individual circumstances of each case, including the severity of the particular disease-causing agent, availability of treatment options should the disease not be adequately contained, the patient’s particular level of infectivity or

communicability, appropriateness of the home environment, and the individual patient’s understanding, ability, and willingness to comply with less restrictive alternatives. For this reason, HHS/CDC has made consideration of less restrictive alternatives a part of the medical review proceeding where evidence may be submitted into the record, testimony obtained, and a recommendation provided by the medical reviewer. As a general matter, however, HHS/CDC clarifies that less restrictive alternatives would refer to reasonable and available alternatives that are adequate to protect the public’s health other than confinement in a guarded facility, such as home quarantine, directly observed therapy, or other forms of supervised release.

In response to concerns about legal representation, HHS/CDC has amended the definition of “Medical representative” to “Representatives” and will now appoint “an attorney knowledgeable of public health practices” in addition to a “physician, nurse practitioner, or similar medical professional qualified in the diagnosis and treatment of infectious diseases.” HHS/CDC hopes that by appointing both an attorney *and* a qualified medical professional for indigent individuals it will alleviate concerns expressed by the public regarding the medical review process. We note that an attorney may become “knowledgeable of public health practices” in a number of ways, for instance, through prior representation of a public health agency or advocacy organization, training provided by a public health or advocacy organization or other training that would ordinarily occur through a Continuing Legal Education (CLE) event, law school coursework, or through independent study. We further note that for individuals qualifying as indigent, HHS/CDC intends to provide independent legal counsel from outside of the agency. In doing so, HHS/CDC may employ a variety of mechanisms, such as through agreements or memorandums of understanding with law school legal clinics, State or local bar associations, or public interest groups representing indigent clients. Individuals who do not qualify as indigent may choose to be represented at the medical review by an advocate (*e.g.*, an attorney, physician, family member) and present a reasonable number of medical experts, of their own choosing and at their own expense.

HHS/CDC also agrees that access to independent judicial review is essential and assures the public that this final rule does not affect the constitutional or statutory rights of individual to seek

judicial review through such traditional mechanisms as a petition for a writ of habeas corpus under 28 U.S.C. 2241. As a Federal agency, however, HHS/CDC would lack the legal authority through regulation to grant Federal courts with jurisdiction that they would not otherwise possess because only Congress may expand a Federal court's jurisdiction.

HHS/CDC received a comment from a partnership of public health legal scholars and organizations stating that the CDC Director should not have unfettered discretion to accept or reject the medical reviewer's decision, but rather should only be allowed to reject a decision based on lack of substantial evidence. HHS/CDC believes that it would be inappropriate to mandate through regulation that the decision of a medical reviewer (which may include an HHS or CDC employee) should displace the decision of the CDC Director, particularly where the statute and delegation of authority have provided otherwise.

HHS/CDC received several comments stating that a medical representative should be appointed to anyone regardless of their ability to pay. HHS/CDC disagrees and notes that appointment of a representative at the government's expense without regard to the patient's indigence is not required. The status of "indigent" is self-reported as HHS/CDC will not require access to an individual's financial records. Those who self-identify as indigent may be required to sign an affidavit or declaration under penalty of perjury stating they meet the threshold of at least 200% of the applicable poverty guidelines.

HHS/CDC received a comment from a non-profit organization contending that the medical review does not comport with due process because there is no limit on the number of reviews that may be consolidated into a single proceeding, no access to legal counsel, no independence of the reviewer from the initial decision-maker, no confrontation or cross-examination of witnesses, no compulsory process for obtaining evidence or testimony, and no judicial review. This group contends that any detention that is non-exigent should occur only based on the "informed explicit written consent" of the patient or "utilize the existing legal procedures for involuntary commitment of persons."

HHS/CDC disagrees that the medical review as described and set forth in the regulations does not comport with due process. While HHS/CDC acknowledges that there is no numerical limit to the number of medical reviews that may be

consolidated, HHS/CDC believes that the circumstances giving rise to the need for consolidation will be exceedingly rare and that medical reviews will generally be conducted on an individual basis.

HHS/CDC also disagrees that there is no access to legal counsel because HHS/CDC will, consistent with principles of preventing communicable disease spread, allow persons subject to public health orders to communicate with family and legal counsel whom they hire at their own expense. Furthermore, as described above, the regulations have been amended to require the appointment of *both* an attorney *and* a medical professional if the detained individual qualifies as an indigent and requests a medical review. Individuals who do not qualify as indigent may also choose to be represented at the medical review by an advocate (*e.g.*, an attorney, physician, family member) and present a reasonable number of medical experts, of their own choosing and at their own expense.

HHS/CDC further believes that reliance on internal reviewers does not violate due process and notes that it is not unusual, for instance, for hospitals to rely on internal decision-makers when determining whether to commit a mental health patient on an emergency basis. The regulations, moreover, explicitly state that the medical reviewer will not be the same individual who initially authorized the quarantine or isolation order. We note further that the definition of both "representatives" and "medical reviewer" would in fact allow for the appointment of non-HHS/CDC employees in these capacities because both terms are broadly defined in terms of the professional qualifications and not employment status of these individuals. Thus, these regulations do not prohibit the CDC Director from appointing personnel from outside of the agency to assist in conducting a medical review. For individuals qualifying as indigent, HHS/CDC intends, generally, to provide independent legal counsel from outside of the agency.

HHS/CDC also clarifies that during the course of a medical review, a detained individual will be permitted to present witnesses and question any witnesses offered by HHS/CDC. Any "confrontation" of witnesses, however, will be conducted in a manner consistent with principles of preventing communicable disease spread. HHS/CDC, as a Federal agency, however lacks the legal authority to allow a detained individual to use compulsory processes, such as a subpoena, to compel the presence of witnesses. HHS/CDC will

nevertheless make reasonable efforts to produce any HHS/CDC employees that would be critical to a detained individual's presentation of evidence during a medical review.

HHS/CDC also disagrees that there is no judicial review and notes that these regulations do not impact an individual's constitutional or statutory rights to contest their Federal detention through such traditional mechanisms as a petition for a writ of habeas corpus under 28 U.S.C. 2241. To the extent, however, that the commenter contends that HHS/CDC should follow legal procedures other than those set forth through the Federal quarantine statute at 42 U.S.C. 264, we disagree. HHS/CDC notes that as a Federal agency it lacks the ability to rewrite Federal statutes or grant Federal courts with legal jurisdiction that they do not already possess. HHS/CDC also rejects as impractical and as insufficient to protect public health, the notion that isolation or quarantine should only occur based upon the consent of the subject individual.

HHS/CDC received a comment from a flight attendant union that as an important "safety net" HHS/CDC should pay for "second medical opinions." HHS/CDC declines to extend payment to medical examinations beyond those required as part of a public health order, but notes that as part of a medical review individuals may submit additional evidence into the record concerning their health status and potential public health risk to others.

One commenter noted language in the NPRM stating that the "medical review is not intended to address the concerns of individuals who take issue with amenities of their confinement . . .," interpreting this to mean that "no provision is made for those who must use a CPAP (continuous positive airway pressure) at night or who need orthopedic appliances, or who have food allergies, to name a few." In response, HHS/CDC states that, when confinement of an individual under Federal public health authorities is needed, HHS/CDC will ensure that such confinement will occur in a location and with necessary amenities to ensure the health and safety of the individual, including provision for medical or dietary requirements. Issues related to health and safety will be addressed at the time of the issuance of the order, or as soon as HHS/CDC is made aware of them, but are beyond the scope of the medical review which is intended to re-evaluate the continued need for the Federal public health order based on a review of the medical and other evidence submitted into the record.

HHS/CDC received a comment from a partnership of public health legal scholars and organizations stating that it should provide for an oral hearing whenever practical. HHS/CDC agrees that an oral hearing is appropriate and has modified the language to state: “The medical review shall be conducted by telephone, audio or video conference, or through other means that the medical reviewer determines in his/her discretion are practicable for allowing the individual under quarantine, isolation, or conditional release to participate in the medical review.”

HHS/CDC received a comment from a partnership of public health legal scholars and organizations that the CDC Director’s written order, which constitutes final agency action, must advise individuals of their rights to appeal to Federal court. We note that the commenters specifically cite the Administrative Procedures Act (APA, 5 U.S.C. 704), which provides that “final agency action for which there is no other adequate remedy in a court are subject to judicial review.” While HHS/CDC agrees that independent judicial review of agency decisions is available, it takes no position as to whether such reviews should occur under the APA (as suggested by the commenters) or through other traditional mechanisms as a petition for a writ of habeas corpus under 28 U.S.C. 2241. For this reason, HHS/CDC believes that due process is satisfied by designating the Director’s written order as “final agency action” without further speculation as to the exact form of further legal review. However, to clarify HHS/CDC’s intended we have added the following language to the regulatory text: “Nothing in these regulations shall affect the constitutional or statutory rights of individuals to obtain judicial review of their federal detention.”

Accordingly, after consideration of these comments, HHS/CDC has modified paragraph (f) of the provisions regarding *medical review of a Federal order for quarantine, isolation, or conditional release* (§§ 70.16 and 71.39) to include the revised definition of “Representatives,” which now requires HHS/CDC to appoint both a medical professional and an attorney “to assist the individual for purposes of the medical review upon a request and certification, under penalty of perjury, by that individual that he or she is indigent and cannot afford a representative.”

j. Administrative Records Relating to a Federal Order for Quarantine, Isolation, or Conditional Release

HHS/CDC received a comment from a flight attendant union concerning whether an overlap existed between CDC’s maintenance of administrative records relating to the issuance of Federal public health orders and an employee’s access to exposure and medical records under OSHA (29 CFR 1910.1020). We note that since HHS/CDC is not a flight attendant’s employer, HHS/CDC would not be covered by this particular OSHA standard under these circumstances. Furthermore, because these regulations do not alter, define, or mandate the employer-employee relationship between flight attendants and their employers, to the extent that this question seeks input regarding an employer’s obligations under OSHA, HHS/CDC views the question as outside the scope of the rulemaking.

HHS/CDC received a comment from a partnership of public health legal scholars and organizations stating that the regulations should require quarterly reporting to Congress to facilitate transparency and oversight. While CDC recognizes the additional transparency that direct reporting of details related to quarantine activities may provide to the public, CDC notes that historically, the issuance of Federal orders is rare (*i.e.*, one to two orders issued per year). Thus, publication of the specifics surrounding individual quarantine cases may raise significant privacy concerns related to the individuals placed under federal orders.

CDC does routinely describe its practices in published Morbidity and Mortality Weekly Reports (MMWR) when new methods, technologies, or other changes make it possible to revise and improve programs (*e.g.* DNB, M&M guidance, change in air contact investigation algorithms), which all serve to enhance transparency. Such information is also found on CDC’s Web site and publicly available standard operating procedures.

After consideration of comments received and as further explained below, HHS/CDC has modified the provisions regarding *Administrative Records* relating to a Federal order for quarantine, isolation, or conditional release (§§ 70.17 and 71.29) to remove paragraphs (5) regarding agreements entered into between HHS/CDC and the individual.

k. Other Due Process Concerns

HHS/CDC received many additional comments from the public concerned over whether this regulation violates

rights guaranteed by the U.S. Constitution, such as Due Process and specifically during the medical review process. HHS/CDC disagrees that the regulations are insufficient to protect the constitutional rights of individuals. In regard to medical reviews, HHS/CDC asserts that allowing individuals to choose at the government’s expense who will conduct the medical review is not required by due process and that there is no conflict of interest in allowing the CDC Director to appoint who will conduct the medical review on the agency’s behalf. HHS/CDC asserts, however, that individuals will be allowed to submit relevant information, including information provided by outside doctors or other medical specialists during the medical review. HHS/CDC will further preserve relevant agency documents for purposes of ensuring a competent legal review in the event that the individual seeks judicial redress of their quarantine or isolation. As explained elsewhere, law enforcement support for quarantine or isolation orders will generally be provided by U.S. Customs and Border Protection, U.S. Coast Guard, or other Federal law enforcement programs, but HHS/CDC may also accept voluntary state and local assistance in enforcing its Federal orders.

HHS/CDC received public comment expressing concern with regard to potential language barriers experienced by foreign nationals during travel. HHS/CDC responds that it has revised those sections of the regulations dealing with issuance of Federal orders to require that HHS/CDC arrange for translation or interpretation services of the Federal order as needed. In circumstances where it would be impractical to provide a line-by-line translation of the order, HHS/CDC may take other steps to reasonably apprise individuals of the contents of the order, for example, by arranging for oral translation services.

One public health organization questioned the feasibility of CDC’s conducting the mandatory reassessment or medical review of a group quarantine order within the specified time frame. In response, HHS/CDC states that a group quarantine order would be issued on the basis of a shared exposure for all individuals in the group; therefore, the mandatory reassessment or medical review could be conducted based on the shared exposure, unless certain individuals in the group were determined to be immune to the quarantinable communicable disease in question. Part of the reassessment would include a determination of whether the group order should be revised as individual orders.

HHS/CDC also received a comment that the duration of a quarantine, isolation, or conditional release period is not adequately defined. HHS/CDC disagrees because the regulations limit these actions to only those who would pose a public health threat, for instance, by being in the “qualifying stage” or a quarantinable communicable disease. The “qualifying stage” of the disease is defined as a communicable stage of the disease or a precommunicable stage, but only if the disease would be likely to cause a public health emergency if transmitted to other individuals. We note that HHS/CDC’s “Health Information for International Travel” (also known as the Yellow Book) provides the public with general guidance regarding the expected length of communicability for many quarantinable communicable diseases. For more information, please see <http://wwwnc.cdc.gov/travel/yellowbook/2016/table-of-contents>.

HHS/CDC received a comment that the qualifications of who may issue a quarantine or isolation order are not defined leading to concerns that such orders will be issued by non-medically trained personnel. In regard to the qualifications of who may issue a Federal public health order, HHS/CDC notes that all orders are issued under the authority of the CDC Director, but that in practice such determinations are made only by personnel trained in public health and licensed to practice medicine in the United States.

One organization requested that HHS/CDC provide notification to the appropriate embassy if a foreign national is placed under a Federal order. In regard to non-resident foreign nationals, HHS/CDC clarifies that it will coordinate closely with the U.S. Department of State to ensure that all rights and obligations under the Vienna Convention on Consular Relations and bilateral agreements will be observed. Because of the complexity of this issue, including reliance on the interpretation of treaties and bilateral agreements, HHS/CDC believes that it is best to ensure compliance through operational procedures, rather than to formalize such obligations through regulatory text.

One commenter requested that HHS/CDC clarify its handling of issues relating to diplomatic immunity. HHS/CDC recognizes that under the Vienna Convention on Diplomatic Relations, diplomats are not liable to any form of “detention.” It is HHS/CDC’s policy to coordinate closely with the U.S. Department of State regarding any public health issues arising in regards to diplomats and HHS/CDC will continue to do so under these regulations.

One public health organization recommended that HHS/CDC include written notification to individuals under public health orders of the duration that the order will be in effect. HHS/CDC responds that it will provide information on the incubation and communicability period of the quarantinable communicable disease, if known, but that the duration of the public health order may depend on a variety of factors, such as demonstration of non-infectiousness through repeated laboratory testing. Thus, HHS/CDC is unable to provide an exact numerical limit (in terms of days or hours) that a public health order will remain in effect.

HHS/CDC received a comment from a partnership of public health legal scholars and organizations stating that in exigent circumstances HHS/CDC may isolate or quarantine an individual, but should then be required to hold a mandatory due process hearing within 48 hours before a neutral decision-maker. At the outset, HHS/CDC agrees with the commenters that the appropriate framework for determining the adequacy of due process procedures are the factors articulated by the Supreme Court in *Mathews v. Eldridge*, 424 U.S. 319 (1976). These factors include: (1) The private interest affected by the government’s actions; (2) the risk of erroneous deprivation of such private interest through the procedures used and the probable value, if any, of additional or substitute procedures; and (3) the government’s interest, including the function involved and the fiscal and administrative burden of proposed additional or substitute procedures. Concerning the private interest at stake, HHS/CDC disagrees that this interest should be measured solely in terms of the physical liberty of the individual, but notes that the private interest also includes an interest in receiving medical treatment and in not harming others, as would occur if the individual was communicable. The Federal government’s interest, moreover, is particularly strong because it is not simply guarding the welfare of a single individual or even a small group of individuals, but rather protecting the public at large against the spread of a quarantinable communicable disease. Most importantly, HHS/CDC believes that mandatory administrative hearings are unlikely to significantly guard against erroneous deprivations. Unlike subjective determinations of behavior which typically form the basis of a mental health “civil commitment,” isolation and quarantine decisions are based on objective criteria such as

manifestations of physical illness or laboratory test results. Thus, weighing these factors, HHS/CDC disagrees that due process requires it to adopt a system of mandatory administrative hearings in the absence of the individual requesting a medical review.

Regarding the use of a “neutral” decision maker, HHS/CDC restates that the definition of both “representatives” and “medical reviewer” would in fact allow for the appointment of non-HHS/CDC employees in these capacities. The regulations, moreover, explicitly state that the medical reviewer will not be the same individual who initially authorized the quarantine or isolation order. Accordingly, HHS/CDC has determined that the procedures it has adopted for medical reviews comport with due process.

#### 1. Privacy

Several people commented on the private nature of the doctor-patient relationship. HHS/CDC appreciates the opportunity to respond to this concern. HHS/CDC is charged with protecting the health of the public. At times, this requires obtaining private information about people’s health or exposure history and taking certain actions to protect others from becoming sick with a communicable disease. HHS/CDC works closely with State and local health departments to ensure that ill people detained or isolated under Federal orders receive appropriate care and treatment. HHS/CDC is also bound by the Privacy Act to protect personally identifiable information collected and maintained under that Act. For a more detailed explanation of how such information is protected, please see <http://www.cdc.gov/sornnotice/09-20-0171.htm>. For information on the retention and maintenance of such records, please see <https://www.archives.gov/records-mgmt/rcs>.

HHS/CDC received a comment from a professor of public health law and ethics stating that HHS/CDC should address how the HIPAA Privacy Rule, Americans with Disabilities Act (ADA), and Administrative Procedure Act (APA) counterbalance the powers set forth in the proposal and reflect “appropriate social distancing practices.” The commenter did not highlight which specific provisions of these laws HHS/CDC should address or the relationship that these laws have to social distancing. Notwithstanding, HHS/CDC may generally state that these regulations will be carried out consistent with Federal law.

We note that HHS is a hybrid entity under HIPAA, but only those parts of the Department that have been

determined to be health care components are subject to the HIPAA Privacy Rule. CDC is generally not a health care component treated as a “covered entity” under the HIPAA Privacy Rule. However, certain specific offices of HHS, CDC, and the National Institute for Occupational Safety and Health (NIOSH) performing activities related to the World Trade Center Health Program are considered health care components of HHS and must comply with HIPAA and the Privacy Rule.

CDC most often acts as a public health authority under the HIPAA Privacy Rule. During the course of a public health investigation it may seek the support of a covered entity, such as a hospital or private physician. The HIPAA Privacy Rule permits the disclosure of public health information to public health authorities, such as the CDC, and their authorized agents for public health purposes including but not limited to public health surveillance, investigations, and interventions. More information concerning the HIPAA Privacy Rule may be found here: <http://www.cdc.gov/mmwr/preview/mmwrhtml/m2e411a1.htm>.

Similarly, we note that this final rule while formalizing administrative policies and practices, does not affect the rights of individuals under the ADA or APA, which are statutes enacted by Congress. One commenter opined that collection of contact information as part of public health prevention measures and maintenance of administrative records raise privacy concerns and that HHS/CDC should consider “super-enhanced privacy protections” consistent with the Model State Public Health Privacy Act of 1999. HHS/CDC disagrees. As a Federal agency, HHS/CDC must abide by the laws established by Congress for the protection of records, specifically the Privacy Act of 1974, 5 U.S.C. 552. On December 13, 2007, HHS/CDC published a system of records notice (72 FR 70867) under the Privacy Act describing, among other things, safeguards for preventing the unauthorized use of information collected from travelers. HHS/CDC will make disclosures from this system only with the consent of the subject individual, in accordance with routine uses published in its system notice, or in accordance with an applicable exception under the Privacy Act.

#### m. Payment for Care and Treatment

HHS/CDC received several comments relating to payment for medical expenses. One commenter stated that HHS/CDC should assume payment for

all related medical expenses, housing costs, and other necessities for individuals or groups subject to deprivations of liberty and that it is “ethically unfair” for HHS/CDC to be the “payer of last resort.” Another commenter stated that “CDC must guarantee financial help after third party payments are exhausted.” While HHS/CDC acknowledges that it has an ethical, moral, and legal obligation to provide care and treatment for individuals under a Federal quarantine or isolation order, HHS/CDC disagrees that it is “ethically unfair” to excuse a medical insurer or other entity with a contractual obligation from paying for medical expenses. Accordingly, HHS/CDC has determined that it is appropriate for it to maintain and affirm its status as a “payer of last resort.”

Two public health organizations asked whether nonmedical costs such as training of staff, replenishing of personal protective equipment, managing and disposing of biological waste and contaminated supplies, etc., are also subject to HHS/CDC payment authorization. While the costs of care and treatment of individual patients under Federal public health orders are authorized by this rule, these additional costs to the extent that they are unrelated to the individual patient’s treatment and care would not be covered by this rule.

HHS/CDC received a comment suggesting that the regulations allow for charging detainees the medical and hospital costs of nonconsensual treatment. HHS/CDC disagrees and first, clarifies that these regulations do not authorize compulsory medical treatment. HHS/CDC further acknowledges that constitutional principles and medical ethics require that those detained under isolation or quarantine have access to adequate nourishment, appropriate accommodation, and medical treatment. However, HHS/CDC has determined that its obligation to pay for medical care and treatment should be secondary to the obligation of any third party, such as a medical insurer that may have a pre-existing contractual obligation with the patient to pay for hospital expenses. Accordingly, HHS/CDC declines to make any changes to the provisions authorizing payment for medical care and treatment.

A flight attendant union commented that HHS/CDC should pay for any outside costs that the flight attendant would normally incur relating to medical treatment, e.g., copayments, deductibles. HHS/CDC declines this suggestion and notes that while it is not HHS/CDC’s intent to unduly burden

individuals with the costs of their own isolation or quarantine, payment for expenses will be made consistent with constitutional and ethical obligations to provide for the basic necessities, e.g., food, medical treatment, for those subject to such public health orders. Furthermore, these regulations do not alter, define, or modify the contractual relationship between insurance companies and the insured.

After consideration of these comments, HHS/CDC has finalized the provisions relating to payment for care and treatment (§§ 70.13 and 71.30) as proposed.

#### n. Agreements

HHS/CDC received comments relating to the intention and use of agreements. Commenters worried that such “agreements” may be coerced, and individuals would be compelled to submit to involuntary testing or “research projects.” One commenter stated that the definition of agreement is circular and confusing because the word “agreement” appears in the definition. This commenter also suggested that what HHS/CDC proposes should more aptly be labeled as an “Affidavit” or “Affirmation” because the definition as proposed by HHS/CDC lacks bilateral obligations on both parties.

Due to the number of public comments received expressing confusion over this public health measure, HHS/CDC has removed the provisions on *Agreements* (70.18 and 71.40), and modified other provisions of the final rule (70.1, 71.1(b), and 70.5) to remove references to “agreements.”

#### o. Penalties

Many commenters expressed concern over the penalties provisions contained within the proposed regulation. Specifically, one association objected to “CDC’s proposed increase in penalties.” Another stated that “CDC is not qualified to decide upon the punishment.” HHS/CDC takes this time to better explain that the penalties listed in today’s final rule, which have been codified as proposed, are set forth by Congress via statutory language and codified into regulation to reflect current practice. This regulation serves to notify the public of the existing statutory penalties for violation of quarantine regulations, which HHS/CDC has no authority to change.

One organization requested that language be added to rules regarding the issuance of penalties if an employer provides an “unsafe work or unhealthful working condition.” HHS/CDC responds that such penalties are beyond the scope of this rule and refers



the commenter to regulations of the Occupational Safety and Health Administration.

HHS/CDC received a comment from a flight attendant union regarding criminal penalties stating that HHS/CDC should provide further clarification as to what constitutes a violation and clarify that flight attendants who act in accordance with their company's practices, policies, or procedures should not be held criminally liable. In response, HHS/CDC notes that while the text of the regulation is being updated, these regulations do not increase the criminal penalties that may be imposed for violations of quarantine regulations or alter the manner in which liability may be assessed. Rather, these regulations serve to inform the public of the criminal penalties that currently exist in statute (42 U.S.C. 271 and 18 U.S.C. 3571). Furthermore, HHS/CDC clarifies that criminal penalties, if any, would be assessed by a court of law based on an indictment or information filed by an Assistant U.S. Attorney based on individualized facts and circumstances, and would not be determined administratively by the CDC.

HHS/CDC offers the following explanation to inform the public regarding this section. As prescribed in section 368 (42 U.S.C. 271) and under 18 U.S.C. 3559 and 3571(c), criminal sanctions exist for violating regulations enacted under sections 361 and 362 (42 U.S.C. 264 and 265). 18 U.S.C. 3559 defines an offense (not otherwise classified by letter grade) as a "Class A misdemeanor" if the maximum term of imprisonment is "one year or less but more than six months." 18 U.S.C. 3571 provides that individuals found guilty of an offense may be sentenced to a fine. Specifically, an individual may be fined "not more than the greatest of"—(1) the amount specified in the law setting forth the offense; or (2) for a misdemeanor resulting in death, not more than \$250,000; or (3) for a Class A misdemeanor that does not result in death, not more than \$100,000. Similarly, an organization, found guilty of an offense may be fined "not more than the greatest of"—(1) the amount specified in the law setting forth the offense; or (2) for a misdemeanor resulting in a death, not more than \$500,000; or (3) for a Class A misdemeanor that does not result in death, not more than \$200,000. 42 U.S.C. 271 sets forth statutory penalties of up to 1 year in jail and a fine of \$1,000. Therefore, it is classified as a Class A misdemeanor under 18 U.S.C. 3559. Because the alternate fines set forth under 18 U.S.C. 3571 are greater

than the \$1,000 set forth under 42 U.S.C. 271 (which sets a maximum penalty of not more than \$1,000 or one year of jail, or both for violation of quarantine laws), and because 42 U.S.C. 271 does not exempt its lower penalties from 18 U.S.C. 3571(e), HHS/CDC has chosen to codify the greater penalties of 18 U.S.C. 3571(b)(5) and (c)(5) and to remove the lower penalties as stated in 42 CFR 71.2 from the regulation.

After consideration of these comments, HHS/CDC has finalized the provisions relating to *Penalties* (70.18 and 71.2) as proposed. *Penalties* has been moved to section 70.18, since proposed 70.18 *Agreements* has been removed from this final rule.

#### p. Economic Impact

Within the analysis published with the NPRM, HHS/CDC solicited public comment regarding the cost and benefit estimates for airlines and vessel operators associated with improved provision of traveler contact data. While HHS/CDC received support for the data collection from two public health associations, HHS/CDC received a comment from industry who misread the proposals to mean that aircraft operators would be required to develop new capacity and processes to capture and store a comprehensive set of sensitive data, archive this data, and then provide it to CDC.

HHS/CDC restates and clarifies that today's final rule does not impose any new burdens upon the airline industry but rather, codifies the current practice of receiving a passenger manifest order (if needed, as CDC currently collects passenger information from CBP via APIS and PNR) and providing HHS/CDC with any data in an airline's possession. This regulatory impact analysis has been revised to clarify that the rule does not require an airline to solicit or store additional data. Therefore, HHS/CDC does not expect that formalizing its current data collection practices will increase costs. Neither airlines nor U.S. Customs and Border Protection (CBP) will need to develop new data systems nor will travelers need to provide data as part of the "check in process."

The same industry organization also commented that they have been complying effectively with the existing requirements, but have, on occasion found it difficult to locate, extract, compile, format and transmit available information within the timeframe specified in orders from HHS/CDC. They note that delays sometimes arise because the manifest order may contain incorrect flight or passenger information. The discussion in the regulatory impact analysis section has

been revised to note that delays in compliance with manifest order requirements may result from HHS/CDC having incorrect traveler information in the manifest order.

The same industry organization also reports that all of the data available to them related to passengers are currently transmitted as Advance Passenger Information System (APIS), and potentially under Passenger Name Record (PNR), data to the Department of Homeland Security (DHS) and that there is no reason to burden airlines with an order for passenger data. HHS/CDC recognizes that industry does submit certain passenger data to DHS and it is not our intent to burden industry with duplicative requirements, but rather to effectively and efficiently protect public health. In the experience of the HHS/CDC, queries from APIS/PNR rarely result in full sets of contact information (*i.e.* the record includes all five additional data fields as outlined in the final rule). The data fields that are most commonly missing from the records are email addresses (missing 90 percent of the time), secondary phone number (missing 90 percent of the time), and street addresses (missing or insufficient for public health contact tracing up to 50 percent of the time). These data elements are vital to a contact tracing investigation. In looking at a random sample of 20% of the compiled international air travel manifests for 2015, those including a compiled data set from NTC and the airlines, 100% were missing at least one of the 5 data fields. Email address and secondary phone number were among those most frequently missing. For context, there were approximately 760,000 scheduled flights that arrived into the United States in 2015. In 2015, CDC issued passenger manifest requests for 64 international flights arriving into the United States. As noted in the RIA of the final rule, from 2010 to 2015, CDC conducted an average of 77 contact investigations per year involving arriving international flights.

Airlines are contacted for the majority of contact investigations using a manifest order document. At a minimum, CDC needs to confirm the ill traveler was on the flight and where the individual sat in relation to other travelers to determine risk of exposure.

In CDC's experience the following has been true:

- Only airlines can quickly and efficiently produce a partial manifest targeting affected rows;
- only airlines can confirm identity of "babes in arms" and their co-travelers (Parent); this is important for measles cases;

- only airlines can quickly confirm whether an individual actually flew (in instances where individuals deplane and do not re-board during a layover); and

- only airlines can confirm a plane's configuration if there is a question with the provided row numbers. Different aircraft have different seating arrangements depending on carrier and layout. It is important to know if a certain seat is separated by a bulkhead or is a window seat.

In addition, HHS/CDC only requires a partial manifest, e.g. 5 rows for travelers with infectious tuberculosis, so that NTC and HHS/CDC staff can limit the investigation to only those passengers at risk and supplement/cross reference with APIS and PNR data. If a partial manifest is not available from the airlines, then each passenger record must be researched individually to find a seat number, and then the configuration of an entire plane must be populated to determine where the index case sat in relation to other at-risk passengers. For large flights from Asia, this can pose a tremendous burden to NTC and CDC staff while slowing the ability of CDC to provide important contact information to state and local health departments. Manually populating multiple 300+ person flights is not feasible in a timely manner.

As part of its plan for retrospective analysis under E.O. 13563, HHS/CDC intends to synthesize, analyze, and report within the next two years on strategies to reduce duplication of the collection of passenger/crew manifest information in coordination with DHS/CBP. The report will include any recommendations (e.g., IT systems improvements to facilitate enhanced search capabilities of passenger data, increased efficiency to relay passenger data, improvements to the existing CDC-CBP MOU) to ensure that the collection of passenger or crew manifest information do not unduly burden airlines, vessels, and other affected entities. HHS/CDC intends to seek public comment on the report and any recommendations regarding the costs and benefits of activities implemented in 42 CFR parts 71.4 and 71.5. Estimates of both costs and benefits in the NPRM regulatory impact analysis were not very large because HHS/CDC is not implementing a new data collection requirement. The regulatory impact analysis for the final rule has been revised to reflect that HHS/CDC will work with CBP to search for responsive data to avoid duplicative data requirements. Estimates of costs in the revised regulatory impact analysis have not been revised because the airline

industry did not provide any new information regarding costs to search for responsive data when receiving manifest orders. The benefit estimate has been revised and is lower than the estimate for the NPRM to indicate that the airlines may not have any more contact data than is already provided in APIS or PNR data submitted to DHS.

HHS/CDC received a number of comments from the general public that compared the relatively small number of measles cases in any given year to the total numbers of vaccine-associated adverse events and health department spending to contain measles outbreaks. Based on this comparison, commenters believed that HHS/CDC and health departments spend too much money on communicable disease control and that resources would be better allocated to other activities. Some commenters suggested that the costs of these adverse events should be included in a Small Business Regulatory Enforcement Fairness Act analysis. In general, this type of analysis is outside the scope of this regulatory impact analysis because this final rule does not require measles vaccination. HHS/CDC's recommended vaccine schedule will not be affected by this final rule. Although HHS/CDC recommends that health departments offer measles vaccine to non-immune individuals exposed during travel, measles is not a quarantinable communicable disease and this final rule does not require any individual to receive a measles vaccine. Because health departments offer measles vaccines to exposed, non-immune travelers, HHS/CDC estimates that the final rule will only result in a small number (6) of additional measles vaccines. The costs of procuring and administering these vaccines is included in the analysis.

As noted in the regulatory impact analysis, there are only 564 travelers exposed to measles during international travel in a given year. Most of these travelers will already have immunity to measles and the final rule is only expected to have a small impact on the ability of health departments to contact travelers. The total costs of all measles vaccine-associated adverse events is outside the scope of the analysis for this final rule as mentioned above.

One commenter suggested that the cost estimates for the NPRM were too low because the analysis did not account for reduced willingness to travel if vaccines against measles and other communicable diseases are required to travel. HHS/CDC disagrees with this suggestion because vaccination is not a requirement in this final rule. HHS/CDC has on occasion

requested that DHS/TSA restrict interstate or international air travel for people known to be infectious with measles who were noncompliant with public health recommendations not to travel. However, HHS/CDC does not recommend restricting the air travel of persons who have not received the measles vaccine.

One commenter questioned whether the estimated value of statistical life (\$9.4 million) should be multiplied by the total number of measles vaccine-associated adverse events in the United States. HHS/CDC appreciates this thoughtful comment. This would result in a larger estimate in the cost of measles vaccine-associated adverse events. However, this is not a correct usage of the value of statistical life, which should only be multiplied by an estimated number of deaths. The regulatory impact analysis has been revised to better explain this distinction.

Another commenter suggested that public health department measles response costs were overestimated by using a model-based approach rather than estimating the cost of hiring of additional staff to deal with measles outbreaks. HHS/CDC addressed the comment in the regulatory impact analysis by clarifying that the analysis is a published model-based analysis and that the cost estimate is based on the opportunity cost of public health personnel and is not based on the cost of hiring additional staff.

HHS/CDC received comments from the airline industry indicating that the definition of ill person under 71.1 does align with Note 1 to Standard 8.15 of ICAO's Annex 9 to the Convention on International Civil Aviation. HHS/CDC also received comments from the airline industry regarding the change to the definition of ill person under 70.1 for interstate flights contending that these changes would increase costs. Specifically, the airline industry reported that not only does the expansion of the definition of *ill person* place a greater burden on airline staff, the ambiguity of that definition amplifies the burden or at least raises questions as to the particular obligations of the flight crew to determine if someone is an "ill person." Moreover, the airline industry wanted to know whether flight crews have an obligation to conduct a physical examination of the passenger to determine fever. The airline industry also noted that under the OSHA blood borne pathogens standard, employers are prohibited from exposing crewmembers to blood or other potentially infectious materials. The airline industry also questioned whether the fever-related illness

reporting in the proposal would require that all carriers have the equipment (thermometers) onboard to determine fever. The proposal, as noted, has two other ways to identify fever (warm to touch or history of fever) which the airline industry wanted to ensure would remain viable options within the final rule.

HHS/CDC notes that there is no expectation that flight crews should perform physical examinations as part of illness reporting. HHS/CDC also notes that the non-thermometer (warm to touch or history of fever) remain in the final rule. Regarding the potential for increased costs associated with the change in illness reporting for interstate flights, HHS/CDC notes that the current illness reporting requirements for interstate travel appear in 42 CFR 70.4 and state that “The master of any vessel or person in charge of any conveyance engaged in interstate traffic, on which a case or suspected case of a communicable disease develops shall, as soon as practicable, notify the local health authority at the next port of call, station, or stop, and shall take such measures to prevent the spread of the disease as the local health authority directs.” Communicable disease is defined in current 42 CFR 70.1 as “illnesses due to infectious agents or their toxic products, which may be transmitted from a reservoir to a susceptible host either directly as from an infected person or animal or indirectly through an intermediate plant or animal host, vector, or the inanimate environment.”

The changes in this final rule will not result in substantially increased costs because airlines would either: (1) Be complying with the current regulatory requirement and report all cases or suspected cases of communicable disease to local health departments; or (2) report illnesses according to HHS/CDC guidance available at <http://www.cdc.gov/quarantine/air/reporting-deaths-illness/guidance-reporting-onboard-deaths-illnesses.html>, which is codified in this final rule. HHS/CDC notes that changes in this final rule align the symptoms requested for international and interstate illness reporting. In addition, according to guidance, reports received by HHS/CDC would be considered sufficient to satisfy the requirement to report to local health departments because HHS/CDC will coordinate response activities with the local health department after receiving an illness report. In response to these comments, HHS/CDC increased the expected number of illness reports in the upper bound analysis regulatory impact analysis for the final rule. This

upper bound analysis finds that a 100% increase in info-only reports and 50% increase in reports requiring response would result in a marginal cost of \$20,573 for airlines and vessel operators. This cost is negligible compared to the annual revenue of the international air and maritime travel markets. HHS/CDC also received a comment to include the cost of training for illness reporting in the regulatory impact analysis. HHS/CDC notes that illness reporting is already required under existing regulations and the changes in this final rule more closely align with ICAO guidance for illness reporting for international flights and represent a reduction in burden for interstate flights, where reporting of all cases or suspected cases of communicable diseases is required. HHS/CDC added an estimate of training costs to the upper bound cost analysis for airlines (an annualized \$356,000 per year).

HHS/CDC received a comment from a local health department concerning the rationale for reporting all illnesses and deaths that occur on interstate flights. This health department asked whether evaluating illnesses and deaths that occur on interstate flights may lead to an increase in costs for State and local health departments. HHS/CDC does not anticipate an increase in costs for State and local health departments because evaluating illnesses and deaths occurring on interstate flights is consistent with existing HHS/CDC guidance and represents a less restrictive alternative compared to the existing reporting requirement in 42 CFR 70.4. Furthermore, the costs to State and local health departments may decrease if HHS/CDC is able to filter out reports that do not require a public health response, which airlines would have previously reported directly to the health departments under 42 CFR 70.4. If there is an increase in the number of illness reports requiring a public health response, HHS/CDC believes the costs to health departments may decrease if the health department is notified earlier.

A public health research center questioned the value of nonmedical personnel being able to differentiate Ebola, Middle East respiratory syndrome (MERS) or measles from other medical issues. HHS/CDC appreciates the concern and notes that the final rule aligns the illness reporting requirement with international guidelines and represents a reduced burden for illness reporting on interstate flights compared to current regulatory language as mentioned above. The intent of illness reporting is not to diagnose disease during flight, but rather to identify a

limited number of instances in which it would be advantageous to follow up with ill travelers for an assessment upon disembarkation. The current numbers of illness reports received are summarized in the regulatory impact analysis and the number of reports is not expected to increase significantly because the regulatory text will better align with publically available HHS/CDC guidance.

A number of comments from the public questioned whether there would be a huge cost resulting from the broad definition of *ill person*. These commenters expressed concern that misdiagnosis by non-medically trained personnel would lead to reduced travel based on the public's fear of being wrongly detained by public health officials. HHS/CDC notes that illness reporting is already required for both interstate and international travel. We note that travelers are not placed under public health orders simply as a result of an illness report. Rather, orders are issued only if a licensed medical officer based on a public health risk assessment has sufficient reason to believe that the individual is infected with a quarantinable communicable disease. In addition, the new definition is consistent with existing international guidelines and HHS/CDC guidance. Thus, HHS/CDC does not believe the changes to illness reporting will result in a large burden to the general public. The cost analysis in the regulatory impact analysis has been updated to include the cost to travelers involved in public health follow-up after an illness report.

One commenter opposed the rule because of a perceived negative economic and/or social impact upon individuals placed under a public health order. Regarding the social impact of the individual who may be ostracized, HHS/CDC notes that public health measures such as quarantine and isolation are not new concepts or practices. HHS/CDC has been implementing these measures to protect public health for many years. We reemphasize that one compelling reason for the publication of this final rule is to make “quarantine” and “isolation” better understood by the public so that these terms, its purposes, and meanings become more familiar and thereby decrease public anxiety over these important protections. For the same reason, HHS/CDC does not believe the provisions in the final rule will increase or decrease the cost of isolation or quarantine. HHS/CDC does provide an estimate of traveler cost in the sections describing Ebola entry enhanced risk assessment and management and illness

reports in the regulatory impact analysis.

One commenter suggested that the costs incurred by airlines would be passed along to the general U.S. population purchasing tickets for air travel. HHS/CDC concurs and mentions this possibility in the regulatory impact analysis. However, changes included in this final rule are a codification of a current practice and estimated total costs are only \$11,000 to \$431,000 per year. Thus, significant changes in ticket prices are not expected.

One commenter suggested that changes in infectious disease caseloads would not result in cost savings to public health agencies or individuals because there is already a public health workforce in place. HHS/CDC calculates such costs based on the opportunity cost of public health staff under the presumption that such staff would be involved in other productive activities if not spending time addressing outbreaks.

HHS/CDC solicited comment from the public regarding potential public willingness to pay to be contacted in the event of an exposure to a communicable disease during travel. This was done to help estimate the potential benefit to the public of HHS/CDC's efforts to work with health departments to contact travelers exposed to meningococcal disease, viral hemorrhagic fevers, MERS or other severe acute respiratory syndromes, measles, and tuberculosis, among other diseases. HHS/CDC received a number of comments from several individuals that they believe public health measures to mitigate measles transmission are unnecessary. Some individuals also noted that Ebola and MERS cases in the United States have not led to widespread transmission. These commenters either indicated or inferred that they would be unwilling to pay to be informed of potential communicable disease exposures during travel. The discussion in the regulatory impact analysis has been updated to incorporate this feedback.

HHS/CDC solicited public comment on willingness to pay to reduce Ebola risk in the United States to near zero if another international outbreak of Ebola with widespread transmission occurs in the future. HHS/CDC received comments from an organization representing flight attendants indicating that they believe it is in the public interest to reduce Ebola risk in the United States to near zero in the event of a future outbreak. They indicated that there is no reason to believe that achieving this objective would require unsustainable levels of funding. HHS/CDC incorporated this comment

regarding public willingness to pay in the regulatory impact analysis.

HHS/CDC also received comments from several individuals regarding the high cost of the measures taken to reduce the risk of Ebola transmission in the United States during the 2014–2016 Ebola epidemic in West Africa. Several of these commenters indicated they had zero willingness to pay for future public health measures in the event of a large Ebola outbreak.

Many commenters stressed the need to reassess whether to implement such activities in the event of a future Ebola outbreak. An example of such comments is provided by a research center studying international response efforts to emerging infectious disease threats, who noted that despite 99% complete active monitoring by health departments, there was no evidence of incident Ebola cases among individuals traveling from Ebola-affected countries. This does not include the two incident cases that preceded active monitoring. The commenters state that given this evidence it is not advisable for HHS/CDC to recommend active monitoring in the event of future Ebola outbreaks.

In addition, a public health research center cautioned against extrapolating costs and benefits calculation methods for measles and tuberculosis to Ebola, MERS, and other rare diseases. The research center further noted that countermeasures for Ebola and MERS do not exist (other than isolation and quarantine). They suggest that this would limit the effectiveness of point of entry measures. These researchers also point to the fact that transmission of Ebola and MERS has not occurred during air travel. They noted that point of entry risk assessment programs may increase anxiety (and costs) if cases are detected in the community after the implementation of point of entry measures. Finally, the research center noted that the costs for State and local health departments to actively monitor all arriving travelers for 21 days were not included in the analysis.

In response to these comments, HHS/CDC concurs that it would not be wise to directly extrapolate approaches for measles and tuberculosis to rare diseases and has tried to provide as much information as possible around the decision to implement the Ebola risk assessment program and recommendations for active monitoring. HHS/CDC did not simply extrapolate the analysis for measles and tuberculosis to Ebola.

HHS/CDC does not have data on State and local spending to achieve the objective of the 21-day active monitoring program and concedes that

the cost of active monitoring would likely exceed the costs incurred at the airports. However, HHS/CDC did provide an estimate of total Federal spending for both domestic and international efforts to attempt to quantify the cost of these efforts. Federal money was used to support State/local surveillance efforts. Federal money was also used to support improvements in laboratory capacity by States and hospital infection control efforts, which should have benefits beyond the 2014–2016 Ebola epidemic. In addition, Federal funding supported research into potential Ebola vaccines and medicines. The cost for the Ebola enhanced entry risk assessment program was just a portion of these costs and HHS/CDC acknowledges that risk assessment program at airports by itself would have limited potential to reduce risk. However, HHS/CDC also notes that the costs of Ebola entry risk assessment at points of entry included efforts to (1) stratify travelers by risk level so that health departments could focus more intense monitoring efforts on travelers at higher risk and (2) educate travelers on Ebola risk factors and symptoms and provide informational materials, a thermometer, and a telephone to all travelers to improve compliance with active monitoring efforts. This led to a higher cost, but more effective program relative to an alternative in which travelers would only be screened once at the airport, such as occurred in other countries implementing screening programs during the 2003 Severe Acute Respiratory Syndrome (SARS) epidemic.

HHS/CDC believes that the risk of Ebola infection in the U.S. population was potentially reduced because of the combination of measures to protect against Ebola transmission in the United States, including risk assessment at ports of entry. HHS/CDC acknowledges the risk was probably very low in the absence of domestic activities.

HHS/CDC further notes that it recommended active monitoring of travelers as a less restrictive alternative to more stringent measures such as quarantines that were being demanded by some members of the public. Widespread implementation of quarantine, particularly for healthcare workers crucial to the response efforts in West Africa and the United States, would have greatly hampered outbreak control measures by providing a strong disincentive to healthcare workers participating in the response.

To estimate the potential benefits of the Ebola risk assessment program at ports of entry, HHS/CDC provided a cost comparison of the incident Ebola cases

that occurred in Texas compared to New York to estimate the difference in costs between an Ebola case that was detected quickly and treated in a pre-selected hospital identified to be capable of Ebola treatment in comparison to an Ebola infection that was not initially suspected to be Ebola leading to community exposures and hospital exposures in a hospital that was not a pre-selected hospital capable of Ebola treatment.

HHS/CDC also examined the recent MERS outbreak in South Korea to demonstrate that even relatively small outbreaks of rare diseases such as MERS and Ebola can have large economic costs despite a relatively small number of cases and deaths. HHS/CDC found that the number of international travelers (non-Korean citizens traveling to South Korea) decreased by 40–50% during the peak months of the 2015 MERS outbreak. HHS/CDC further notes that these declines in travel occurred in the absence of widespread travel restrictions. The costs incurred by South Korea during the outbreak were used to demonstrate the potential costs of a larger Ebola outbreak in the United States.

Given the evidence from the programs implemented to mitigate risk during the 2014–16 Ebola epidemic, *i.e.*, the small number of international air travelers from countries with widespread Ebola transmission that later developed Ebola and the very limited risk of transmission by asymptomatic individuals with Ebola infection, HHS/CDC may not elect to implement an Ebola entry risk assessment program in the event of a future outbreak or to recommend 21-day active monitoring of travelers from countries with widespread transmission.

HHS/CDC emphasizes that it will continue to consider cost and work with multiple U.S. government agencies, as well as with airport authorities and health departments in U.S. States and territories, to apply the latest evidence to future decision-making. In addition, HHS/CDC will try to employ the least restrictive measures to achieve public health objectives. HHS/CDC notes that, during the period that the Ebola entry risk assessment and monitoring program was in effect, only 0.08% (29/38,344) of travelers assessed at U.S. airports were recommended for medical evaluation at hospitals and that no Federal quarantine or isolation orders were issued during the epidemic, although some States did issue such orders under their own authorities. These considerations have been added to the regulatory impact analysis in the final rule. Since this analysis concerns a codification of

existing authorities, this analysis has been moved to a separate appendix after incorporating public feedback.

A number of commenters suggested that HHS/CDC did not include the cost for people participating in the Ebola enhanced risk assessment program. However, HHS/CDC did provide such an analysis of these costs. One public commenter suggested that the psychological cost of quarantine should be considered in the economic impact analysis. Although HHS/CDC generally concurs with the idea of accounting for all of the costs associated with time spent in quarantine, HHS/CDC's authority to issue quarantine orders will not change with the publication of this final rule. Thus, this final rule does not incur new psychological costs for persons under quarantine orders.

HHS/CDC notes the opportunity costs for persons undergoing risk assessment at airports and/or evaluation at hospitals during the 2014–16 Ebola entry risk assessment and management program. HHS/CDC estimates their opportunity costs based on average wage rates, but did not have additional data to estimate a marginal psychological cost. Opportunity costs were also estimated for a more restrictive option compared to the Ebola entry risk assessment and management program, *i.e.* a suspension of entry for 21 days after having been in an Ebola-affected country.

One commenter suggested that this rulemaking does not represent the “least burden on society” because HHS/CDC has failed to clearly identify a “compelling public need” for the rule. HHS/CDC appreciates the comment and responds that the regulatory impact analysis cites a specific market failure addressed by this final rule. The market failure is that the costs associated with the spread of communicable diseases impacts the entire U.S. population, not just the group of persons currently infected with communicable diseases. Since this final rule is primarily implementing current practice, HHS/CDC does not anticipate major new benefits or costs.

One commenter stated that the cost/benefit analyses was very vague, meaning that there is no accountability or way to measure whether or not the final rule will achieve its intended result of preventing the spread of quarantinable communicable diseases via travel, which the commenter stated was already an extremely low risk. HHS/CDC concurs that there is uncertainty in the regulatory impact analysis. However, HHS/CDC has tried to indicate that one of the reasons for this uncertainty is that this final rule is primarily implementing current

practice. Thus, where possible, HHS/CDC tried to provide data on the current burden of the provisions that are being updated in this final rule. HHS/CDC does not expect any major changes in practice as a result of this final rule.

One commenter suggests that the cost/benefit analyses was confusing because quarantinable and non-quarantinable diseases were not clearly identified. HHS/CDC appreciates this feedback and has updated the analyses to more clearly differentiate quarantinable and non-quarantinable diseases.

One commenter suggested that HHS/CDC took an unnecessarily extreme position in analyzing an alternative of removing all enforcement of current regulations. HHS/CDC used this as an alternative because this final rule is a codification of current practice and does not impose new regulatory burdens.

#### q. Paperwork Reduction Act

HHS/CDC published notices related to modifications and a new information collection in the Notice of Proposed Rulemaking. Those information collections are as follows:

(1) Foreign Quarantine Regulations (42 CFR part 71) (OMB Control No. 0920–0134)—Nonmaterial/non-substantive change—National Center for Emerging, and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

(2) Restrictions on Interstate Travel of Persons (42 CFR part 70) (OMB Control No. 0920–0488)—Nonmaterial/non-substantive change—National Center for Emerging, and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

(3) Airline and Vessel and Traveler Information Collection (42 CFR part 71)—New Information Collection Request—National Center for Emerging, and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

One commenter stated that there are no estimates of additional information collection requirements resulting in a clear violation of the Paperwork Reduction Act. The commenter further stated that requesting information when HHS/CDC has no idea of the impact is not a well thought out or planned rulemaking. This commenter further questioned the value of providing comment when the agency purportedly has no idea what additional burden it is imposing on the public. HHS/CDC disagrees with these assessments.

The focus of the final rule is to codify current practices and to update currently approved information collections to better align with operational procedures and other

industry guidance related to illness reporting on aircraft and vessels. Those information collections are currently approved under OMB control numbers 0920–0134 (Foreign Quarantine Regulations), 0920–0488 (Restrictions on Interstate Travel of Persons), and the new information collection request Airline and Vessel and Traveler Information Collection (42 CFR part 71), which is currently pending OMB approval. The estimates of the burden provided in the Paperwork Reduction Act section of the NPRM were based on previous experience with particular information collections solicited or required from the public or industry in the past. In some cases, larger estimates of the burden to account for an increased number of reports to HHS/CDC during disease outbreaks or public health emergencies were included. There are no information collections requirements that are wholly new, unreasonably burdensome, or outside the scope of historical HHS/CDC practices implemented to prevent the introduction or spread of communicable disease into or within the United States.

Another commenter suggested that training in recognizing ill travelers is a burden that was not adequately considered. HHS/CDC disagrees because it does not mandate specific training for recognition of ill travelers. HHS/CDC is seeking to better align the ill person definition with the ICAO standard and thus is not the only organization that has this requirement. HHS/CDC provides specific guidance for how to recognize ill travelers and report to HHS/CDC on its Web site. HHS/CDC also believes this training is most likely already part of the training process for flight crews. An analysis of potential training costs has been added to the upper bound cost analysis in the Regulatory Impact Analysis. The upper bound annualized costs for additional training are estimated at \$356,000.

Finally, HHS/CDC is re-inserting “Has a fever that has persisted for more than 48 hours” as a component in the definition of *Ill person* in § 70.1 General definitions and “Has acute gastroenteritis, which means either diarrhea, defined as three or more episodes of loose stools in a 24-hour period or what is above normal for the individual, or vomiting accompanied by one or more of the following: One or more episodes of loose stools in a 24-hour period, abdominal cramps, headache, muscle aches, or fever (temperature of 100.4 °F [38 °C] or greater)” in § 71.1 General definitions. This language was quoted verbatim in the preamble of the NPRM at 81 FR

54305 but was inadvertently omitted from the proposed regulatory text.

#### *B. Provisions Applicable Only to Part 70 Only (Domestic)*

##### a. General

HHS/CDC received comments from the public asserting that State and local public health regulations already in place are sufficient to protect individuals without the need for Federal involvement. HHS/CDC agrees that State and local authorities play an integral role in protecting public health, but disagrees that there is no Federal role. HHS/CDC’s DGMQ maintains quarantine stations at major U.S. ports of entry that fulfill a primary purpose in preventing the introduction of communicable diseases into the United States, but also play an important role in containing the interstate spread of communicable disease. There are several broad areas of cooperation between quarantine field staff and State and local health agencies, such as contact tracing, which provide a framework for responding to communicable disease threats arising from interstate travel and at the local level. It is through these networks and established partnerships, in keeping with current practice, that the provisions of the final rule will be successfully implemented.

HHS/CDC received a comment to the effect that quarantine specifically should be left to the States. HHS/CDC received another comment stating that Federal authority should not take precedence over State authority. In contrast, a public health association suggested that these regulations should indicate that Federal public health measures “supersede activities taken by States.” We respond that while HHS/CDC works closely with State and local public health authorities, the Federal government has a traditional role in preventing introductions and spread of communicable diseases at ports of entry and interstate. HHS/CDC also disagrees with the suggestion that it should not intervene in the event of inadequate local control or lacks authority to protect the public’s health within the authority granted to it by Congress. Under 42 U.S.C. 264(e), Federal public health regulations do not preempt State or local public health regulations, except in the event of a conflict with the exercise of Federal authority. Other than to restate this statutory provision, this rulemaking does not alter the relationship between the Federal government and State/local governments as set forth in 42 U.S.C. 264. Under, 42 CFR 70.2, HHS/CDC

make take action to prevent the interstate spread of communicable diseases in the event that the CDC Director determines that inadequate local control exists. This longstanding provision on preemption in the event of a conflict with Federal authority is left unchanged by this rulemaking.

One public health organization requested clarification of the process to transfer an individual from Federal to State custody and further stipulated that the State authority should require an independent State assessment of risk under State law. In response, HHS/CDC notes that the issuance of Federal public health orders is coordinated with State and, when appropriate, local public health authorities. Transfer of an individual from Federal to State custody would be similarly coordinated such that the State would need to agree to assume custody and the State’s order would need to be in place prior to HHS/CDC’s rescinding the Federal order. When custody of an individual is transferred to a State authority, the State may choose, but would not be under a Federal mandate, to conduct an independent assessment of risk pursuant to its own policies and procedures. Furthermore, once the transfer of custody has occurred, the State’s laws and standards for due process would apply.

Another public health authority asked for clarification of how jurisdictional issues regarding transfers of authority affecting more than one State would be handled for individuals under Federal quarantine. HHS/CDC responds that if more than one State is affected by the transfer of authority, HHS/CDC will work with all relevant States to determine the most appropriate State or local jurisdiction to accept custody of the individual. If it is necessary to transport the individual to another State, for example to the individual’s State of residence, HHS/CDC will work with the affected States to facilitate such a transfer under Federal orders.

One public health organization requested clarification of the procedures HHS/CDC would use to rescind a public health order. HHS/CDC responds that it would issue the detained individual a written order rescinding the isolation, quarantine, or conditional release. This would be based on either one of two criteria: The individual is determined to no longer pose a public health threat or custody of the individual has been transferred to a State or local public health authority.

HHS/CDC received a comment from a public health department stating that the regulations should include language that HHS/CDC will coordinate with

State and local public health authorities and law enforcement regarding any intended surveillance and enforcement activities. HHS/CDC strongly believes that coordination with State and local public health authorities, as well as relevant law enforcement entities, is essential to the public health response to individual cases as well as outbreaks of communicable disease. On the few occasions that HHS/CDC has issued Federal isolation orders for travelers with infectious tuberculosis, HHS/CDC has worked closely with State and local health departments to coordinate transportation, medical evaluation, and treatment of the ill traveler, including law enforcement when needed. During the 2014–2016 Ebola epidemic, HHS/CDC issued guidance and alerted health care and EMS workers to consider a diagnosis of Ebola if patients had compatible symptoms and had visited an affected country within the previous three weeks. HHS/CDC and State and local health departments worked closely to assess any potentially exposed individuals with symptoms compatible with Ebola to determine whether medical evaluation was needed and, if so, to ensure safe transportation to a medical facility designated by the health department. In light of HHS/CDC's history of close coordination with State and local public health authorities, including cooperating law enforcement entities when needed, HHS/CDC has determined that specific regulatory language is unnecessary.

#### b. Requirements Relating to Travelers Under a Federal Order of Isolation, Quarantine, or Conditional Release

Some commenters questioned HHS/CDC's authority, as well as the need, to restrict the movement of individuals who are not ill but have been exposed. HHS/CDC thanks these commenters for their review and input. Some quarantinable communicable diseases, such as novel pandemic influenza strains, may be contagious before the infected person becomes symptomatic. Therefore, in these situations, it may be necessary to restrict the movement of asymptomatic exposed people to make sure they do not expose others inadvertently while they are not aware that they are contagious. It may also be necessary to restrict movement of an exposed person if public health authorities are unable to ensure appropriate monitoring of the person, for example, if an individual is known to have a history of noncompliance with public health recommendations. Exposed people whose movement is restricted through quarantine or other means may be offered vaccination, if a

vaccine is available, but only with informed consent.

One commenter noted that the regulation allows HHS/CDC to issue interstate travel permits to an infected individual conditioned upon the individual taking "precautionary measures" as prescribed by HHS/CDC. This commenter requested that HHS/CDC clarify what precautionary measures may be prescribed and stated that such conditions should not be based on factors unrelated to the individual's health condition, *e.g.*, socio-economic, ethnic status. While HHS/CDC agrees that the issuance of a travel permit should not be based on such factors as race, gender, ethnicity, or socio-economic status, we note that the issuance of a travel permit may be conditioned on such factors as the individual's ability and willingness to comply with the terms of the permit. Furthermore, while the exact precautionary measures prescribed may vary based on the infectious agent, such measures, for instance, may include: Agreeing to minimize time in congregate settings while traveling; avoiding eating in restaurants or other enclosed public places; traveling with no other people in the vehicle or, if other people are needed to safely operate the vehicle, agreeing to wear a mask and ensure good ventilation; and reporting to the local health department upon arrival or on route as needed.

This commenter also requested clarification of the legal impact of a person who is denied a permit or has had a permit revoked. We note that per the terms of the regulation persons denied a travel permit or who have had a travel permit revoked may submit a written appeal. The right to a written appeal, as well as the means by which an appeal may be requested, will be addressed in the written order denying the request for a travel permit or revoking an existing permit. The appeal will be decided by an HHS/CDC official who is senior to the employee who denied or revoked the permit. HHS/CDC declines to speculate as to what else this commenter may be referring to by the term "legal impact," but notes that the regulation does not impair the ability of persons to seek judicial review of final agency actions through the Administrative Procedure Act.

This commenter also requested clarification of how long an individual may be restricted in his or her travel under a Federal travel permit. We note first that the restriction only applies to those under a Federal public health order or under a State or local order if the State or local health department of jurisdiction requests Federal assistance

or there is inadequate local control. In further response, HHS/CDC notes that the restriction would remain in place so long as the individual is infected or capable of infecting others. This commenter further requested clarification of the impact of a disagreement between HHS/CDC and State or local public health authorities. We note that by the terms of 42 U.S.C. 264(e), Federal public health regulations do not preempt State or local public health regulations except in the event of a conflict with the exercise of Federal authority. Moreover, per the terms of 42 CFR 70.2, HHS/CDC may take action to prevent the interstate spread of communicable diseases in the event that the CDC Director determines that inadequate local control exists.

HHS/CDC received a comment from a flight attendant union requesting clarification as to whether an employee could be held criminally liable for knowingly transporting someone in violation of the terms of a travel permit as specified under section 70.5. In response, HHS/CDC clarifies that the term "operator" is defined under 70.1 consistent with 14 CFR 1.1 and with respect to an aircraft means, "any person who uses, causes to use or authorizes to use an aircraft, with or without the right of legal control (as owner, lessee, or otherwise)." We further note that criminal liability, if any, will be determined by a court of law and not administratively by HHS/CDC. Accordingly, we decline to speculate as to whether employees who knowingly violate the terms of a travel permit may be held criminally liable.

One public health organization asked for clarification of how local health departments would be engaged in conducting communicable disease screening activities or enforcing Federal public health travel restrictions for individuals traveling interstate, given that HHS/CDC staff are not present at many points of interstate travel. HHS/CDC acknowledges this limitation in their presence at some ports of entry and in regard to interstate travel and intends to address this through future guidance and discussion with stakeholders.

In regard to interstate air travel, HHS/CDC clarifies that the Federal public health Do Not Board tool will deny boarding of persons known to pose a public health risk to other air travelers. This tool is applicable to persons boarding a commercial aircraft with an origin or destination in the United States, including interstate travel. See 80 FR 16400 (Mar. 27, 2015).

For other modes of travel, HHS/CDC does not have a systematic mechanism



of denying boarding and these situations may need to be addressed on a case-by-case basis, either through direct communication with a conveyance operator or through application of other movement restrictions such as the issuance of State or Federal public health orders. Such situations will likely require the participation of State or local public health authorities; however, as noted by the commenting organization, the Federal and State/local costs and resources required during such operations are not known. The specific roles of State or local health departments will be addressed through future guidance or stakeholder discussion.

HHS/CDC received a comment contending that the extension of travel permits to intrastate travel is in violation of the Commerce Clause. HHS/CDC disagrees. We note that HHS/CDC will only require intrastate travel permits when a State or local health authority of jurisdiction requests federal assistance or in the event that State and local actions are inadequate to prevent interstate communicable disease spread. Under 42 U.S.C. 264, Congress acting pursuant to its Commerce Clause jurisdiction, has authorized HHS/CDC to take measures to prevent the foreign introduction and interstate spread of communicable diseases. It is well established that the Federal government may act to protect interstate commerce, even though the threat may come entirely from intrastate activities. *See United States v. Lopez*, 514 U.S. 549, 558–559 (1995).

One commenter requested that HHS/CDC replace the word “traveler” with “passenger” with respect to mandatory public health assessments, as a traveler could be taken to mean “anybody in a private vehicle lined up at a toll booth.” In response, HHS/CDC states that the use of the word “traveler” with respect to conveyances is intended to include both passengers and crew. Furthermore, HHS/CDC states that its authority extends to all individuals engaging in interstate travel including those traveling by private vehicle, particularly if they are in the “qualifying stage” of a quarantinable communicable disease.

HHS/CDC received a comment from a partnership of public health legal scholars and organizations expressing concern that requiring application for a travel permit may be unduly burdensome because individuals who are served with a conditional release order at an airport would then need to apply for a separate travel permit to travel to their home State of residence. HHS/CDC disagrees because under such circumstances the conditional release

order itself would include authorization for these individuals to continue travel to their home State of residence provided that they subsequently report to public health authorities as needed. For example, during the response to Ebola, CDC worked with state public health authorities to allow certain individuals who met certain risk thresholds to travel in private vehicles to their place of residence while maintaining a focus on protecting public health. This was done on a case by case basis, depending on distance of travel and risk of exposure, and distance from a health care facility with adequate capacity to treat and contain Ebola. CDC would make similar assessments in the event that conditional release orders are needed for other quarantinable communicable diseases. We note that the conditional release order itself would provide permission to travel and have added clarifying language to the text.

HHS/CDC clarifies, however, that after arriving in their home State, should the individuals wish to engage in further travel, a travel permit may be needed at that time. In response to comments from this partnership organization, HHS/CDC also clarifies that the travel permit, as provided for in the regulations, will only be required under circumstances where the individual is already under a Federal, State or local order of quarantine, isolation, or conditional release. Because the travel permit requirement is only applicable to individuals who are already under a Federal, State, or local public health order, HHS/CDC believes that this provision does not impermissibly restrict an individual’s right to travel.

In response to comments regarding the time with which CDC may consider a travel permit request, the CDC Director shall respond to a request for a travel permit within 5 business days. Likewise, one public health association suggested that, in the event a travel permit is denied, these regulations should state the timeframe that HHS/CDC will issue a response to the appeal; another proposed the time period for CDC’s response to be 72 hours. In response to these comments, HHS/CDC has added a requirement in the regulation that in the event that a request for a travel permit is denied, it must decide an appeal from that denial within three (3) business days. HHS/CDC believes that this timeframe is appropriate because this provision only applies to individuals who already have had their travel restricted through the issuance of a public health order and deciding an

appeal may involve coordination with affected state or local jurisdictions.

After consideration of comments received, HHS/CDC has modified paragraphs (a), (b)(1), (b)(2), and (c) of the provision concerning *Requirements Relating to Travelers Under a Federal Order of Isolation, Quarantine, or Conditional Release* (§ 70.5) to remove “agreements,” referring to agreements entered into by the CDC. We have also modified paragraph (a)(5) to require that HHS/CDC must issue a written response to an appeal within three (3) business days. Other provisions of this section are finalized as proposed.

#### c. Report of Death or Illness Onboard Aircraft Operated by an Airline

Several commenters expressed concern that the new regulations remove the requirement for a local health authority to be notified when a passenger falls ill or dies on board a flight. The commenters insisted that this could interfere with effective local response to important communicable disease threats. They propose that local authorities should be notified in a timely manner, such as within one hour of initial reporting, and that HHS/CDC should consult with local health authorities on the necessary steps to contain the spread of communicable diseases. In contrast, one airline supported the direct reporting to HHS/CDC.

HHS/CDC carefully considered these comments and responds that it will continue its long standing partnership with local authorities. The rationale behind asking airlines to submit reports of deaths or reportable illnesses directly to HHS/CDC as opposed to local authorities is to simplify and streamline the reporting process for these airlines. Under the final rule, airlines will not be required to know the current points of contact for multiple local jurisdictions, but rather may report to HHS/CDC as a single point of contact. HHS/CDC will continue to share public health information with State and local health departments through approved electronic disease reporting networks such as the Epidemic Information Exchange (Epi-X), HHS/CDC’s secure, Web-based system. HHS/CDC may also notify State or local authorities via phone calls.

Some commenters questioned whether HHS/CDC has adequate resources to be the first responder at the local level. HHS/CDC responds that it regularly coordinates with Federal, State and local agencies and other partners in the airport environment. HHS/CDC intends to continue working closely with Federal, State, and local partners,

including first responders such as EMS and State and local health agencies, when assistance is needed.

One commenter suggested that the reporting of ill travelers “would be an invasion of our liberty and privacy.” HHS/CDC disagrees. The report of illness or death on board a carrier is a longstanding regulatory provision and practice. This final rule only changes to whom the report is made (directly to HHS/CDC), rather than to the local health department of destination. We further note that personally identifiable information collected and maintained under the Privacy Act will be handled in accordance with that Act and CDC’s system of records notice published at 72 FR 70867.

Another commenter worried that “having flight reservations require health reports will significantly impede air travel.” It is not HHS/CDC practice, nor a requirement under this regulation, for individuals to submit health reports prior to or after making a flight or vessel reservation. The only instance when health documents may be required prior to travel, is if a person is known to be infectious with a communicable disease that could spread during travel and has been placed on the Federal Public Health Do Not Board described in 80 FR 16400 (Mar. 27, 2015). Because this practice is not new, HHS/CDC believes it will not impede air travel.

A flight attendant association suggested that HHS/CDC should adopt training and awareness requirements for airline employers to provide to flight attendants concerning “what entails a qualifying stage.” Industry also expressed concern that flight crews may be held responsible and penalized for missed illness identification. HHS/CDC understands that the statutory definition of “qualifying stage” may be confusing to lay persons and does not expect air or vessel crewmembers to be trained in the nuances of such language. Instead, we have crafted a definition of *ill person* to focus, in plain language, on the signs and symptoms of communicable diseases of public health concern and quarantinable communicable diseases, while taking into account the medical resources available to aircrew. HHS/CDC intends to enforce this provision consistent with how reports of deaths and illnesses are currently handled in regard to foreign arrivals. We note that flight crews have not been penalized in the past for missed reports of illness.

HHS/CDC received comments from industry that the report of death or illness should not be limited only to the pilot in command, given the many duties already under his/her responsibility. HHS/CDC disagrees. We

clarify first that this domestic provision was proposed to mirror the current foreign provision under 42 CFR 71.21(b)—which HHS/CDC did not propose to change—and which states “*the commander* of an aircraft destined for a U.S. airport shall report immediately . . . any death or ill person among passengers or crew.” While we acknowledge the many duties of the pilot in command, because this individual is directly responsible and has final authority over the operation of the aircraft, in keeping with the practice already established through regulation under 42 CFR 71.21(b), we believe that the responsibility for reporting ill persons onboard should ultimately rest with the pilot in command as stated in the regulation. Thus, the text of the regulation has not changed from the proposal.

One industry group commented that the role of flight attendants in identifying sick travelers on board should be addressed through guidance developed in conjunction with HHS/CDC and industry. HHS/CDC responds that it routinely issues guidance for flight crews, including standard guidance for the recognition and reporting of ill travelers and disease- or situation-specific guidance during outbreaks. Such guidance is published on HHS/CDC’s Web site and disseminated through established list serves, industry associations, and any other available means. HHS/CDC will coordinate with industry partners to determine whether additional guidance may be needed and, if necessary, work with these partners to develop such guidance.

One industry organization commented that the proposed rule failed to recognize that airlines employ intermediary professional medical personnel. HHS/CDC responds that it recognizes the role of intermediary professional medical personnel in assisting flight crews in managing an ill traveler onboard and references such personnel in industry guidance issued at <http://www.cdc.gov/quarantine/air/index.html>.

It is not HHS/CDC’s intent for the public health assessment conducted by HHS/CDC public health officers to replace this role in medical management. However, HHS/CDC restates that the reporting of ill travelers to HHS/CDC is the ultimate responsibility of the pilot in command as noted above.

One association requested that the report of deaths on board a carrier be modified and limited to those deaths which resulted from a possible communicable disease. HHS/CDC

disagrees. In keeping with current practice, HHS/CDC will continue to require and receive the reports of *all* deaths that occur on board a carrier, regardless of the suspected cause, to allow a public health official to conduct an assessment.

One public health organization raised concerns about replacing reporting to local health authorities with reporting to HHS/CDC. In response, HHS/CDC notes that extensive input was sought in 2012 from the Association of State and Territorial Health officers (ASTHO) and National Association of County and City Health Officials (NACCHO). Representatives from those organizations recommended that requirements and protocols should be the same for international and interstate flights and procedures should be outlined describing how this would occur. These representatives recommended that airlines should report ill persons on domestic flights to HHS/CDC and that HHS/CDC should subsequently notify State or local health departments. Subsequently, HHS/CDC posted guidance to this effect on its Web site and has continued response planning and development of standard operating procedures to implement these recommendations. Thus, this rulemaking codifies the current practice and is consistent with recommendations provided by ASTHO and NACCHO.

One commenter stated that it appears HHS/CDC is “attempting to move towards mandatory reporting by carriers and border personnel, requiring reporting of persons with signs of illness as they cross borders, as opposed to having to do large-scale individual contact interviews and investigations after an outbreak occurs.” In response, HHS/CDC states that reporting by carriers is already required under the existing regulations and that this regulation only codifies current practice and guidance. In addition, DHS notifies HHS/CDC of ill travelers detected by border personnel. HHS/CDC and DHS agreed to this notification process in a memorandum of understanding and therefore changes to this regulation are unnecessary. HHS/CDC additionally coordinates notification and investigation of contacts during exposure or outbreak situations when necessary based on a public health risk assessment. Such investigations are standard public health practice and not mutually exclusive of reporting by carriers or notifications by border personnel.

After consideration of these comments, the title of the *Radio Report of Death or Illness* (71.21) in the provision has been finalized as

proposed to remove the word “Radio,” and now reads *Report of Death or Illness*.

*C. Provisions Applicable to Part 71 Only (Foreign)*

One commenter questioned the seriousness of communicable disease spread on aircraft and vessels. Another commenter noted an “extreme unlikelihood of contracting any communicable disease while traveling” and that, therefore, HHS/CDC failed to prove a “compelling need” for the proposed regulations. HHS/CDC appreciates the opportunity to respond to these comments. The spread of communicable diseases on aircraft and vessels is well documented. There are numerous reports in the medical and public health literature of spread of measles, tuberculosis, SARS-coronavirus, and influenza virus on aircraft. Outbreaks of varicella (chickenpox), influenza, and gastrointestinal viruses such as norovirus are common on cruise ships, and spread of other diseases such as measles, rubella (German measles), tuberculosis, and other gastrointestinal diseases has also been reported. Aircraft and vessels have people together in confined spaces for prolonged periods of time. Therefore, conducting contact investigations for certain communicable diseases identified on aircraft or vessels is standard public health practice, both in the United States and internationally, similar to public health practice in community settings.

HHS/CDC received comments from industry regarding ongoing efforts with DHS/CBP to improve passenger data collection, as announced in the NPRM. Several commenters stated that HHS/CDC should delay this final rule until DHS/CBP has published a regulation to ensure that a coordinated system is put in place. HHS/CDC thanks these commenters for their input but disagrees that this final rule should be delayed. This comprehensive regulation seeks to protect public health, by implementing, among other things, current passenger and crew data collection practices.

One commenter objected to the collection of health information prior to using public transportation. Another commenter opposed the idea of carriers being “forced to collect and report 17 data elements on American travelers.” A public health association also insisted that data elements should only be collected from people if there is a reasonable belief that the person is infected. This final rule does not require carriers to collect or transmit any data elements that are not currently collected and transmitted to CBP via APIS and

PNR as a result of normal operating procedures. We also take this time to emphasize two important points. First, passengers are not required by HHS/CDC to submit specific data elements provided by passengers. Second, HHS/CDC will only seek this information from CBP or the airline in the event of a confirmed or suspected communicable disease on board a carrier which requires contacting fellow passengers to inform them of possible exposure.

While HHS/CDC received support for the data collection from two public health associations, a commenter misread the proposals to mean that aircraft operators would be required to develop new capacity and processes to capture and store a comprehensive set of sensitive data, archive this data, and then provide it to HHS/CDC. HHS/CDC takes this opportunity to restate and clarify that these final regulations do not impose any new burdens upon the airline industry but rather, codify the current practice of receiving a passenger manifest order (as needed) and providing HHS/CDC with any data in an airline’s possession. This rule places no requirement on the airline to solicit or store additional data than current practices allow. Therefore, HHS/CDC does not expect this formalization of current practice to have an impact on operations, including “check-in process.” If an airline does not have in its possession the five additional data elements, it is not required to collect or submit them to CDC.

One airline industry group commented that the collection of information from screened individuals for the purpose of contact tracing should apply only to passengers because crewmember information would be provided by the employer. HHS/CDC responds that this may be the case operationally; however, HHS/CDC reserves the right to collect information directly from crew members if necessary.

HHS/CDC received a comment expressing concern that individuals may provide false contact information, *e.g.* emails and telephone numbers, to airlines, and thus that HHS/CDC would lack the means of contacting individuals. In response, HHS/CDC notes that airlines are not required to verify the accuracy of information collected and HHS/CDC takes no position on what consequences the airline may impose if a traveler refuses to provide information or provides inaccurate information.

One public health organization commented on the scope of HHS/CDC’s protocols for when contact investigations are conducted and how

exposed contacts are defined following exposures to measles or varicella on aircraft or vessels. HHS/CDC appreciates the comment but seeks to clarify that these protocols were mentioned in the NPRM solely for the purposes of providing context for the economic analysis and that the content of the protocols themselves is beyond the scope of this rulemaking.

One public health organization commented on the fact that buses and trains typically do not maintain or have access to passenger manifests that would allow for the collection of information by HHS/CDC for the purpose of contact tracing. HHS/CDC agrees with this comment and notes that these regulations do not require operators of buses or trains to maintain passenger manifests for purposes of contact tracing. The organization also commented on the utility of the requirement that operators of buses or trains not knowingly transport individuals subject to a Federal public health order. In response, HHS/CDC notes that it is useful to prohibit conveyance operators from knowingly transporting someone under a Federal public health order without a travel permit or in violation of the terms of a permit because this may limit communicable disease spread. This prohibition, however, would only apply in circumstances where the operator would know or have reason to know that a travel permit is required, for instance, if the conveyance operator has been directly informed by the HHS/CDC or another cooperating Federal, State, or local agency.

A non-profit organization also commented that requiring airlines to disclose passenger information, upon request, but without a warrant, for purposes of notifying passengers of their potential exposure to a communicable disease violates the Fourth Amendment to the U.S. Constitution. This organization also contends that HHS/CDC lacks the legal authority to require that travelers provide certain contact information, such as information concerning their intended destination, health status, and travel history as part of a public health investigation. Specifically, this group contends that “examination” as used in 42 U.S.C. 264(d)(1) should be understood as referring only to an “inspection” not an “interrogation.” This group further contends that because HHS/CDC lacks the legal authority to collect information under 42 U.S.C. 264 it also lacks the authority to collect information under the Privacy Act of 1974. Lastly, this group contends that any compulsory questioning of travelers about “acts of

assembly or association” violates the First Amendment to the U.S. Constitution.

HHS/CDC disagrees with these comments. HHS/CDC notes that the requirement of a judicial warrant is not applicable to requiring passenger and crew information from air carriers. Rather, this activity is permitted without a warrant under the special-needs doctrine articulated by the Supreme Court in *Skinner v. Railway Labor Executives’ Ass’n*, 489 U.S. 602 (1989) because of the “special need” in preventing communicable disease spread. Furthermore, requiring passenger information from airlines and questioning travelers is authorized under 42 U.S.C. 264(a), which allows for the promulgation of regulations necessary for preventing the spread of communicable diseases from foreign countries into the United States and interstate. In carrying out and enforcing these regulations, 42 U.S.C. 264(a), authorizes “inspection” and “other measures” as may be necessary which allows for inspection of airline records and questioning of travelers regarding their health status and travel history. While 42 U.S.C. 264(d)(1) is not directly implicated in questioning of travelers because such questioning may occur without a specific reason to believe that the individual traveler may be infected with a quarantinable communicable disease, we note that the commenter’s suggestion that an “examination” excludes “interrogation” is not supported by common understanding or language usage. We note that Merriam Webster defines “examination” among other things as “a formal interrogation.” Thus, this commenter’s suggestion that because HHS/CDC purportedly lacks the legal authority to collect traveler information under 42 U.S.C. 264 it also lacks authority to collect information under the Privacy Act is without merit.

HHS/CDC also rejects the suggestion that questioning of travelers violates their rights to free association under the First Amendment. The U.S. Supreme Court has recognized a “freedom of association” in only two distinct areas: (1) Choices to enter into and maintain certain personal human relationships (as an element of personal liberty); and (2) a right to associate for the purpose of engaging in other activities protected by the First Amendment, *i.e.*, speech, assembly, petition for redress of grievances, exercise of religious freedom. *City of Dallas v. Stanglin*, 490 U.S. 19, 23–24 (1989). The purpose of this proposed requirement is to protect the vital health interests of passengers and crew so that individuals who have been exposed to a communicable

disease during travel may be contacted, informed, and provided with appropriate public health follow-up. HHS/CDC measures to prevent the introduction, transmission, or spread of communicable diseases do not implicate any of these constitutionally-protected areas.

HHS/CDC further notes that its purpose in collecting passenger information is to notify passengers who have been potentially exposed to communicable diseases of public health concern. For some of these diseases, there are preventive medications or vaccines that the individual may be made aware of and wish to obtain to keep from becoming sick. Therefore, HHS/CDC considers the collection of passenger locating information to be of benefit to these passengers and in keeping with standard public health practice to prevent further communicable disease transmission.

After considering these comments, HHS/CDC has finalized these provisions (71.4 and 71.5) as proposed, with the exception that the title has been modified to remove references to “collection” and “storage” of information to more accurately reflect the requirements under this section. References to the CDC have also been replaced with Director throughout these sections.

#### a. Suspension of Entry of Animals, Articles, or Things From Designated Foreign Countries and Places Into the United States

Regarding provision 71.63 *Suspension of entry of animals, articles, or things from designated foreign countries and places into the United States*, one public health association proposed that the restriction of animals should include an exception for ports of entry that could provide for physical inspection. In response, HHS/CDC clarifies that if the CDC Director determines an imported animal (or product) poses a significant public health threat, this provision requires the Director to designate the period of time and conditions under which entry into the United States shall be suspended, which may include limiting entries to certain ports where physical inspections are available. In keeping with current practice, HHS/CDC will implement public health protection measures that strike the appropriate balance between protecting the public’s health and continued importation and trade.

HHS/CDC received a comment that the term “thing” as used in 71.63 authorizing the suspension of “animals, articles, or things,” based on the existence of communicable disease in a

foreign country is unduly vague. In response, we explain that HHS/CDC may take public health measures in regard to animals, articles, or things, to prevent the introduction, transmission, and spread of communicable diseases into the United States and interstate. “Article” generally refers to an article of commerce, such as a specific product that someone wishes to import into the United States or move between States that poses a public health risk. In contrast, a “thing” simply refers to a material object that poses a public health risk regardless of whether there is a specific intent to import or move between States. For instance, on July 10, 2001, CDC issued an order under the authority of section 71.32(b) requiring that imports of “lucky bamboo” (a decorative plant) shipped in standing water be prohibited from entering the United States because the water (*i.e.*, the method of packing the lucky bamboo) constituted a potential vector for mosquito-borne illnesses. *See* 66 FR 35984 (July 10, 2001). In contrast, shipments of “lucky bamboo” that were packed dry (not in standing water) were permitted entry into the United States. In this case, “lucky bamboo” (the decorative plant) would constitute the “article” and the standing water would constitute the “thing.”

HHS/CDC received a question regarding the fate of animals or articles denied entry under this regulation, stating that “articles might presumably be forfeited and pets will be executed,” and questioning whether this provision aligns with due process, particularly with respect to the right to appeal. In response, HHS/CDC states that the provision authorizing temporary suspension of entry of certain animals, articles and things based on the existence of a communicable disease in a foreign country and to protect the public’s health is intended to prevent the arrival of these items at a U.S. port of entry. Therefore, HHS/CDC will seek to ensure travelers are informed of the restriction and will also work with carriers to prevent these animals or items from being loaded onto aircraft or vessels traveling to the United States. If such animals or items do arrive at a U.S. port of entry, HHS/CDC will take measures as needed to protect the public’s health. Such measures will be determined on a case-by-case basis and may include, at the owner’s expense, confinement, re-exportation, or destruction. Re-exportation may be considered if there is no public health risk during travel. HHS/CDC would also consider euthanasia of animals if there

are no other reasonable alternatives to protect the public's health.

In response to the concern expressed about an "appeal," HHS/CDC notes that the Director's suspension order would ordinarily constitute "final agency action" under the Administrative Procedure Act, 5 U.S.C. 704. However, HHS/CDC will consider the appropriateness of offering an administrative appeal as it develops the relevant suspension order.

After considering these comments, HHS/CDC has finalized the *Suspension of Entry of Animals, Articles, or Things From Designated Foreign Countries and Places Into the United States* (71.63) provision as proposed.

## VI. Alternatives Considered

Under Executive Order 13563 agencies are asked to consider all feasible alternatives to current practice and the rulemaking as drafted. One less restrictive alternative would be for HHS/CDC to stop enforcing its regulations and make compliance with current regulations voluntary. Under this scenario, HHS/CDC would not obtain contact data from airlines or provide such data to health departments in order to conduct contact investigations. HHS/CDC would not require illness and death reports on aircraft or vessels, but would still follow-up with airlines and vessel operators upon request. This alternative would put travelers at greater risk of becoming infected with communicable diseases, reduce the ability of public health departments to offer post-exposure prophylaxis or other measures to prevent communicable disease spread from travelers known to have been exposed, and generally increase the risk of communicable disease transmission in the United States.

Another alternative, is to extend the scope of the regulations by closing U.S. borders and ports of entry to incoming traffic from countries experiencing widespread transmission of quarantinable communicable diseases to protect public health is also analyzed based on the 2014–16 Ebola outbreak in West Africa as well as recent importations of Middle East respiratory syndrome. HHS/CDC believes this approach is neither practicable nor is it desirable.

In a separate appendix, alternatives are considered to increase or decrease HHS/CDC's required payments for care and treatment for individuals under Federal orders as specified in 42 CFR 70.13 and 42 CFR 71.30. Also in a separate appendix, alternatives are also considered in which HHS/CDC does not implement temporary animal import

embargos (less restrictive) or does not allow importation of animals under temporary embargos for science, education, and exhibition when accompanied by a special permit.

We believe the regulations described above and set forth below in text offer the best solutions for protecting U.S. public health while allowing for continued travel. HHS/CDC believes that this rulemaking complies with Executive Order 13563; all of these changes provide good alternatives to the current baseline.

## VII. Required Regulatory Analyses

### A. Executive Orders 12866 and 13563

HHS/CDC has examined the impacts of the final rule under Executive Order 12866, Regulatory Planning and Review (58 FR 51735, October 4, 1993)<sup>2</sup> and Executive Order 13563, Improving Regulation and Regulatory Review, (76 FR 3821, January 21, 2011).<sup>3</sup> Both Executive Orders direct agencies to evaluate any rule prior to promulgation to determine the regulatory impact in terms of costs and benefits to United States populations and businesses. Further, together, the two Executive Orders set the following requirements: Quantify costs and benefits where the new regulation creates a change in current practice; define qualitative costs and benefits; choose approaches that maximize net benefits including potential economic, environmental, public health and safety, and other advantages; support regulations that protect public health and safety; and minimize the adverse impact of regulation. HHS/CDC has analyzed the final rule as required by these Executive Orders and has determined that it is consistent with the principles set forth in the Executive Orders and the Regulatory Flexibility Act,<sup>4</sup> as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA)<sup>5</sup> and that, relative to the status quo, the final rule will not be economically significant because the sum of

<sup>2</sup> Executive Order 12866 of September 30, 1993: Regulatory Planning and Review. **Federal Register**. Monday, October 4, 1993; 58(190). <http://www.archives.gov/federal-register/executive-orders/pdf/12866.pdf>. Accessed January 2016.

<sup>3</sup> Executive Order 13563 of January 18, 2011: Improving Regulation and Regulatory Review. **Federal Register**. Friday, January 21, 2011; 76(14). <http://www.gpo.gov/jdsys/pkg/FR-2011-01-21/pdf/2011-1385.pdf>. Accessed January 2016.

<sup>4</sup> U.S. Small Business Administration. Regulatory Flexibility Act. <http://www.sba.gov/advocacy/823>. Accessed January 2016.

<sup>5</sup> Summary of the Unfunded Mandates Reform Act. 2 U.S.C. 1501 *et seq.* (1995). <http://www2.epa.gov/laws-regulations/summary-unfunded-mandates-reform-act>. Accessed January 2016.

annualized costs and benefits are estimated to be much less than \$100 million in any given year.

However, there is uncertainty about the appropriate analytic baseline, and relative to some possible baselines, the effects of the rule are non-negligible. For example, if in the absence this rule, some aspects of future HHS/CDC screening or risk assessment activities are found to be legally impermissible, then the status quo baseline would not represent a reasonable approximation of the state of the world without the rule. Relative to a non-status quo baseline, the rule would lead to activities (e.g., the 2014–16 Ebola risk assessment and management program) that have both substantial costs and substantial benefits. Analyses relative to this non-status quo baseline are presented in a separate appendix.

This Regulatory Impact Analysis (RIA) section presents the anticipated costs and benefits that are quantified where possible are relative to the status quo baseline. Where quantification is not possible, a qualitative discussion is provided of the costs and/or benefits that HHS/CDC anticipates from issuing these regulations.

### Need for Rule

The 2014–2016 Ebola response highlights the inadequacies and limitations of the current regulatory provisions on the traveler data collection process in which CDC must request traveler manifests from airlines and manually search for contact data in order to know *who* enters the United States, *where* they go, and *how* to contact them.

Airlines have been slow to respond to HHS/CDC requests for traveler manifests:

- 30% arrive more than three days after a request,
- 15% arrive more than six days late.

In addition, available locating information is usually incomplete: HHS/CDC receives only the name and seat number for 61% of travelers, and one or more additional pieces of information for 39% of travelers. This final rule clarifies HHS/CDC's existing authority to request any available contact data from airlines and vessel operators, which may improve the timeliness and completeness of future requests from airlines or vessel operators for data not already submitted to the Department of Homeland Security.

Some traveler contact data is available in the APIS/PNR dataset already submitted by airlines to CBP. In the experience of the HHS/CDC, queries from APIS/PNR rarely result in full sets

of contact information (*i.e.* the record includes all five additional data fields as outlined in the final rule). The data fields that are most commonly missing from the records are email addresses (missing 90 percent of the time), secondary phone number (missing 90 percent of the time), and street addresses (missing or insufficient for public health contact tracing up to 50 percent of the time). These data elements are vital to a contact tracing investigation. In looking at a random sample of 20% of the compiled international air travel manifests for 2015, those including a compiled data set from NTC and the airlines, 100% were missing at least one of the 5 data fields. Email address and secondary phone number were among those most frequently missing. For context, there were approximately 760,000 scheduled flights that arrived into the United States in 2015. In 2015, HHS/CDC issued passenger manifest requests for 64 international flights arriving into the United States. As noted in the RIA of the final rule, from 2010 to 2015, HHS/CDC conducted an average of 77 contact investigations per year involving arriving international flights.

Airlines are contacted for the majority of contact investigations using a manifest order document. At a minimum, HHS/CDC needs to confirm the ill traveler was on the flight and where the individual sat in relation to other travelers to determine risk of exposure. Further, in HHS/CDC's experience, only airlines can:

- Quickly and efficiently produce a partial manifest targeting affected rows
- confirm identity of "babes in arms" and their co-travelers (Parent); this is important for measles cases;
- quickly confirm whether an individual actually flew (in instances where individuals deplane and do not re-board during a layover); and
- confirm a plane's configuration if there is a question with the provided row numbers. Different aircraft have different seating arrangements depending on carrier and layout. It is important to know if a certain seat is separated by a bulkhead or is a window seat.

In addition, HHS/CDC only requires a partial manifest, *e.g.* 5 rows for travelers with infectious tuberculosis, so that NTC and HHS/CDC staff can limit the investigation to only those passengers at risk and supplement/cross reference with APIS and PNR data. If a partial manifest is not available from the airlines, then each passenger record must be researched individually to find a seat number, and then the configuration of an entire plane must be

populated to determine where the index case sat in relation to other at-risk passengers. For large flights from Asia, this can pose a tremendous burden to NTC and CDC staff while slowing the ability of CDC to provide important contact information to state and local health departments. Manually populating multiple 300+ person flights is not feasible in a timely manner.

Finally, CDC wishes to reiterate its desire for the above-described operations to be published in regulation to provide the public, as well as industry, with understanding of the efforts made by CDC to protect public health.

The other change to the economic baseline that may result from this final rule was the need to change the definition of an "ill person" to better match HHS/CDC guidance and the guidelines contained in Note 1 to paragraph 8.15 of Annex 9 to the Convention on International Civil Aviation. Where possible, the marginal costs and benefits of these changes relative to the status quo baseline are monetized.

In addition, HHS/CDC believes that there is a need to better communicate to the public the actions that it has taken in accordance with its regulatory authority under *42 CFR 70.6 Apprehension and detention of persons with specific diseases, 42 CFR 71.32 Persons, carriers, and things, and § 71.33—Persons: Isolation and surveillance*. HHS/CDC believes it is necessary for the public to better understand actions that may be taken to prevent the importation of communicable diseases and to explain the due process available to individuals under Federal orders for isolation, quarantine, or conditional release. HHS/CDC also believes it is important to explain when HHS/CDC may authorize payment for the care and treatment of individuals subject to medical examination, quarantine, isolation and conditional release.

Finally, HHS/CDC believes it is important to explain its regulatory authority to suspend entry of animals, articles or things from designated foreign countries and places into the United States when importation increases the risk of the introduction and/or transmission of a communicable disease within the United States.

The specific market failure addressed by these regulations is that the costs associated with the spread of communicable diseases impacts the entire U.S. population, not just the group of persons currently infected with communicable diseases or with business interests in providing interstate or

international travel to persons or animals infected with communicable diseases.

The economic impact analysis of this final rule is subdivided into four sections:

1. An analysis of *42 CFR 70.1, 42 CFR 71.1/71.4/71.5*, for which the primary costs may be incurred by aircraft and vessel operators and the primary benefit is improved public health responsiveness to assess and provide post-exposure prophylaxis to travelers exposed to communicable diseases of public health concern.

2. An analysis of a number of provisions that aim to improve transparency of how HHS/CDC uses regulatory authorities to protect public health. These changes are not intended to provide HHS/CDC with new regulatory authorities, but rather to clarify the agency's standard operating procedures and policies, and due process rights for individuals. HHS/CDC believes that improving the quality of its regulations by providing clearer explanations of its policies and procedures is an important public benefit. However, HHS/CDC is not able to attach a dollar value to this added benefit in a significant way. In a separate appendix, HHS/CDC analyzes the costs and benefits associated with the 2014–2016 Ebola enhanced risk assessment and management program are used to illustrate the costs and benefits of implementation of some of these authorities, and are especially relevant when analyzing the effects of the rule relative to a non-status quo baseline.

3. In a separate appendix, HHS/CDC provides an analysis of the revisions to *42 CFR 70.13/71.30: Payment for care and treatment*, which are not expected to lead to a change in HHS/CDC policy under which HHS/CDC may act as the payer of last resort for individuals subject to medical examination, quarantine, isolation, and conditional release under Federal orders. The primary benefit of codification is increased transparency around HHS/CDC policies to assist in paying for treatment or transportation for individuals under Federal orders. The analysis for these provisions is an examination in potential transfer payments between HHS/CDC and healthcare facilities that provide treatment to individuals under Federal orders or to other payers.

4. In a separate appendix, HHS/CDC provides an analysis of *42 CFR 71.63: Suspension of entry of animals, articles, or things from designated foreign countries and places into the United States*. In this final rule, HHS/CDC is

explaining its existing regulatory authority. HHS/CDC cannot predict how often such authority may be used in the future or for what purpose. HHS/CDC previously exercised this authority on June 11, 2003, when under 42 CFR 71.32(b), HHS/CDC implemented an immediate embargo on the importation

of all rodents from Africa (order Rodentia).<sup>6</sup> A simple economic impact analysis of this embargo is performed to demonstrate the costs and benefits of one example, but HHS/CDC does not anticipate an increase in frequency of such actions based on the provisions included in this final rule. The primary

purpose of the analysis is to demonstrate potential costs and benefits using a realistic example.

Table 1 provides a summary of whether quantitative or qualitative analyses were performed for each of the provisions in the final rule.

TABLE 1—SUMMARY OF PROVISIONS INCLUDED IN THIS FINAL RULE

Provision	Qualitative impacts only	Codification of existing authority
§ 70.1/§ 71.1 General Definitions .....	No <sup>a</sup> .....	Yes (except definition of “ill person”).
§ 70.5 Requirements relating to travelers under a federal order of isolation, quarantine, or conditional release	Yes .....	Yes.
§ 70.6 Apprehension and detention of persons with specific diseases; § 71.32 Persons, carriers, and things (no change to title).	Yes .....	Yes.
§ 70.10/§ 71.20 Public health prevention measures to detect communicable disease .....	Yes <sup>b</sup> .....	Yes.
§ 70.11 Report of death or illness onboard aircraft operated by an airline .....	Yes .....	Yes.
§ 70.12/§ 71.36 Medical examinations .....	Yes .....	Yes.
§ 70.13/§ 71.30 Payment for Care and Treatment .....	Yes <sup>c</sup> .....	Yes.
§ 70.14/§ 71.37 Requirements relating to the issuance of a Federal order for quarantine, isolation, or conditional release.	Yes .....	Yes.
§ 70.15/§ 71.38 Mandatory reassessment of a federal order for quarantine, isolation, or conditional release ...	Yes .....	Yes.
§ 70.16/§ 71.39 Medical review of a federal order for quarantine, isolation, or conditional release .....	Yes .....	Yes.
§ 70.17/§ 71.29 Administrative records relating to federal quarantine, isolation, or conditional release .....	Yes .....	Yes.
§ 70.18/§ 71.2 Penalties .....	Yes .....	Yes.
§ 71.4 Requirements relating to collection, storage and transmission of airline passenger, crew and flight information for public health purposes.	No <sup>a</sup> .....	Yes.
§ 71.5 Requirements relating to collection, storage and transmission of vessel passenger, crew, and voyage information for public health purposes.	No <sup>a</sup> .....	Yes.
§ 71.33 Persons: Isolation and surveillance .....	Yes .....	Yes.
§ 71.63 Suspension of entry of animals, articles, or things from designated foreign countries and places into the United States.	Yes <sup>d</sup> .....	Yes.

<sup>a</sup> Analyzed in RIA.

<sup>b</sup> The costs and benefits associated with the 2014–2016 Ebola enhanced risk assessment and management program are used to illustrate the costs and benefits in a separate appendix.

<sup>c</sup> In a separate appendix, an analysis of previous HHS/CDC payments for care and treatment is provided. However, the provisions in the Final Rule are not expected to lead to a change in HHS/CDC policy under which HHS/CDC may act as the payer of last resort for individuals subject to medical examination, quarantine, isolation, and conditional release under Federal orders.

<sup>d</sup> In a separate appendix, HHS/CDC provides an analysis of this provision based on past experience when HHS/CDC implemented an immediate embargo on the importation of all rodents from Africa.

Executive Summary of the Costs and Benefits of 42 CFR 70.1, 42 CFR 71.1/71.4/71.5

Estimated Costs

The quantified costs and benefits of the final rule are estimated for the following stakeholders: Air and maritime conveyance operators, State and local public health departments (PHDs), individuals exposed to communicable diseases during travel and United States Government (USG). The most likely estimates of primary costs are low (\$32,622, range \$10,959 to \$430,839) because the final rule primarily codifies existing practice or improves alignment between regulatory text and the symptoms reporting guidelines provided by the International Civil Aviation Organization (ICAO). The

cost estimates are based on an increase in:

- The number of illness reports delivered by airlines and vessel operators to CDC, relay of air illness reports to CDC by the Federal Aviation Administration (FAA) when such reports are received by FAA air traffic service units, illness reports processed by HHS/CDC and time for travelers;
- increased costs for airlines and vessel operators to comply with HHS/CDC requests for traveler contact data;
- increased costs for State and local public health departments to follow up with a larger number of travelers exposed to communicable diseases during travel;
- The upper bound cost estimate also includes a substantial increase in training costs for the changes to illness reporting.

Estimated Benefits

The best estimate of quantified benefits of the final rule is also relatively small \$110,045 (range \$26,337 to \$297,393). This estimate is based on expected improvements in illness reporting and in the timeliness, completeness, and accuracy of contact data. These improvements should result in increased efficiencies for HHS/CDC and State and local public health departments in conducting contact investigations among travelers exposed to communicable diseases on aircraft and vessels and reduced illness costs associated with the reduced risk of measles and tuberculosis morbidity and mortality in exposed travelers.

Other potential but non-quantified benefits of the final rule would be associated with future outbreaks of



infectious disease cases for which improved compliance by airlines and vessel operators to provide available traveler contact data would reduce onward spread of disease in the destination communities of exposed travelers. In addition, the change to the definition of “ill person” may also increase reporting of communicable diseases of public health concern onboard conveyances. Reduction in onward spread would also lead to the ability of the public health establishment to reduce effects of disease outbreaks, e.g., delay the spread of disease until a vaccine is available or limit the numbers of outbreaks and cases or reduce public anxiety associated with the risk of transmission. There may also be a reduction in the economic costs of many business sectors such as avoidance of costs to the travel and tourism industry<sup>7,8</sup> when a disease is contained in its early stages.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of [\$146,000,000 in 2015 USD] or more.” Not only will this final rule not cost State, local and tribal governments any expenditure, it is possible that these stakeholders who might be engaged in contact tracing may see a reduction in costs if the final rule is implemented and there is an improvement in airline compliance with HHS/CDC requests to provide traveler data.

#### The Final Rule

Traveler contact information will only be requested by HHS/CDC after a case of serious communicable disease (index case) is reported in a person who traveled on a commercial airline or vessel while contagious. Examples of serious communicable diseases include measles, novel influenzas, and viral hemorrhagic fevers such as Ebola among others. This type of situation necessitates identifying and locating passengers seated near the index case in order to conduct a contact investigation (CI). This final rule would lead to better health outcomes if public health departments are more quickly and

effectively able to contact persons potentially exposed to the index case on an aircraft or vessel. These increased efficiencies should lead to smaller infectious disease outbreaks and fewer public health resources needed to control an outbreak.

There are multiple communicable diseases including quarantinable (e.g., tuberculosis, MERS, and Ebola) and non-quarantinable (e.g., measles, varicella, pertussis, rabies, meningococcal, and rubella) diseases that may necessitate a contact investigation to prevent spread of disease in the community. HHS/CDC notes that for non-quarantinable diseases, HHS/CDC efforts would primarily be limited to assisting health departments to notify individuals of their potential exposures. HHS/CDC was unable to quantify the benefits of preventing the spread of all diseases as a group because of differences in the characteristics of each disease. The differences with respect to potential spread and impact make it difficult to assess the benefits that may accrue from reduced spread of all diseases. The quantified analysis focuses on the two diseases that generate the greatest number of contacts to follow up: Measles and tuberculosis.

The ongoing persistence of measles in the United States provides a good example of the need for this final rule. In 2000, measles was declared no longer endemic in the United States due to high vaccination rates. Cases and outbreaks of measles continue to occur, however, as a result of importation from other countries and lack of adherence to the recommendation for measles vaccination (<http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/mmr.html>). The United States is currently discovering the greatest number of measles cases that have been identified since the declaration of measles elimination; 97% of recent cases were associated with importations from other countries. Of 45 direct importations, 40 occurred in U.S. citizens after traveling abroad.<sup>9</sup>

Among air travelers exposed to measles during flights, post-exposure prophylaxis (PEP) with measles-containing vaccine (within 72 hours) or immune globulin (within 6 days) can prevent onset of disease,<sup>10</sup> halting outbreaks before they begin. However,

without accurate and timely contact data, it is frequently difficult to intervene within these timelines. A recent analysis showed that 9 cases likely occurred as a result of exposure during 108 flights with 74 case-travelers over 3 years. Although there was no onward transmission from these 9 cases,<sup>11</sup> future cases may lead to larger outbreaks.

Measles outbreaks can have substantial associated costs. One model-based analysis showed that 16 outbreaks with 107 confirmed measles cases cost an estimated \$2.7 million to \$5.3 million U.S. dollars for public health departments to contain.<sup>12</sup> The estimate is based on outbreak-specific travel expenses and the opportunity cost of diverting public health staff to outbreak response activities and is not based on the cost of hiring additional staff. This corresponds to an average cost per outbreak of about \$250,000 in 2015 USD. In comparison, a total of 125 cases occurring in 8 States and three countries were associated with a single measles outbreak that originated in late December 2014 in amusement theme parks in Orange County, California.<sup>13</sup> Thus, the number of cases in this one outbreak exceeded the total number of outbreak-associated cases identified in 16 outbreaks during 2011. The source of the initial exposure has not been identified so it is not possible to determine where this index case was exposed. However, this example demonstrates the speed with which communicable diseases can be transmitted and the importance of quickly identifying persons that may have been exposed during air or maritime travel. It is possible that the costs of this one outbreak, which spread across 8 States, exceeded the total costs of all 16 outbreaks that occurred in 2011 and were estimated to cost public health departments a total of \$2.7 million to \$5.4 million dollars.<sup>14</sup>

In the absence of interventions by public health departments, travelers

<sup>7</sup> Rassy D, Smith RD. The economic impact of H1N1 on Mexico's tourist and pork sectors. *Health Econ.* 2013;22(7):824–34. doi: 10.1002/hec.2862. PubMed PMID: 23744805.

<sup>8</sup> Keogh-Brown MR, Smith RD. The economic impact of SARS: How does the reality match the predictions? *Health Policy.* 2008;88(1):110–20.

<sup>9</sup> Gastañaduy, P.A., S.B. Redd, A.P. Fiebelkorn, J.S. Rota, P.A. Rota, W.J. Bellini, J.F. Seward and G.S. Wallace (2014). “Measles—United States, January 1–May 23, 2014.” *MMWR* 63(22): 496–499.

<sup>10</sup> Nelson, K., Marienau, K.J., Schembri, C. and Redd, S. (2013). “Measles transmission during air travel, United States.” *Travel Medicine and Infectious Disease* (2013) 11, 81e89 11: 81–89.

<sup>11</sup> Nelson, K., Marienau, K.J., Schembri, C. and Redd, S. (2013). “Measles transmission during air travel, United States.” *Travel Medicine and Infectious Disease* (2013) 11, 81e89 11: 81–89.

<sup>12</sup> Ortega-Sanchez, I.R., M. Vijayaraghavan, A.E. Barskey and G.S. Wallace (2012). “The economic burden of sixteen measles outbreaks on United States public health departments in 2011.” *Vaccine* 32(11).

<sup>13</sup> Jennifer Zipprich, Kathleen Winter, Jill Hacker, Dongxiang Xia, James Watt, Kathleen Harriman. (2015) Measles Outbreak—California, December 2014–February 2015. *MMWR/February 20, 2015/ Vol. 64/No. 6:* 153–154.

<sup>14</sup> Ortega-Sanchez, I.R., M. Vijayaraghavan, A.E. Barskey and G.S. Wallace (2012). “The economic burden of sixteen measles outbreaks on United States public health departments in 2011.” *Vaccine* 32(11).

infected with measles during international travel would be as likely as any other individuals to initiate a measles outbreak. In the absence of HHS/CDC efforts to retrieve and transmit contact data, public health departments would not be able to contact travelers to offer post-exposure prophylaxis and to recommend self-monitoring for potential measles symptoms.

Summary of Quantifiable and Qualitative Results of the Regulatory Impact Analysis

The Summary Table provides estimated total monetary results for stakeholders' costs and benefits of implementing the final rule. The Summary Table (Table 2) includes estimates associated with changes to the definition of 'ill person' in 42 CFR 70.1/71.1 and the codification of international traveler data collection processes of aircraft and vessel contact investigations under 42 CFR 71.4/71.5. The best estimates of annual costs are \$32,622 compared to the best estimate of annual benefits at \$110,045. The upper bound annual quantified costs are

\$430,839 and the upper bound quantified benefits are \$297,393. Lower bound quantified costs are \$10,959 and benefits are \$26,337.

The measles and tuberculosis examples should not be considered a complete estimate of non-quantified benefits associated with this final rule, because the impact of this final rule to mitigate many different types of infectious disease outbreaks cannot be quantified. It just provides examples based on the two diseases for which contact investigations are most frequently undertaken. Besides communicable diseases commonly reported in the United States (e.g., measles, tuberculosis), this final rule may also improve HHS/CDC's ability to respond to diseases that are infrequently diagnosed in the United States (e.g., Ebola, novel influenza, Middle East Respiratory Syndrome). For example, it is possible that HHS/CDC may need to prepare to address both Ebola and another disease such as novel influenza or Middle East Respiratory Syndrome (MERS) occurring in two separate countries or regions during a given year.

For example, in 2014, two international travelers on commercial flights from the Middle East arrived in the United States while infected with MERS and two international travelers on commercial flights from West Africa arrived while infected with Ebola. Regardless of the infectious disease scenarios faced by HHS/CDC in a given year, this final rule should improve HHS/CDC's ability to mitigate infectious diseases in the future. To the extent that the final rule would lead to improved responsiveness of airlines and vessel operators to HHS/CDC traveler data requests via manifest orders, HHS/CDC may become better able to respond to infectious diseases threats and (1) reduce case-loads during infectious disease outbreaks, (2) reduce public anxiety during disease outbreaks, (3) mitigate economic impacts on businesses as a consequence of reduced public anxiety, and (4) reduce the amount of personnel labor time to conduct large-scale contact investigations in response to a new infectious disease or one with serious public health and medical consequences like Ebola.

TABLE 2—SUMMARY OF MONETIZED AND QUALITATIVE BENEFITS AND COSTS OF THE FINAL RULE [2015 USD]

Category	Most likely estimate	Lower bound estimate	Upper bound estimate	Source citation (RIA, preamble, etc.)
<b>BENEFITS</b>				
Annual monetized routine benefits from reduced effort by CDC and health department to search for exposed contacts (0% discount rate).	\$12,218	\$0	\$12,218	RIA.
Annual monetized routine benefits from reduced illness (0% discount rate)	\$97,828	\$26,337	\$272,958	RIA.
Total annual monetized routine benefits (0% discount rate) .....	\$110,045	\$26,337	\$285,175	RIA.
Qualitative (unquantified benefits) .....	To the extent that airlines or vessel operators have data available and improve responsiveness of airlines and vessel operators to HHS/CDC traveler data requests results from the implementation of the provisions in this final rule, HHS/CDC may become better able to respond to infectious diseases threats and (1) reduce case-loads during infectious disease outbreaks, (2) reduce public anxiety during disease outbreaks, (3) mitigate economic impacts on businesses as a consequence of reduced public anxiety, and (4) reduce the amount of personnel labor time to conduct large-scale CIs in response to a new infectious disease or one with serious public health and medical consequences like Ebola.			RIA.
<b>COSTS</b>				
Annual monetized costs for changes to illness reporting (airlines and vessel operators, 0% discount rate) *.	\$0	\$0	\$376,554	RIA.
Annual monetized costs for changes to codification of manifest order process (airlines and vessel operators), 0% discount rate) *.	\$12,654	\$0	\$25,308	RIA.
Annual monetized costs for additional activities by health department contacting individuals exposed to communicable diseases during international travel (0% discount rate).	\$19,968	\$10,959	\$28,977	RIA.
Total annual monetized routine costs (0% discount rate) .....	\$32,622	\$10,959	\$430,839	RIA.

TABLE 2—SUMMARY OF MONETIZED AND QUALITATIVE BENEFITS AND COSTS OF THE FINAL RULE—Continued  
[2015 USD]

Category	Most likely estimate	Lower bound estimate	Upper bound estimate	Source citation (RIA, preamble, etc.)
Annual quantified, but unmonetized, costs .....		None		RIA.
Qualitative (unquantified) costs .....		None		RIA.

The second analysis in this final rule is of a number of provisions that aim to improve transparency of how HHS/CDC uses its regulatory authorities to protect public health. These changes are not intended to provide HHS/CDC with new regulatory authorities, but rather to clarify the agency’s standard operating procedures and policies with regard to pre-existing regulations in 42 CFR parts 70 and 71 including due process rights for individuals under Federal orders. HHS/CDC believes that improving the quality of its regulations by providing clearer explanations of its policies and

procedures is an important public benefit. However, HHS/CDC is not able to attach a dollar value to this added benefit in a significant way.

Economic Baseline

Regulated Entities: Airlines and Vessel Operators

The group of entities that may be affected by this final rule would include international and interstate aircraft operators, vessel operators, travelers, State or local health departments and the Federal government agencies that interact with these groups. Since this

final rule primarily updates regulatory requirements to better match current practice, the economic impacts are marginal changes to current practice that result from codification of current practices.

The North American Industry Classification System (NAICS) is used by Federal statistical agencies in classifying business establishments for the purpose of collecting, analyzing, and publishing statistical data related to the U.S. business economy. A summary of the total numbers of each entity is summarized in Table 3.

TABLE 3—SUMMARY OF THE NUMBER OF FIRMS ENGAGED IN INTERSTATE AND INTERNATIONAL AIR AND MARITIME TRAVEL

NAICS codes	NAICS description	Number of firms in industry
481111 .....	Scheduled Passenger Air Transportation .....	264
481112 .....	Scheduled Freight Air Transportation .....	212
481219 .....	Other Nonscheduled Air Transportation .....	516
483111 .....	Deep Sea Freight Transportation .....	191
483112 .....	Deep Sea Passenger Transportation .....	54
483113 .....	Coastal and Great Lakes Freight Transportation .....	337
483114 .....	Coastal and Great Lakes Passenger Transportation .....	110
483211 .....	Inland Water Freight Transportation .....	318
483212 .....	Inland Water Passenger Transportation .....	193

Statistics of U.S. Businesses, 2013 U.S. all industries.<sup>15</sup>  
2012 North American Industry Classification System (NAICS).<sup>16</sup>

According to a report by the Federal Aviation Administration, in 2012, U.S. civil aviation-related economic activity generated \$1.5 trillion and supported 11.8 million jobs with \$459.4 billion in earnings.<sup>17</sup> In 2015, the domestic U.S. market for air travel included 696 million passengers and the international market included another 198 million travelers.<sup>18</sup>

In 2011, there were approximately 11 million North American cruise ship passengers spending 71.8 million passenger nights on board vessels. The cruise ship market was highly concentrated with four firms accounting for 98% of the total market.<sup>19</sup> In total, approximately 18 million travelers enter the United States each year via cruise or cargo ships.<sup>20</sup>

The domestic/international air carrier market is an ever-shifting corporate

landscape. Both U.S. and foreign airlines engage in “code-sharing” arrangements, whereby the marketing carrier places its call sign (or code) on the operating carrier’s flight. For purposes of this rule, reporting duty would require the operating carrier to report on *all* passengers and crewmembers, whether traveling on the operator’s code or another carrier’s.

The complexity of the domestic/foreign airline-corporations’ legal and financial arrangements makes it very difficult to ascertain exactly how each and every domestic and foreign airline would be affected by the implementation costs associated with this final rule; presumably, some of the costs might be passed along to the carrier putting its code on the operating carrier, pursuant to the particular terms of each applicable contract.

<sup>15</sup> <http://www.census.gov/econ/susb/>.

<sup>16</sup> <https://www.census.gov/cgi-bin/sssd/naics/naicsrch>.

<sup>17</sup> U.S. Department of Transportation, Federal Aviation Administration (January 2015) The Economic Impact of Civil Aviation on the U.S. Economy: Economic Impact of Civil Aviation by State. [http://www.faa.gov/air\\_traffic/publications/media/2015-economic-impact-report.pdf](http://www.faa.gov/air_traffic/publications/media/2015-economic-impact-report.pdf) (Accessed 5/2/2016).

<sup>18</sup> Bureau of Transportation Statistics T-100 Market data. <http://www.transtats.bts.gov/DataElements.aspx?Data=1> (Accessed 5/2/2016).

<sup>19</sup> U.S. Department of Transportation Maritime Administration (March 2012) North American Cruise Statistical Snapshot, 2011 [http://www.marad.dot.gov/wp-content/uploads/pdf/North\\_American\\_Cruise\\_Statistics\\_Quarterly\\_Snapshot.pdf](http://www.marad.dot.gov/wp-content/uploads/pdf/North_American_Cruise_Statistics_Quarterly_Snapshot.pdf) (Accessed 5/2/2016).

<sup>20</sup> According to the U.S. Department of Homeland Security, 54,236 passengers and crew arrive via vessel each day, which correspond to approximately 18 million per year. <https://www.transportation.gov/policy/aviation-policy/us-international-air-passenger-and-freight-statistics-report> Accessed on 5/2/2106.

Under this final rule, the operator of any airline operating a flight arriving into the United States must make certain contact information described below available within 24 hours of a request by HHS/CDC, to the extent that such data are available to the operator. This requirement also applies to the operator of any vessel carrying 13 or more passengers (excluding crew) and, which is not a ferry as defined in under 46 U.S.C. 2101 and U.S. Coast Guard (USCG) regulations (46 CFR 2.10–25). This requirement is a codification of current practice, and applies to any of the data elements that the airline or vessel operator may have available and authorizes the airline or vessel operator to transmit the contact information in any format and through any system available and acceptable to both the airline and HHS/CDC. Again, because this is a codification of current practices, HHS/CDC assumes airlines and vessel operators will continue to submit data through current mechanisms, although HHS/CDC will accept others that are mutually acceptable.

To simplify the analysis and to develop conservative cost estimates, HHS/CDC assumed that all costs to airlines and vessel operators would be passed along to U.S.-based airlines, vessel operators, or U.S. consumers.

Diseases Affected by the Rule

HHS/CDC has gathered statistics, or reported information on, a number of notifiable and quarantinable diseases (Table 4) that form the basis for estimates of quantitative and qualitative benefits. The final rule provides CDC with the authority to take certain actions with regard to both quarantinable and non-quarantinable diseases. For non-quarantinable diseases, efforts would be primarily limited to early identification and notification of exposed individuals and transmission of contact data to local and State health departments. For

quarantinable diseases, efforts could include issuance of Federal orders for quarantine, isolation, or conditional release of exposed/infected individuals.

TABLE 4—DISEASES ANALYZED

Non-quarantinable	Quarantinable
Measles Pertussis Rabies Meningococcal disease Varicella Rubella	Tuberculosis. Viral Hemorrhagic Fevers. Middle East Respiratory Syndrome Coronavirus (MERS).

In addition, these diseases for which HHS/CDC currently issues manifest orders and conducts contact investigations can also be subdivided to identify those encountered with some frequency (routine diseases): Tuberculosis, measles, meningococcal disease, pertussis and rubella. Among these diseases, only tuberculosis is a quarantinable disease. The second class is a group of new or emerging diseases, or diseases with serious public health and medical consequences, that are not currently prevalent, but are foreseeable as a future threat, e.g., severe acute respiratory syndromes (including SARS and MERS), Ebola. This second group only includes quarantinable diseases, which may be updated in the future by Executive Order, but which are not being updated as a part of the final rule. Although HHS/CDC may help identify travelers ill with or exposed to measles, meningococcal disease, pertussis, rubella, rabies, and varicella, HHS/CDC does not have the authority to place any travelers with such illnesses or exposures under Federal orders. For quarantinable diseases, illness reporting could lead to issuance of Federal orders if travelers are reasonably believed to be infected with a quarantinable communicable disease in a qualifying stage. Such restrictions would not occur based simply on an illness report by

airline or vessel operator staff and would require a medical assessment by a public health professional.

Contact Investigations and Diseases— Interstate and International

The number of travelers exposed to an index case that are subject to a contact investigation (CI) varies by disease and may include only the two passengers sitting adjacent to the index case (meningococcal disease or pertussis) or as much as the entire aircraft (e.g., initial investigations of cases of MERS or Ebola) (Table 5). The entire aircraft or vessel may be subject to CI if the disease is new and transmission patterns are not well understood (e.g., MERS) or if the disease is felt to have serious medical or public health consequences (e.g., Ebola). Some CIs are only initiated for long-duration travel (e.g., tuberculosis for flights of 8 hours or longer). For other diseases (e.g., measles, MERS), CIs are undertaken regardless of duration.

The table also includes criteria to be considered a contact for persons exposed on vessels. In contrast to air contact investigations, most maritime contact investigations are undertaken before travelers disembark from vessels. Another difference between air and maritime contact investigations is that varicella contact investigations are frequently undertaken among maritime travelers on vessels, but are not pursued for air travelers. In addition, HHS/CDC has not yet had to conduct a contact investigation for Middle East Respiratory Syndrome or viral hemorrhagic fever for travelers exposed on vessels. The criteria listed in Table 5 are current as of October 2016, but may be updated in the future based on reviews of the effectiveness of contact investigations. For example, HHS/CDC stopped providing contact data to health departments for mumps investigations after reviewing evidence of the effectiveness of mumps contact investigations.

TABLE 5—CONTACT INVESTIGATION CRITERIA BY DISEASE, PHD FOLLOW UP

Disease	CI initiated if	Persons contacted, aircraft	Persons contacted, vessels	Recommended activities
Ebola (Quarantinable).	All cases .....	All passengers and crew as of April 2016. In the future, the recommendation may change to include fewer passengers and crew.	Cruise vessel—any passenger or crew who made have come into contact with the index case’s body fluids while the index case was symptomatic. Cargo vessel—all on board the vessel while the index case was symptomatic.	Monitoring for 21 days after last potential exposure.

TABLE 5—CONTACT INVESTIGATION CRITERIA BY DISEASE, PHD FOLLOW UP—Continued

Disease	CI initiated if	Persons contacted, aircraft	Persons contacted, vessels	Recommended activities
Measles (Non-quarantinable).	All cases if notification received within 21 days of flight.	Passengers seated within 2 rows either direction of the index case, all babies-in-arms, crew in same cabin. All passengers and crew on flights with <50 seats.	Direct face-to-face contact or shared confined space >1 hour with symptomatic case-patient.	Offer MMR vaccination if non-immune and <72 hrs. since exposure; immune globulin if indicated and within 6 days of exposure.
Meningo-coccal disease (Non-quarantinable).	Case meets the definition of meningococcal disease within 14 days of travel. For air travel: Flight >8 hrs. (or shorter flights if direct exposure reported).	Passengers or crew sitting directly to the left and right of the index case or with potential for direct contact with oral or respiratory secretions.	Cruise vessels—Cabin mates of or potential for direct contact with oral or respiratory secretions of case-patient during the 7 days prior to symptom onset until 24 hours after implementation of effective antimicrobial therapy. Cargo vessels—All on board the vessel during the 7 days prior to symptom onset of case-patient until 24 hours after implementation of effective antimicrobial therapy.	Post-exposure chemoprophylaxis.
New or re-emerging influenza viruses (Quarantinable).	All cases during early stages of international spread.	All passengers and crew .....	All crew and passengers .....	Monitoring for 10 days after last potential exposure; possible serologic testing.
Pertussis (Non-quarantinable).	All cases if notification is received within 21 days of travel.	Passengers sitting next to index case.	Direct face-to-face contact or shared confined space >1 hour with symptomatic case-patient.	Post-exposure chemoprophylaxis.
Rubella (Non-quarantinable).	All cases if notification is received within 60 days of travel.	Passengers seated within 2 rows + crew in same cabin. All passengers and crew on flights with <50 seats.	Direct face-to-face contact or shared confined space >1 hour with symptomatic case-patient.	Serologic testing and guidance for pregnant women.
Severe Acute Respiratory Syndromes (Quarantinable).	All cases .....	SARS-Coronavirus: All passengers and crew. MERS: All passengers and crew contacted during 2014 CIs. Future CIs will include passengers seated within 2 rows of index case.	Cruise vessel—any passenger or crew who had direct face-to-face contact or shared confined space >1 hour with symptomatic case-patient. Cargo vessel—all on board the vessel while the index case was symptomatic.	Monitoring for 10–14 days after last potential exposure; potential serologic testing.
TB (Quarantinable).	Notification received within 3 months of travel, clinical criteria met For air travel: Flight >8 hrs.	Passengers seated within 2 rows.	Cargo vessel: All crew members within 3 months of diagnosis who worked with case-patient. Cruise vessel: Passenger travel companions or crew working in close proximity/sharing living quarters.	Aircraft: Testing for latent TB infection; chest radiograph if the LTBI test is positive. Vessels: Clinical assessment for symptoms and chest radiograph.
Varicella (Non-quarantinable).	All cases on vessels .....	NA .....	Any person who has had ≥5 minutes of direct face-to-face contact with a varicella case during the infectious period.	Varicella vaccination if unvaccinated/non-immune and <3 days since exposure (possibly up to 5 days). High-risk contacts evaluated Varicella Zoster immune globulin if <10 days after exposure.

The Quarantine Activity Reporting System (QARS), which contains, among other data, information collected under OMB Control Numbers 0920–0134, 0920–0488, 0920–0821, and 0920–0900, is a web-based and secure electronic system that supports collection of data for ill persons on inbound or interstate

flights and vessels and at land border crossings; infectious disease threats, and follow-up actions. Currently, HHS/CDC Quarantine Stations at U.S. ports of entry are using the system to record their daily activities. All CIs undertaken by HHS/CDC are documented in QARS.

CIs for international flights from January 2010 through December 2015 are summarized in Table 6. More than half (73.2%) were initiated as a result of tuberculosis cases. Measles is the next most common disease (20.8%). The remaining 6% are subdivided across rubella, pertussis, meningococcal

disease and other diseases. This table also includes CIs undertaken for MERS.

TABLE 6—INTERNATIONAL AIR CONTACT INVESTIGATIONS, AVERAGE NUMBER OF ANNUAL INVESTIGATIONS AND CONTACTS BY DISEASE, JAN 2010 THROUGH DEC 2015 [QARS data]<sup>a</sup>

Disease	Total investigations	Total contacts	Average investigations per year	Average contacts per year	Percent of total contacts
Influenza, avian .....	0	0	0.0	0.0	0.0
MERS Coronavirus <sup>b</sup> .....	2	270	0.3	45.0	1.7
Measles .....	94	3,381	15.7	563.5	20.8
Meningococcal disease .....	8	9	1.3	1.5	0.1
Other .....	3	97	0.5	16.2	0.6
Pertussis .....	11	18	1.8	3.0	0.1
Rabies .....	3	4	0.5	0.7	0.0
Rubella .....	17	532	2.8	88.7	3.3
TB (clinically active) .....	318	11,928	53.0	1,988.0	73.2
Viral hemorrhagic fever .....	7	53	1.2	8.8	0.3
<b>Total</b> .....	<b>463</b>	<b>16,292</b>	<b>77.2</b>	<b>2,715</b>	.....

<sup>a</sup>In May 2011, CIs were discontinued for international outbound flights. To give a better picture of what CIs will look like under this new protocol, flights from January 2010 to May 2011 have been excluded from the above-reported counts. In addition, CIs for mumps have been discontinued. Prior to discontinuation, there were approximately 25 contacts per year investigated for mumps.

<sup>b</sup>For these CIs, contact information for the entire flight was required. In rare instances, a disease is ruled out after a CI has happened.

HHS/CDC also requests traveler contact data to support contact investigations for travelers exposed to infectious diseases on interstate flights. The numbers of investigations and contacts during 2010–15 are

summarized in Table 7. In contrast to international flights, very few contact investigations for tuberculosis were undertaken on interstate flights, because most interstate flights do not meet the 8-hour time requirement for

tuberculosis contact investigations (Table 5). The majority of contacts were investigated after exposure to measles cases (76%) followed by MERS (8.4%) and viral hemorrhagic fevers including Ebola (8.0%).

TABLE 7—INTERSTATE AIR CONTACT INVESTIGATIONS, AVERAGE NUMBER OF ANNUAL INVESTIGATIONS AND CONTACTS BY DISEASE, JANUARY 2010 THROUGH DECEMBER 2015 [QARS data]

Disease	Total investigations	Total contacts	Average number of investigations per year	Average number of contacts per year	Percent of total contacts
Measles .....	72	3033	12.0	505.5	76.1
Meningococcal disease .....	1	1	0.2	0.2	0.0
MERS Coronavirus <sup>a</sup> .....	2	334	0.3	55.7	8.4
Other .....	0	0	0.0	0.0	0.0
Pertussis .....	43	83	7.2	13.8	2.1
Rabies .....	3	3	0.5	0.5	0.1
Rubella .....	8	172	1.3	28.7	4.3
TB (clinically active) .....	2	40	0.3	6.7	1.0
Viral hemorrhagic fever .....	4	319	0.7	53.2	8.0
<b>Total</b> .....	<b>135</b>	<b>3,985</b>	<b>22.5</b>	<b>664.2</b>	.....

**Notes:**

<sup>a</sup>For these CIs, contact information for the entire flight was required. In rare instances, a disease is ruled out after a CI has happened.

The numbers of contacts for maritime contact investigations are summarized in Table 8. For maritime investigations, the majority of contacts were investigated for varicella (~79%) followed by tuberculosis (~13%) and

measles (~6%). Most of the varicella and measles contact investigations were initiated while travelers were still on vessels. Besides the investigations listed in Table 8, gastrointestinal illness cases on cruise vessels carrying 13 or more

passengers are reported to HHS/CDC's Vessel Sanitation Program and cases of Legionnaires' disease are reported directly to HHS/CDC's Respiratory Diseases Branch.

TABLE 8—MARITIME PASSENGER DATA COLLECTION, AVERAGE NUMBER OF ANNUAL CONTACTS BY DISEASE  
[January 2010–December 2015]

Passengers per voyage	Total investigations	Total contacts	Average number of investigations per year	Average number of contacts per year	Percent of total contacts
Measles .....	5	288	0.83	48	6.3
Meningococcal disease .....	3	22	0.5	3.67	0.5
MERS Coronavirus** .....	0	0	0	0	0.0
Other .....	1	9	0.17	1.5	0.2
Pertussis .....	3	14	0.5	2.33	0.3
Rabies .....	0	0	0	0	0.0
Rubella .....	2	26	0.33	4.33	0.6
TB (clinically active) .....	50	585	8.3	97.5	12.8
Viral hemorrhagic fever .....	0	0	0	0	0.0
Varicella (chickenpox) <sup>a</sup> .....	206	3,627	34.3	604.5	79.3
Total .....	270	4,571	45	761.8	100.0

<sup>a</sup>One CI for varicella involved entire crew of the vessel (1224).

#### Traveler Manifest Orders for Airlines

Contact tracing is most effective at reducing cases of communicable disease at the early stages of a potential outbreak as soon after initial exposure as possible. Therefore, if an efficient contact system is not in place when the first ill travelers arrive, the benefits of contact tracing are greatly diminished.

Contact data requests only occur after a case of serious communicable disease (index case) is reported in a person who traveled on a commercial airline or vessel while contagious. This type of situation necessitates identifying and locating travelers seated near the index case in order to conduct a CI.

At present, HHS/CDC uses a multi-step process to obtain traveler contact information from airlines. HHS/CDC issues a written order to the airline that requires the airline to provide HHS/CDC with contact information about the index case and traveler contacts. The order cites current regulatory language in 42 CFR 71.32(b), as authorized by 42 U.S.C. 264. HHS/CDC requires that the airline provide it with the traveler's first and last name, seat number, two phone numbers and email address. HHS/CDC instructs airlines and vessel operators to provide data when available or to report when data are unavailable. The time it takes for HHS/CDC to obtain the available traveler contact data can range from a few hours to a few days. From 2010 through May 2015, about 70% of manifests from airlines arrived within 3 days of the request, 15% arrived between 3 and 6 days after a request, 15% arrived after more than six days, and nine requests took more than a month or were never received by HHS/CDC.

At present, HHS/CDC requests that airlines and vessels provide available traveler contact data within 24 hours for

“urgent” manifest requests. In current practice, requests for contact data are only considered “non-urgent” for contact investigations in which travelers had rubella (for which there is no available prophylaxis) or tuberculosis or for situations in which HHS/CDC is not notified of travelers diagnosed with some communicable diseases until after a certain amount of time during which prophylaxis would be effective (*e.g.*, for measles: 6 days). If the analysis is limited to diseases where requests for traveler contact data are marked “urgent” by HHS/CDC (measles, meningococcal disease, MERS, viral hemorrhagic fevers, and rabies), performance improved such that 51% arrived within 24 hours of a request, 33% arrived between 1–3 days after a request, 13% between 3–6 days and only 3% arrived after 6 days. HHS/CDC notes that there may be instances where CDC may not have included the correct information in a manifest order (*e.g.*, flight number or port of entry). The provision of incorrect flight information may have caused delay submission in some of the instances cited above.

While HHS/CDC requires that all information be provided upon first order for information, HHS/CDC has consistently seen that the information provided by a majority of airlines appears limited to frequent flyer information, or other limited contact information. Overall, the completeness of data provided by airlines varied such that airlines generally fell into two categories. Some airlines always provided only the passenger name and seat number. Other airlines would provide some additional contact information for passengers. However, even among these airlines, contact data for some of the passengers only included names and seat numbers.

Considering all requests from 2014, at least one additional piece of contact information was provided for only about 39% of passengers. If the sample were restricted to only flights for which any contact information was provided (1,270 out of 2,411 total passengers), the fraction of passengers with at least one piece of contact information beyond name and seat number increased from 39% to 73.9%. This contact information would include U.S. address for 41.7% of passengers and one phone number for 45% of passengers. As a result of HHS/CDC's use of available information and technology and its partnerships with other Federal agencies, contact tracing of exposed travelers can now be accomplished more rapidly than would be possible if only the contact data provided by airlines were used. However, if airlines or vessel operators have additional data relative to what is currently provided to DHS, the efficiency of contact investigations could improve.

#### Change to Definition of an “Ill Person”

HHS/CDC is updating the definition of “ill person” in 42 CFR 70.1 and 71.1 to better facilitate identification of communicable diseases of public health concern aboard flights and voyages. However, HHS/CDC currently requests that aircraft and vessels report several of the symptoms included in the revised definition of ill person. Besides aircraft and vessel operators, quarantine stations also receive illness reports from U.S. Customs and Border Protection, U.S. Coast Guard, State and local health departments, and health facilities. These reports are not included in this analysis, which focuses on reporting during travel.

HHS/CDC has crafted the definition of “ill person” in such a way that it should



be understood by non-medically trained crewmembers and used to discern illnesses of public health interest that HHS/CDC would like to be made aware of according to 42 CFR 70.4 from those that it does not (e.g., common cold), while more closely aligning the definition with the symptoms reporting guidelines published by ICAO in *Note 1 to paragraph 8.15 of Annex 9 to the Convention on International Civil Aviation*. To further assist flight crewmembers (and vessel crewmembers under part 71) in identifying individuals with a reportable illness, HHS/CDC provides the following in-depth explanations and examples of the communicable diseases that such signs and symptoms might indicate. Note that these explanations also apply to the definition of “ill person” under part 71 and are discussed in the preamble of this final rule.

The current illness reporting requirements for interstate travel are summarized in 42 CFR 70.4 and state that “The master of any vessel or person in charge of any conveyance engaged in interstate traffic, on which a case or suspected case of a communicable disease develops shall, as soon as practicable, notify the local health authority at the next port of call, station, or stop, and shall take such measures to prevent the spread of the disease as the local health authority directs.” Communicable disease is defined in 42 CFR 70.1 as “illnesses due to infectious agents or their toxic products, which may be transmitted from a reservoir to a susceptible host either directly as from an infected person or animal or

indirectly through the agency of an intermediate plant or animal host, vector, or the inanimate environment.”

Thus, the changes in this final rule would amount to fewer illness reports than may be anticipated under the current regulation. However, in practice, according to CDC guidance available at <http://www.cdc.gov/quarantine/air-reporting-deaths-illness/guidance-reporting-onboard-deaths-illnesses.html>, the symptoms requested for international and interstate illness reporting are the same subset. In addition, according to guidance, reports received by HHS/CDC would be considered sufficient to satisfy the requirement to report to local health departments since HHS/CDC would coordinate any response activities with the local health department after receipt of the illness report.

This final rule would align the definition from CDC guidance with regulatory text by requiring reports of ill travelers with fever and persistent cough, persistent vomiting, difficulty breathing, headache with stiff neck, decreased consciousness, travelers appearing obviously unwell, or unexplained bleeding. In practice, the codification of such guidance may increase costs to some or all airlines and vessel operators who submit illness reports based only upon symptoms currently identified in 42 CFR 71.1 and not based on HHS/CDC guidance. For illness reports from aircraft, DOT/FAA may also incur additional costs if the number of illness reports made by aircraft pilots in command to air traffic control and reported to HHS/CDC via the Domestic Events Network increases.

For aircraft, the updated definition better aligns with symptoms reporting guidelines published by ICAO in Note 1 to paragraph 8.15 of Annex 9 to the Convention on International Civil Aviation. Therefore, HHS/CDC does not anticipate much additional burden on airlines and vessel operators to report ill travelers during travel.

Although HHS/CDC estimates the net change will be no cost to airline or vessel operators, it may be possible to examine the potential increase using simple assumptions. Table 9 shows the number of reports by pilots in command during flights and recorded in HHS/CDC’s Quarantine Activity Reporting System (QARS). These include reports of illness that fit the illness definition specified in current 42 CFR 71.1, reports based on HHS/CDC’s guidance for airlines and vessel operators, reports made based on the guidelines in Note 1 to paragraph 8.15 of Annex 9 to the Convention on International Civil Aviation, or illness reports unrelated to current regulation or guidance. Such reports can also be subdivided into reports requiring HHS/CDC response (“response reports”) and reports that HHS/CDC receives, but which do not require an HHS/CDC response (“info-only reports”). Info-only reports may include symptoms included in HHS/CDC guidance, but for which the underlying condition can easily be diagnosed not to be a communicable disease of public health concern (e.g., influenza-like illness on an aircraft). Info-only reports can also be based on illnesses not requested by HHS/CDC guidance (e.g., motion sickness).

TABLE 9—TOTAL NUMBERS OF REPORTS MADE DURING FLIGHT BY AIRCRAFT OPERATORS, 2011 TO 2015 [HHS/CDC QARS data]

Year	Category	Based on symptoms included in current regulation	Based on symptoms included in final rule	Reports not based on symptoms included in either current regulation or final rule	Total
2015	Info-only	30	55	43	128
	Response	33	22	15	70
2014	Info-only	33	61	42	136
	Response	19	36	12	67
2013	Info-only	31	46	29	106
	Response	21	25	4	50
2012	Info-only	34	58	38	130
	Response	12	18	2	32
2011	Info-only	27	39	25	91
	Response	25	29	13	67
Average, Info-only		31	51.8	35.4	118.2
Average Response		22	26	9.2	57.2
Average, total		53	77.8	44.6	175.4

In addition to illness reports, HHS/CDC receives an average of 10 death reports during air travel each year. Since death reporting requirements are not changing, these are not analyzed.

Table 9 shows that HHS/CDC already receives a number of reports based on symptoms included in HHS/CDC guidance that will be codified with this final rule. On average, among the total 175 illness reports per year, about 78 annual reports are based on symptoms included in the final rule, but not in current regulations compared to 53 reports based on symptoms already listed in current regulations. The remaining 45 reports would include those based on fever alone or based on

symptoms not included either in current regulatory text or in this final rule.

The number of illness reports from master of vessels during voyages is summarized in Table 10. Compared to the breakdown in reports for aircraft, the vast majority of illness reports during voyages are for response as opposed to info-only. There may be greater specificity in reports from cruise vessels because of the presence of medical officers onboard vessels. On average, there were about 208 reports requiring

follow-up and 10.6 info-only reports each year. In contrast to reports from aircraft, most of the reporting for vessels pertains to symptoms included in the current regulation (175 per year) as opposed to those specified in this final rule (32 per year). Very few reports from vessels (3.4 per year) were based on fever only or based on symptoms not included in either current regulation or specified in this final rule.

**TABLE 10—TOTAL NUMBERS OF ILLNESS REPORTS (EXCLUDING INFLUENZA-LIKE ILLNESS) MADE DURING VOYAGE BY MASTERS OF VESSELS, 2011 TO 2015**  
[HHS/CDC QARS data]

Year	Type of report	Based on symptoms included in current regulation	Based on symptoms included in final rule	Reports not based on symptoms included in either current regulation or final rule	Total
2015 .....	Info-only .....	5	4	4	13
	Response .....	179	21	1	201
2014 .....	Info-only .....	6	3	3	12
	Response .....	168	21	12	201
2013 .....	Info-only .....	1	1	3	5
	Response .....	145	48	11	204
2012 .....	Info-only .....	5	7	3	15
	Response .....	167	19	1	187
2011 .....	Info-only .....	1	3	4	8
	Response .....	196	32	19	247
Average, Info-only .....		3.6	3.6	3.4	10.6
Average Response .....		171	28.2	8.8	208
Average, total .....		174.6	31.8	12.2	218.6

In addition to the illness reports reported in the table, HHS/CDC receives about 115 reports of death during maritime travel each year. In addition, HHS/CDC requests, but not require reporting of influenza-like-illness from cruise vessels (also not included in above table).

**Baseline Contact Investigation Process for Routinely Imported Diseases**

This section reports the primary steps of CIs for routine diseases:

- A traveler (the index case) is identified as ill either during the flight or voyage with a reportable illness or after with a notifiable disease. The aircraft pilot in command or master of vessel may report the illness directly to HHS/CDC. Illnesses on aircraft may also be reported indirectly to HHS/CDC via air traffic control. The FAA then passes the report to CDC through the Domestic Event Network. If the report occurs after travel, a healthcare facility would then report the illness either to HHS/CDC or public health departments (PHDs).

- If CI criteria are met, HHS/CDC contacts the airlines for
  - a manifest to determine where the index case was seated in relation to other passengers or crew members,
  - HHS/CDC then requests information available from DHS’ databases to verify or obtain passenger contact information not included in the manifest.

- If data are not available in DHS databases, HHS/CDC will require (as part of the manifest order) for the airlines to provide any available traveler contact information. The number of travelers for which contact data will be requested is based on the disease-specific criteria listed in Table 5.

Once HHS/CDC has the traveler contact information and flight-seating chart, the CI begins. Current CI procedures are cumbersome, in part because of the difficulties associated with obtaining traveler contact information. HHS/CDC staff may contact airlines more than once to obtain traveler contact data including email address, one or two phone numbers, and address in the United States for U.S. citizens and permanent residents.

When passenger contact information is delayed or partial, State/local public health departments are delayed in starting CIs and, depending on the disease, this delay could make it impossible to prevent illness and/or the transmission of disease. Further, PHDs

could have improved success contacting passengers with more accurate or timelier data.

The model for estimating the benefits of CIs is: Current number of CIs × (reduction in HHS/CDC and health department staff time/resources per contact) × value of staff time.

The rest of this section reports both the quantifiable benefits arising from streamlining the CI process and a discussion of health benefits. The differential impacts of the various diseases make it hard to summarize the final rule’s effects given uncertainty around future probabilities of case(s) of multiple such notifiable disease(s). The timeliness of contact investigations could also be improved if improvements in illness reporting led to earlier diagnoses of communicable diseases.

**Estimating the Number of Infected Travelers**

Most air travelers with illness are not identified in flight, but rather seek medical care and are identified as an

index case after their travel is completed. Compared to air travelers, maritime travelers spend more time on vessels during voyages and medical officers may be employed on cruise vessels.

When communicable diseases are diagnosed after travel, the medical practitioner should notify HHS/CDC or a PHD if the diagnosed disease is on either the list of quarantinable communicable diseases or the list of notifiable diseases. If HHS/CDC can draw upon improved contact information based on the codification of requests for traveler contact data to aircraft and vessel operators as set forth in this final rule, the risk of onward disease transmission can be reduced. By contacting ill travelers more quickly, HHS/CDC may slow the spread and the severity of the outbreak. The benefits therefore depend on:

- How many infected travelers are expected to enter the United States;
- How many quarantinable or notifiable diseases are detected either on-board the aircraft/vessel or reported to HHS/CDC by PHDs;
- How many exposed travelers will become ill as a result of exposure during travel;
- How the infection will be transmitted within the U.S. population;
- How effective public health agency contact tracing will be with and without the final rule.

In addition to improved efficiencies associated with more timely or more complete provision of traveler contact data by airlines and vessel operators, there may also be an increase in the number of reports of ill travelers during travel that require HHS/CDC follow-up. Under the most likely scenario, there will not be a change in these reports, since the new definition better corresponds to reporting guidelines published by ICAO in Note 1 to paragraph 8.15 of Annex 9 to the Convention on International Civil Aviation and current HHS/CDC guidance. However, there may be an increase in illness reports depending on whether airlines and vessel operators increase reporting for required rather than recommended symptoms.

Contact Investigations Supported by CDC and Undertaken by Partners at State and Local Health Departments

The change to the definition of an “ill person” for the purposes of illness reporting and the codification of HHS/CDC requests from airlines and vessel operators for traveler contact data may improve HHS/CDC’s ability to respond effectively and mitigate infectious disease outbreaks. There are a number

of intermediate steps between either an illness report or receiving more complete or timelier traveler data and stopping an infectious disease outbreak. For example, the travelers exposed to the infectious disease would have to be contacted by health departments and comply with recommended public health measures, which could include some form of public health or medical follow up to mitigate their risk of becoming ill, or self-monitoring/quarantine to mitigate the risk of transmitting that disease to other individuals.

The amount of time HHS/CDC staff spend per air or maritime contact varies with the size of the CI because some tasks are CI-specific, such as filling out reports or obtaining manifests, and some are contact-specific such as determining a specific traveler’s contact information. The CI-specific labor time costs less per contact when an investigation includes more contacts, e.g., a manifest that takes 60 minutes of HHS/CDC staff time to obtain for 2 contacts is the equivalent of 30 minutes-staff-time-per-contact while the same manifest listing 30 contacts is the equivalent of 2 minutes-staff-time-per-contact. On the other hand, the traveler-specific time tends to increase-per-contact with less information and decrease-per-contact with more information.<sup>21</sup> Further, the QARS system used to document and follow up on CIs requires full-time personnel to maintain the system, pull regular reports, and monitor follow-up of travelers contacted during CIs. Finally, HHS/CDC has two full-time persons regularly assigned as liaisons to DHS whose duties include gathering contact information from DHS systems. Therefore, for HHS/CDC staff time to initiate and follow up on different sized CIs, to track down traveler contact information from multiple sources, to work with PHDs, document and report on CIs, update and train in systems, and manage the staff involved in CIs, a cost of \$180 per contact is estimated. This is the equivalent of 2 hours of a HHS/CDC staff person’s being paid the salary of a GS–13, step 4 plus 100% for benefits and employee overhead costs (Table 11).

For PHD resources, HHS/CDC also estimated a cost-per-contact of \$180, which is consistent with HHS/CDC costs and a recent publication adjusted to 2015 dollars.<sup>22</sup> PHD processes vary greatly from State to State and at the

local level within a State. A couple of examples:

- One State assigns 2 registered nurses (RNs) who perform 5 CIs or fewer per year for the entire State another State assigns 3 RNs, a Public Health Service Medical Officer, a physician, and a data analyst and conducts about 25 CIs a year.<sup>23</sup>

- When one State receives information about passenger contacts from HHS/CDC, the State epidemiologist creates several documents to fax to the relevant county health departments, a team of an epidemiologist and RNs at the county then either call or visit the contacts if there is an address. But the State epidemiologist will make every effort to locate travelers even if their final destination is unclear.<sup>24</sup>

Finally, different diseases may elicit different levels of response at the PHD level, with a more rapid response for highly infectious diseases like measles that can be prevented with timely post-exposure prophylaxis and a more measured response for less infectious diseases like TB. By using the same cost for HHS/CDC and for PHDs, HHS/CDC believes the potential reductions in cost from reduced effort for PHDs to locate infectious disease contacts are conservatively estimated.

TABLE 11—COST-PER-CONTACT

CDC	PHD
\$180 .....	\$180

Infectious Disease Transmission During International Travel

For some diseases, there is empirical data from which onboard transmission can be estimated. According to a published analysis of the outcomes of measles contact investigations (74 case-travelers on 108 flights resulting in 3,399 contacts) in the United States between December 2008 and December 2011, HHS/CDC could not assign 9% of measles contacts (322) to a health department due to insufficient contact data. Another 12% of these contacts (397) were believed to be outside the United States.<sup>25</sup> After HHS/CDC provides contact data to State health departments, HHS/CDC requests, but does not require health departments to

<sup>23</sup> Personal communication from states to Dr. Margaret S. Coleman 2010.

<sup>24</sup> Discussion between Dr. Brian Maskery, Dr. Margaret S. Coleman and State and County Health Department contacts 11/21/2014.

<sup>25</sup> Nelson, K., Marienau, K.J., Schembri, C. and Redd, S. (2013). “Measles transmission during air travel, United States.” *Travel Medicine and Infectious Disease* (2013) 11, 81e89 11: 81–89.

<sup>21</sup> Margaret S. Coleman, unpublished data.  
<sup>22</sup> Coleman, M.S., Marienau, K.J., Marano, N., Marks, S.M., Cetron, M.S. (2014). “Economics of United States tuberculosis airline contact investigation policies: a return on investment analysis.” *TMAID* 12(1):63–71.

provide data on the outcomes of their attempts to follow-up with travelers. Among the 2,673 contacts assigned to U.S. public health departments in 2008–11, HHS/CDC only received outcome data for 1,177 out of the 2,673 assigned contacts. This outcome data included reports from State health departments that 225 out of the 1,177 assigned contacts could not be located (19%). Among the 952 contacts for which HHS/CDC received measles outcome data from health departments, there were 9 lab-confirmed measles cases (1%). Since there may be reporting bias from health departments (*i.e.* health departments would be more likely to report outcome data for contacts that developed measles than for other exposed travelers that did not develop measles, HHS/CDC considers a range of measles incidence rates among exposed travelers from 9 cases/2,673 contacts assigned to health departments (0.34%) to 9 cases/952 exposed contacts with outcome data reported to HHS/CDC (0.95%). This probability could overstate or understate the true transmission rate depending on the length of the flight and seating configuration. On the other hand, it may understate the probability if cases were not reported or occurred overseas.

The majority of travelers exposed to measles on aircraft (~74%) had pre-existing immunity based on past measles immunization, past measles illness, or being born prior to 1957 and thus likely to have measles immunity even if they do not recall experiencing the disease.<sup>26</sup> Among the 952 exposed travelers, 8 cases occurred in the 247 contacts (3.2%) without known pre-existing immunity compared to 1 case in the 705 contacts with past history of vaccination or measles illness (0.1%). The median age of measles cases in exposed air traveler contacts was 1.6 years.

Intervention by public health departments mitigates the risk of measles transmission in two ways. First, exposed travelers without measles immunity may be offered voluntary post-exposure prophylaxis with measles-containing vaccine (within 72 hours) or immune globulin (within 6 days),<sup>27</sup> which can prevent onset of disease, halting outbreaks before they begin. Under the status quo, relatively few exposed travelers receive post-exposure prophylaxis (just 11 out of 248

travelers with no history of measles immunization or infection). Second, exposed travelers would be counseled by health departments to self-isolate and seek treatment if they started to experience symptoms consistent with measles onset. For example infants exposed during travel and too young to be vaccinated could arrange for special precautions if they visit a pediatrician after becoming ill with measles-like symptoms to minimize the transmission to other unvaccinated infants. Both activities will limit the possibility of measles transmission to family members or others in the community. The attack rate for measles is estimated to be 90%, but the high background immunization rate and high efficacy of measles vaccine attenuates the burden of measles outbreaks in the United States.

In summary, the potential size of a measles outbreak occurring depends on:

- The number of persons contacted by the infectious measles patient
- Background immunity among persons contacted
  - Survey estimates have shown considerable heterogeneity in background vaccination rates such that 80% of unvaccinated children live in counties comprising 40% of the total population.<sup>28</sup>

For tuberculosis, it is difficult to estimate the transmission rate on an aircraft or vessel. A modeling study suggests that the risk of infection is about 1/1000 on an 8.7 hour flight and that persons seated closer to the index case are at greater risk of infection.<sup>29</sup> Only 5–10% of persons infected with the bacteria *Mycobacterium tuberculosis* will go on to develop active, infectious disease and the risk of progression is greatest within the first two years after infection.<sup>30</sup>

An analysis of the epidemiology and outcomes of HHS/CDC-led flight-related tuberculosis contact investigations conducted in the United States from January 2007 to June 2008 examined 131 case-travelers and 4,550 passenger-contacts.<sup>31</sup> Among 3,375 (74%)

passenger-contacts whose information was provided to health departments, HHS/CDC received results for 861 (26%). HHS/CDC found that 103/861 (12%) had a previous history of a positive TB screening test result or treatment for latent tuberculosis or active disease and were not re-tested. Of the remaining 758 passenger contacts, 182 (24%) tested positive. The majority of travelers with data about TB risk factors (other than exposure to cases during air travel) had at least one risk factor (130/142 or 92%). Risk factors included having been born or lived in a country with high TB prevalence (prevalence >100 per 100,000 population). Although passenger-contacts with risk factors were more likely to have pre-existing latent tuberculosis infection, the authors could not exclude the possibility that infection was acquired during the flights when the travelers were exposed.

Furthermore, because outcomes data were reported for only 26% of passenger contacts forwarded to U.S. health departments (19% of all passenger contacts) the precise determination of in-flight transmission risk of *M. tuberculosis* was not feasible.<sup>32</sup>

The results from this investigation were used in a cost-effectiveness study to estimate the return on investment for tuberculosis CIs. The authors examined a range of latent tuberculosis prevalence rates among exposed travelers that varied between 19% and 24% for two different HHS/CDC CI protocols for flight-related TB investigations. The return on investment was calculated based on the likelihood that travelers with latent tuberculosis infection would initiate and complete a treatment regimen to clear the infection, the average cost of tuberculosis treatment, a tuberculosis case fatality rate of 5% and a conservative value of statistical life estimate of \$4.2 million (in 2009 USD) to account for the value of mortality risk reduction from avoided tuberculosis disease. The return on investment depended on the probability assumed for persons with latent TB infection to develop active disease (5–10%) and variation in the costs to health departments to locate exposed travelers (\$28 to \$164). Using the expected latent tuberculosis prevalence rate of 19% in travelers identified for contact investigations on flights and a health department cost per contact of \$164, the return on investment was estimated to

<sup>28</sup> Smith P, Marcuse E, Seward J, Zhao Z, WA O. Children and Adolescents Unvaccinated Against Measles: Geographic Clustering, Parents' Beliefs, and Missed Opportunities. *Public Health Rep.* 2015;5:485–504.

<sup>29</sup> Ko G, Thompson KM, Nardell EA. Estimation of tuberculosis risk on a commercial airliner. *Risk Anal* 2004;24:379e88.

<sup>30</sup> Marienau KJ, Cramer EH, Coleman MS, Marano N, Cetron MS. Flight related tuberculosis contact investigations in the United States: comparative risk and economic analysis of alternate protocols. *Travel Med Infect Dis.* 2014;12(1):54–62.

<sup>31</sup> Marienau KJ, Burgess GW, Cramer E, et al. Tuberculosis investigations associated with air travel: US Centers for Disease Control and Prevention, January 2007–June 2008. *Travel Med Infect Dis* 2010;8:104e12.

<sup>32</sup> Marienau KJ, Burgess GW, Cramer E, et al. Tuberculosis investigations associated with air travel: US Centers for Disease Control and Prevention, January 2007–June 2008. *Travel Med Infect Dis* 2010;8:104e12.

<sup>26</sup> Nelson, K., Marienau, K.J., Schembri, C. and Redd, S. (2013). "Measles transmission during air travel, United States." *Travel Medicine and Infectious Disease* (2013) 11, 81e89 11: 81–89.

<sup>27</sup> Nelson, K., Marienau, K.J., Schembri, C. and Redd, S. (2013). "Measles transmission during air travel, United States." *Travel Medicine and Infectious Disease* (2013) 11, 81e89 11: 81–89.

vary between \$1.01 and \$3.20. The return on investment formula was calculated based on (Expected benefits – Expected costs)/Expected costs. Thus, for each \$1 in Federal and State resources spent on contact investigations and offering treatment to persons infected with latent tuberculosis infections would result in benefits in excess of costs equal to \$1.01 to \$3.20<sup>33 34</sup> on average. At the upper bound latent tuberculosis prevalence estimate (24%), the return on investment was estimated to vary between \$1.35 and \$3.92.

There is also empirical data for SARS infections occurring on an aircraft. A study reported that 37 infections resulted from 40 flights with infectious passengers on board. Of the 40 flights, four have documented aircraft sizes. They average 127 passengers per plane.<sup>35</sup> Therefore the on board transmission rate could be estimated to be 0.73% among all travelers. In comparison, there is no evidence of transmission of MERS Coronavirus or

viral hemorrhagic fevers during travel on aircraft or vessels. However, there have not been enough observations to determine that there is no risk.

For the remainder of the diseases, empirical data does not exist. Like measles, immunizations are recommended to prevent pertussis, rubella, and meningococcal disease. Since meningococcal conjugate vaccine was more recently added to the United States vaccination schedule, it is likely that background immunity is much lower relative to measles, rubella or pertussis.

In the absence of data for some diseases, the infection rate of measles is used to estimate the infection rates by using the ratio of basic reproduction numbers ( $R_0$ ). The basic reproduction number is a measure of disease infectiousness. Specifically, it is an estimate of new infections in a completely susceptible population. For example, rubella has an  $R_0$  of 9 to 10 while measles has an  $R_0$  of 15 to 17.<sup>36</sup> The infection rate of measles is

multiplied (0.0034 to 0.0095) by the ratio of the average basic reproductive numbers (9.5/16) to arrive at a transmission rate (0.002 to 0.006) for rubella on airplanes. This rate is approximately 60% of the rate for measles. The estimated transmission rates for some diseases are reported in Table 12. The exceptions are for meningococcal disease and tuberculosis. For meningococcal disease, the risk of transmission in household contacts 0.002 to 0.004<sup>37</sup> is used in the absence of other data and taking account that CIs are only performed for travelers sitting adjacent to the index case or in the event of other known exposures. For tuberculosis, the probability that exposed travelers have latent tuberculosis<sup>38</sup> (19%–24%) is used, although infection may have occurred prior to air travel. For the purposes of evaluating the economic impact of tuberculosis investigations, it does not matter if travelers were infected during travel or before.

TABLE 12—ESTIMATED TRANSMISSION RATE ON PLANE FOR EXPOSED TRAVELERS

Disease	$R_0$	Estimated transmission rate on aircraft to exposed passengers	
		Lower bound	Upper bound
Diphtheria (quarantinable) .....	11 to 14 .....	0.0026	0.0074
Measles (non-quarantinable) .....	15 to 17 .....	0.0034	0.0095
Meningococcal Disease (non-quarantinable) .....	NA .....	<2/1000	<4/1000
Pertussis (non-quarantinable) .....	4 to 5 .....	0.001	0.003
Rubella (non-quarantinable) .....	9 to 10 .....	0.002	0.006
TB (quarantinable) .....	NA .....	0.19	0.24

Estimated Number of Cases in Traveler Contacts

The number of potential contacts for each disease can be multiplied by the estimated transmission rate by disease in Table 12 to generate a rough estimate of the annual number of cases among traveler contacts. These numbers of contacts for each disease are summarized in Tables 6 and 7 for interstate and international CIs

respectively. Contact investigations on vessels are excluded for this analysis. Based on this analysis, tuberculosis (19 to 48) and measles cases (3.6 to 10.1) are the most likely diseases that will be diagnosed among contacts exposed during travel (Table 13). Tuberculosis contact investigations only occur for international flights with the very rare exception of a domestic flight with a duration greater than 8 hours. The numbers of contacts and outcomes are

much more uncertain for other diseases. The number of tuberculosis cases are adjusted from the number of contacts with tuberculosis by assuming that only 5% (lower bound) to 10% (upper bound) of infected contacts will go on to develop clinical disease.<sup>39</sup>

For viral hemorrhagic fevers and MERS, there is no evidence of transmission, but there have not been very many observations.

<sup>33</sup> Coleman M, Marienau K, Marano N, Marks S, Cetron M, Dis TMI. Economics of United States Tuberculosis Airline Contact Investigation Policies. Travel Medicine and Infectious Disease. 2014;12:63–71.

<sup>34</sup> Marienau KJ, Burgess GW, Cramer E, et al. Tuberculosis investigations associated with air travel: US Centers for Disease Control and Prevention, January 2007–June 2008. Travel Med Infect Dis 2010;8:104e12.

<sup>35</sup> Mangili A, Gendreau MA. Transmission of infectious diseases during commercial air travel. Lancet. 2005;365:989–96.

<sup>36</sup> Anderson RM. The concept of herd immunity and the design of community-based immunization programmes. Vaccine. 1992;10(13):928–35.

<sup>37</sup> Chapter 14. Meningococcal Disease, The Pink Book, CDC <http://www.cdc.gov/vaccines/pubs/pinkbook/mening.html> Accessed 5/2/2016.

<sup>38</sup> Marienau KJ, Burgess GW, Cramer E, et al. Tuberculosis investigations associated with air travel: US Centers for Disease Control and Prevention, January 2007–June 2008. Travel Med Infect Dis 2010;8:104e12.

<sup>39</sup> Coleman M, Marienau K, Marano N, Marks S, Cetron M, Dis TMI. Economics of United States Tuberculosis Airline Contact Investigation Policies. Travel Medicine and Infectious Disease. 2014;12:63–71.

TABLE 13—ANNUAL ESTIMATED NUMBER OF CASES AMONG INTERNATIONAL PASSENGER CONTACTS BY DISEASE

Passengers per flight	Number of contacts	Expected incidence among contacts (lower bound)	Expected incidence among contacts (upper bound)	Expected number of new cases (lower bound)	Expected number of new cases (upper bound)
MERS Coronavirus (quarantinable) .....	101	Insufficient data			
Measles (non-quarantinable) .....	1,069	0.0034	0.0095	3.6	10.1
Meningococcal Disease (non-quarantinable) .....	1.7	0.00200	0.00400	0.0033	0.0067
Pertussis (non-quarantinable) .....	16.8	0.001	0.003	0.02	0.04
Rubella (non-quarantinable) .....	117	0.002	0.006	0.2	0.7
TB <sup>a</sup> (quarantinable) .....	1,995	<sup>b</sup> 0.19	<sup>b</sup> 0.24	<sup>c</sup> 18.9	<sup>c</sup> 47.90
Viral Hemorrhagic Fever (quarantinable) .....	62.0	Insufficient data			
Total .....	3,362	.....	.....	22.8	58.7

<sup>a</sup> For tuberculosis, travelers contacts are typically found to test positive for infection, but do not have active disease.

<sup>b</sup> These probabilities indicate the likelihood that a contact will test positive for infection.

<sup>c</sup> The expected numbers of cases adjust for the finding that only 5–10% of individuals that test positive for infection will go on to develop clinical disease.

These estimates of cases may be a lower bound, because potential cases resulting from flights in which contact investigations were not performed are not included. Especially for tuberculosis cases, many international travelers may return to their home countries before seeking treatment and such cases may not lead to contact investigations if HHS/CDC is not informed.

Marginal Costs of Final Rule

Data Collection

Since the final rule does not change the timeframe or amount of data requested from airlines or vessel operators, the most likely economic impact is a small change in the amount of effort for airlines to provide more complete and timely information. To the extent that airlines would respond more quickly or with additional data, it would require some airline information technology staff to expedite requests or to search in more depth for available data. HHS/CDC estimates this may require one hour of staff time per request. HHS/CDC has no way to predict how much more complete, timely, or accurate contact from airlines would become as a result of this final rule. On

average, HHS/CDC acted upon 77 requests per year to airlines for international traveler contact data between 2010 and 2015 (Table 6). In addition, HHS/CDC made 22.5 requests per year for interstate traveler data (Table 7) over the same period. There were 45 contact investigations per year among travelers on vessels (Table 8); however, most of these were undertaken before travelers disembarked vessels in which case contact data could be collected directly from exposed travelers as part of the investigation. The number of maritime contact investigations requiring manifest requests after disembarkation is estimated to be less than 10 per year.

Overall, including international air and maritime activities, the estimated number of contact data requests after disembarkation was estimated at 100 to account for the fact that HHS/CDC sometimes requests traveler contact data for infectious disease events prior to confirmed diagnoses. On occasion, it turns out that travelers are not infected with diseases that require a public health response. This rounding up should also account for a year in which there is a significant increase in the

number of contact investigations among exposed air or maritime travelers. HHS/CDC notes the manifest order process for interstate flights is not codified in the final rule. The data is provided here for completeness.

The average wages for computer and information systems managers (occupation code 11–3021) reported in the Bureau of Labor Statistics, May 2015 Occupational Employment Statistics<sup>40</sup> were \$63.27 per hour. On average, under the baseline, HHS/CDC assumes that it would require 6 hours of work by airlines to search databases and provide data. For the final rule, HHS/CDC assumes that a management-level computer specialist will spend additional time to provide the best possible contact data for potentially exposed travelers. The base salary is multiplied by an overhead multiplier of 100% to account for non-wage benefits and other overhead costs for supporting each employee (Table 14). The lower bound estimate (\$0) is no change from current practice, while the upper bound estimate assumes 2 hours of time instead of one (\$25,308). These costs are applied to an estimated 100 manifest requests per year.

TABLE 14—ESTIMATE OF COSTS FOR AIRLINES AND VESSEL OPERATORS TO IMPROVE COMPLIANCE WITH HHS/CDC REQUESTS FOR TRAVELER CONTACT DATA, 2015 USD

	Average number of manifest requests per year	Increased effort to provide more complete or timelier passenger contact data (hrs.)	Average hourly wage rate of IT staff (2015 USD)	Overhead multiplier (%)	Total cost
Baseline .....	100	6	\$63.27	100	\$75,924
Best estimate .....	100	1	63.27	100	12,654

<sup>40</sup> [http://www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm).

TABLE 14—ESTIMATE OF COSTS FOR AIRLINES AND VESSEL OPERATORS TO IMPROVE COMPLIANCE WITH HHS/CDC REQUESTS FOR TRAVELER CONTACT DATA, 2015 USD—Continued

	Average number of manifest requests per year	Increased effort to provide more complete or timelier passenger contact data (hrs.)	Average hourly wage rate of IT staff (2015 USD)	Overhead multiplier (%)	Total cost
Lower bound .....	100	0	63.27	100	0
Upper bound .....	100	2	63.27	100	25,308

Illness Reporting Costs

When reports are received, public health officers at Quarantine Stations perform case assessments, may request follow-up information, and may consult with HHS/CDC medical officers to determine if additional action such as a contact investigation, onboard response, or notification to State and local health departments is warranted. Under one assumed upper bound scenario, the change in the definition of “ill person” included in the final rule could result in a 100% increase in the number of info-only reports from airlines and a 25% increase from vessels. On average, there are 129 info-only reports for aircraft and vessels each year and these increases would correspond to an annual increase of 119 info-only reports on aircraft and 3 info-only reports on vessels (Table 15). If the average time for each report is estimated to be 2 minutes for aircraft pilots in command or masters of vessels to make the report, 10 minutes for a traveler to discuss the illness with

public health officer, and 60 minutes for HHS/CDC to document the info-only report, the estimated cost of the additional reports can be estimated based on the opportunity cost of time for each type of personnel. In addition to the time required for aircraft pilots in command and masters of vessels to make reports, the personnel in the Department of Transportation’s Federal Aviation Administration (DOT/FAA) may incur additional costs to relay reports of suspected cases of communicable disease received by air traffic control to CDC through the Domestic Events Network. The amount of DOT/FAA staff time is estimated at 26 minutes for a government employee at GS-level 15, step 6 based in Washington, DC. In reality, there would be three DOT/FAA employees involved including 1 GS–15/16 level employee at air traffic control (10 minutes), 1 GS–15 level employee at the Domestic Events Network (10 minutes), and 1 GS–14 level employee at DOT/FAA’s

Washington Operations Center Complex (6 minutes).<sup>41</sup>

For aircraft pilots in command or masters of vessels (occupation codes 53–2011 and 53–5021) and travelers (average across all occupations code 00–0000), their opportunity cost is estimated from Bureau of Labor Statistics, May 2015 Occupational Employment Statistics<sup>42</sup> based on the average salary of aircraft pilots or copilots (\$57.35 per hour), traveler (\$23.23 per hour) or vessel captain, mate, or pilot (\$39.95 per hour). For HHS/CDC employees, the average wage rate is based on the Federal government’s general salary scale for a GS–12, step 5 employee based in Atlanta, GA). Base salaries are multiplied by an overhead multiplier of 100% to account for non-wage benefits and other overhead costs for supporting each employee. Travelers do not have overhead costs. The annual quantified costs of 122 additional info-only reports would be \$17,471.

TABLE 15—CHANGES IN NUMBERS OF INFO-ONLY REPORTS AND ASSOCIATED COSTS FOR THE FINAL RULE UPPER BOUND, 2015 USD

Employee type	Change in number of info-only reports	Amount of time required per report (min)	Estimated wage rate (2015 USD per hr.)	Overhead multiplier (%)	Estimated cost
<b>Aircraft:</b>					
Aircraft Pilots or Copilots .....	119	2	\$57.35	100	\$455
CDC employee .....	119	60	39.83	100	9,480
DOT/FAA employees .....	119	26	70.57	100	7,278
Traveler .....	119	10	23.23	0	461
Air total .....					17,213
<b>Vessels:</b>					
Air or maritime conveyance officer .....					
Captains, Mates, and Pilots of Water Vessels .....	3	2	39.95	100	8
CDC employee .....	3	60	439.83	100	239
Traveler .....	3	10	23.23	0	12
Maritime total .....					259
Total costs, aircraft and vessels .....					17,471

Notes: Assumes 100% increase in info-only reports from airlines and 25% from vessel operators.

<sup>41</sup> Personal communication between Dr. Brian Maskery and DOT/FAA.

<sup>42</sup> [http://www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm).



Besides the possible change in costs of info-only reports, the other potential change would be an increase in the number of reports that require HHS/CDC follow-up. Under the most likely scenario, there will not be a change in these reports since the new definition better corresponds to HHS/CDC guidance and to reporting guidelines published by ICAO in Note 1 to paragraph 8.15 of Annex 9 to the Convention on International Civil Aviation. However, there may be an increase in the number of reports requiring a response. Under this scenario, there may be an increase in costs for air or masters of vessels to report illnesses. The upper bound increase in reports requiring response is assumed to be 50% of the average annual illness reports from airlines and a 10% increase from vessels (refer to Tables 10 and 11 for baseline number of

reports): 29 reports per year on aircraft and 21 reports per year on vessels. HHS/CDC assumes that the time required to submit illness reports and for DOT/FAA staff to relay reports requiring responses is the same as for info-only reports (2 minutes for pilots in command and masters of vessels and 26 minutes for DOT/FAA to relay reports, Table 16). Further, HHS/CDC assumes that travelers could spend up to 60 minutes talking to HHS/CDC and/or State and local public health officers for reports requiring response. The upper bound estimate of total costs associated with the increase in the number of illness reports requiring response is estimated to be \$3,102.

There would likely be no change or a decrease in HHS/CDC costs because earlier reporting would lead to a more efficient HHS/CDC response relative to an alternative in which the illness was

not reported during travel, but instead was later reported by a public health department to HHS/CDC. In addition, the public health response to the illness would likely be more efficient because exposed travelers could be contacted earlier. In rare situations, such travelers may potentially be informed of their potential exposure at the gate after disembarking the aircraft or vessel. Such actions should not result in significant delays by holding travelers on board.

HHS/CDC did not include any training costs because the change in the “ill person” definition in this final rule is consistent with the internationally recognized and accepted illness reporting guidelines published by ICAO for international travelers and represents a reduced burden compared to the previous illness reporting regulations for interstate travelers.

TABLE 16—CHANGES IN ANNUAL NUMBERS OF REPORTS REQUIRING RESPONSE AND ASSOCIATED COSTS FOR THE FINAL RULE UPPER BOUND, 2015 USD

Employee type	Change in number of reports	Amount of time required per report (min)	Estimated wage rate (2015 USD per hr.)	Overhead multiplier (%)	Estimated cost (2015 USD)
<b>Aircraft:</b>					
Aircraft Pilots or Copilots .....	29	2	\$57.35	100	\$111
CDC employee .....	29	0	39.83	100	0
DOT/FAA employee .....	29	26	70.57	100	1,774
Traveler .....	29	60	23.23	0	674
<b>Total .....</b>					<b>2,558</b>
<b>Vessels:</b>					
Captains, Mates, and Pilots of Water Vessels .....	21	2	39.95	100	56
CDC employee .....	21	0	39.83	100	0
Traveler .....	21	60	23.23	0	488
<b>Total .....</b>					<b>544</b>
<b>Total .....</b>					<b>3,102</b>

**Notes:** Assume 50% increase in air illness and a 10% increase in maritime illness reports requiring response (international and interstate).

There may also be a one-time cost associated with updating training to reflect the new regulatory text. As noted above, HHS/CDC reiterates that the change to regulatory text is a codification of HHS/CDC guidance and better aligns with international guidance (Note 1 to paragraph 8.15 of Annex 9 to the Convention on International Civil Aviation). Further for interstate travel, these changes result in relaxed illness reporting compared to status quo regulatory text. Thus any airlines using either ICAO or HHS/CDC guidance to support training efforts for illness reporting should not need to change training materials. At most, it may be necessary to clarify that some symptoms that were previously requested are now required. However, for some airlines or

vessel operators, it may be necessary to revise training materials.

The cost of training was estimated based on the number of pilots and flight attendants and their average wage rates as reported in the Bureau of Labor Statistics, May 2015 Occupational Employment Statistics.<sup>43</sup> HHS/CDC assumes that the opportunity cost of employee time spent in training would be the primary cost as opposed to the cost of developing training materials. As an upper bound, HHS/CDC assumed the cost of training could be estimated based on assuming that all employees would require 10 minutes of training to summarize the changes. As noted above, since this change aligns regulatory text

with existing HHS/CDC and ICAO guidance documents, this change may not result in a new training requirement for all airlines since some presumably already use HHS/CDC guidance in training. This 10 minute estimate does not necessarily mean all 230,000 pilots and flight attendants each require 10 minutes of training. For example, 50% of each could require 20 minutes of training, while the other 50% may already conduct training in accordance with either CDC or ICAO guidance. The total cost of the one-time change in training is about \$3.1 million. If this cost is annualized over 10 years, the average annual cost depends on the discount rate assumed and varies from \$313,000 per year (7% discount rate) to \$416,000 (0% discount rate). These

<sup>43</sup> [http://www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm).

results are summarized in Table 17. These costs (3% discount rate) are added to the upper bound cost estimate

for illness reporting. The lower bound and best estimates are \$0 since the

changes to the definition better align with existing CDC and ICAO guidance.

TABLE 17—ESTIMATED COSTS FOR ONE-TIME TRAINING ABOUT CHANGES IN ILLNESS REPORTING FOR AIRLINES, 2015 USD

Employee type	Number of employees	Amount of time required for training per employee (minutes)	Estimated wage rate (2015 USD per hr.)	Overhead multiplier (%)	Estimated cost or benefit (2015 USD)	
Aircraft Pilots or Copilots .....	121,110	10	57.35	100	2,315,220	
Flight attendants .....	108,510	10	22.46	100	812,465	
Total .....					3,127,685	
Annualized cost over 10-year time horizon	3% discount rate ...	\$355,981	0% discount rate ...	\$416,179	7% discount rate ...	\$312,768

The monetized annual costs resulting from the change in the definition of “ill

person” are summarized in Table 18. The benefits in regard to reductions in

communicable disease transmission are summarized in a subsequent section.

TABLE 18—BEST ESTIMATE, LOWER BOUND AND UPPER BOUND OF THE CHANGES IN ANNUAL MONETIZED BENEFITS AND COSTS AS A RESULT OF THE CHANGE TO THE REPORTABLE ILLNESS DEFINITION, 2015 USD

	Best estimate	Lower bound	Upper bound
<b>Costs</b>			
Final Rule:			
Aircraft .....	\$0	\$0	\$375,751
Vessels .....	0	0	802
Total .....	0	0	376,554

The total costs of the final rule are summarized in Table 19 and include the

costs of the change to the definition of an “ill person” and the codification of

the requirement for airlines to provide passenger contact data for the final rule.

TABLE 19—TOTAL COSTS AND BENEFITS RESULTING FROM CODIFICATION OF TRAVELER DATA COLLECTION (71.4 AND 71.5) AND CHANGE TO DEFINITION OF “ILL PERSON” (70.1 AND 71.1)

	Best estimate	Lower bound	Upper bound
<b>Costs</b>			
Final Rule:			
71.4 and 71.5 Passenger data collection .....	\$12,654	\$0	\$25,308
70.1 and 71.1 Change in definition of an “ill person” .....	0	0	376,554
Total costs .....	12,654	0	401,862

Benefits From Streamlining the CI Process for Routinely Imported Diseases

This section reports the benefits that HHS/CDC anticipates from implementation of the final rule in avoiding the costs incurred annually for CIs of infectious diseases. The model for estimating the benefits of CIs is: Current number of CIs × (reduction in HHS/CDC and health department staff time/resources per contact) × value of staff time.

HHS/CDC obtained the total number of contacts traced (2,715 per year, Table

6) for all diseases reported on international flights. International flight data were extracted for this analysis because the codification of the requirements to provide timelier and more complete contact data is limited to international arrivals. In comparison, HHS/CDC requests contact information for approximately 664 contacts per year on interstate flights (Table 7). HHS/CDC also supports contact investigations affecting an average of 762 contacts per year for illnesses on board vessels (Table 8); however, many of these investigations occur before travelers

disembark vessels. By limiting the analysis to contacts on international flights, HHS/CDC conservatively estimates the potential benefits associated with this final rule. HHS/CDC multiplied the average annual number of contacts on international flights by the cost-per-contact for HHS/CDC and PHDs (Table 11) to estimate the costs of CIs under the current baseline.

To estimate the benefits (Tables 20 and 21), HHS/CDC assumed a percent reduction in staff time for CIs at HHS/CDC (0–3%) and PHD levels (0–2%)

based on internal conversations with personnel directly involved in the CI process. The reduction in staff time that would result from implementation of this final rule would arise from the ability of HHS/CDC to have a better starting point with which to provide traveler contact data to State and local health departments as a result of the receipt of more complete and timely traveler contact data from airlines. The impact of codification is expected to be limited and would depend on instances in which airlines have more data than what is currently provided to DHS. Better data would improve HHS/CDC's ability to transmit information to destination States more quickly and for States to contact exposed travelers earlier. This would allow States to start their investigations more quickly, contact more travelers faster to conduct public health assessments and potentially offer preventive medications

or vaccines in a more timely fashion or to recommend self-monitoring to mitigate onward transmission. In addition, it would be less likely that HHS/CDC would send incorrect contact data to States. With all of the preceding factors in mind, HHS/CDC estimated that the final rule would reduce labor time by between 0% to 3% at HHS/CDC, and 0% to 2% at PHDs. The higher percentage of avoided costs at HHS/CDC reflect reduced efforts by HHS/CDC to search for accurate contact data for travelers due to untimely or inaccurate data. The lower percentage of avoided costs at PHDs reflects a more diffuse (e.g., multiple local PHDs in a State) infrastructure and the more labor-intensive tasks of following up on individuals. These estimates are small because the change is a clarification and codification of a current practice authorized under broad statutory and regulatory authority rather than a new

regulatory requirement. In addition, the change to the definition of "ill person" may lead to the earlier diagnoses of some travelers with communicable disease, which may lead to earlier and more efficient public health responses.

HHS/CDC annual costs to engage in international air, interstate air, and maritime CIs are about \$745,000 or roughly the equivalent of 3.8 HHS/CDC full-time employees (FTEs) at the wage level of GS-13, step 4 plus benefits and overhead (Table 21). The final rule should have the greatest effect on the international air CIs. The annual reduction in contact tracing costs from implementing the final rule (Table 22) for HHS/CDC ranged from \$0 to \$14,661 based on a 0–3% reduction in effort on international CIs. For PHDs, the reduction in costs ranged from \$0 at the lower bound to \$9,774 at the upper bound (Table 22).

TABLE 20—ANNUALLY FOR HHS/CDC AND PHD: BASELINE COSTS

	Annual number contacts	HHS/CDC	PHD costs	Total costs
<b>HHS/CDC and PHD Baseline Costs (Current Practice)</b>				
International air contacts .....	2,715	\$488,700	\$488,700	\$977,400
Interstate air contacts .....	664	119,520	119,520	239,040
Maritime contacts .....	762	137,160	137,160	274,320
Total baseline costs .....	4,141	745,380	745,380	1,490,760
Viral hemorrhagic fever, MERS, and SARS contacts .....	163	29,340	29,340	58,680

TABLE 21—ANNUAL FOR HHS/CDC AND PHDs: BASELINE COSTS, FINAL RULE COSTS, BENEFITS WITH THE FINAL RULE (NUMBER CONTACTS ANNUALIZED FROM JANUARY 2010 TO DECEMBER 2015), 2015 USD

<b>HHS/CDC and PHD Baseline Costs (Current Practice)</b>				
	Annual number contacts	HHS/CDC	PHD	
International contacts .....	2,715	\$488,700	\$488,700	
<b>HHS/CDC and PHD Costs With the Final Rule</b>				
	Estimated Costs for HHS/CDC After Efficiency Improvement with Final Rule		Estimated Costs for PHDs After Efficiency Improvement with Final Rule	
	0%, Lower bound	3%, Upper bound	0%, Lower bound	2%, Upper bound
International contacts costs assuming reduction in time (2,715) ....	\$488,700	\$474,039	\$488,700	\$478,926
<b>Benefits From Implementing the Final Rule</b>				
	HHS/CDC 0% and 3% Reduction in effort		PHD (0% and 2% Reduction in effort)	
Benefits (Reduced costs) .....	\$0	\$14,661	\$0	\$9,774

The best estimate of benefits are the midpoint of the lower bound and upper bound estimates for both HHS/CDC and

PHDs (\$12,218). The lower bound (\$0) and upper bound estimates (\$24,435) for

both entities are also reported in Table 22.

TABLE 22—BEST ESTIMATE, LOWER BOUND AND UPPER BOUND OF BENEFITS FROM INCREASED EFFICIENCIES FOR HHS/ CDC AND PHDS TO CONDUCT CONTACT INVESTIGATIONS WITH PROVISION OF BETTER DATA FROM AIRLINES (FINAL RULE), 2015 USD

	HHS/CDC benefits	PHD benefits	Total
Best estimate .....	\$7,331	\$4,887	\$12,218
Lower bound .....	0	0	0
Upper bound .....	14,661	9,774	24,435

The total annual monetized benefits by stakeholder from the potential reduced effort for contact investigations are summarized in Table 23.

TABLE 23—BEST ESTIMATE, LOWER BOUND AND UPPER BOUND OF BENEFITS FROM INCREASED EFFICIENCIES FOR HHS/ CDC AND PHDS TO CONDUCT CONTACT INVESTIGATIONS WITH PROVISION OF BETTER DATA FROM AIRLINES, 2015 USD

	HHS/CDC benefits, USD	PHD benefits, USD	Airlines, USD	Total
Best estimate .....	\$7,331	\$4,887	\$0	\$12,218
Lower bound .....	0	0	0	0
Upper bound .....	14,661	9,774	0	24,435

Marginal Impact of Final Rule—Measles Health Outcome Benefits

On average, HHS/CDC identified 564 travelers exposed to measles cases on international flights during 2010–2015 (Table 6). The final rule may affect the cost for health departments to implement public health measures in two ways: (1) Health departments may contact exposed travelers more quickly and (2) health departments may be able to contact a higher percentage of exposed travelers. For the first set of travelers that are contacted earlier with the final rule than under the status quo, the cost to both the contacted travelers and to health departments should be less than under the status quo. For measles contacts, earlier follow-up with public health departments should lead to more travelers being offered voluntary measles vaccines within 72 hours. This would potentially reduce the cost of following up with exposed travelers at which time health departments could offer to administer immune globulin or health departments may monitor travelers that have been located after the 72-hour window in

which measles vaccination would reduce their risk of developing symptomatic measles. At present, very few travelers receive post-exposure prophylaxis, 11/248 or 4.4%.<sup>44</sup> In addition, health departments have implemented quarantine (usually voluntary) for unvaccinated, high risk measles exposures.<sup>45</sup> HHS/CDC notes that measles is not a quarantinable communicable disease under Federal regulations, but may be quarantinable under a State’s authorities. HHS/CDC also notes that measles vaccine is recommended for all persons lacking immunity. Thus, the costs of vaccination for exposed travelers as part of the contact investigation may have been incurred at a later date if travelers’ health care providers recommended measles vaccination at a more routine health care visit in the future.<sup>46</sup> However, to be conservative, HHS/CDC includes the full additional cost to administer such vaccines to persons contacted.

Among the contacts, HHS/CDC estimates that approximately 25% (141 contacts per year) cannot be located by

public health departments (Table 24), either because HHS/CDC cannot assign the contacts to health departments or because the information provided by HHS/CDC is not sufficient to enable health departments to locate contacts after assignment from HHS/CDC. Among these contacts, HHS/CDC assumes that 10% of all contacts (56) are not located because HHS/CDC cannot assign contacts to State health departments due to insufficient data. For these contacts, health departments would not incur any contact tracing costs because such contacts would not be assigned. HHS/CDC assumes a 15% improvement from baseline as a result of this final rule (Table 24). This would result in 8.5 additional contacts per year assigned to health departments for contact tracing. As shown in Table 11, HHS/CDC estimates that health departments incur an estimated cost of \$180 per contact. The marginal cost incurred from this final rule for additional measles contacts assigned to health departments would be  $180 \times 8.5 = \$1,530$  per year (Table 25).

TABLE 24—ESTIMATED MARGINAL IMPROVEMENT IN THE NUMBERS OF MEASLES CONTACTS WHO COULD BE TREATED WITH FINAL RULE

Description	n	Reference
Average contacts per year for measles, (a) .....	564	Table 6.
Estimated number of contacts for which HHS/CDC cannot assign to a health department, (b) = 10% × (a).	56	Nelson et al. 2013. <sup>47</sup>

<sup>44</sup> Nelson K, Marienau K, Schembri C, Redd S. Measles transmission during air travel, United States. *Travel Medicine and Infectious Disease* (2013) 11, 81e89. 2013;11:81–9.

<sup>45</sup> P Kutty, J Rota, W Bellini, SB Redd, A Barskey, G Wallace. (2014) *Manual for the Surveillance of Vaccine-Preventable Diseases: Chapter 7 Measles.* <http://www.cdc.gov/vaccines/pubs/surv-manual/chpt07-measles.html> Accessed 5/8/2016.

<sup>46</sup> CDC (2015) *Epidemiology and Prevention of Vaccine-Preventable Diseases: Measles.* <http://www.cdc.gov/vaccines/pubs/pinkbook/meas.html> Accessed 5/8/2016.

TABLE 24—ESTIMATED MARGINAL IMPROVEMENT IN THE NUMBERS OF MEASLES CONTACTS WHO COULD BE TREATED WITH FINAL RULE—Continued

Description	n	Reference
Estimated improvement in HHS/CDC's ability to assign contacts to health department (c) = 15% × (b).	8.5	Assumption.
Numbers of people who are not currently contacted due to lack of contact information, (d) = (a) × 25%.	141	Nelson et al. 2013.
Expected numbers of people who could be contacted with final rule, (e) = (d) × 15% .....	21	Assumption.
Among those contacted, 70% would have evidence of measles immunity (f) = (e) × 70% .....	15	Nelson et al. 2013 (Table 2).
Among those contacted, 30% may be susceptible to measles (g) = (e) × 30% .....	6	Nelson et al. 2013 (Table 2).

<sup>47</sup>Nelson, K., Marienau, K.J., Schembri, C. and Redd, S. (2013). "Measles transmission during air travel, United States." *Travel Medicine and Infectious Disease* (2013) 11, 81e89 11: 81–89.

TABLE 25—ESTIMATED MARGINAL COSTS FOR HEALTH DEPARTMENTS TO CONTACT EXPOSED TRAVELERS AND OFFER MEASLES POST-EXPOSURE PROPHYLAXIS (VACCINATION), 2015 USD

Number of additional names sent to health department, (c) .....	8.5
Additional cost per contact to health department to search for and examine contacts (USD per contact) (h) .....	\$180
Additional cost to health department to search for contacts, total (USD), (i) = (c) × (h) .....	\$1,530
MMR vaccine price per dose (USD) (j) .....	\$39
Vaccine administration (k) .....	\$31
Estimated cost prophylactic measles vaccine per person (USD), (l) = (j) + (k) .....	\$70
Number of individuals who may receive measles vaccine, (g) .....	6
Cost of measles vaccination, total (USD) (m) = (g) × (l) .....	\$420
Total additional annual cost to follow up with more contacts (USD), (i) + (m) .....	\$1,950

In addition, HHS/CDC assumes that the final rule could improve health departments' abilities to contact 15% of those who could not be currently contacted because of insufficient contact information (21 contacts per year). HHS/CDC does not have any data to measure the magnitude of improvement and applies a range of 10% to 20% to calculate lower and upper bounds. If airlines and vessel operators do not have any additional data besides what is already transmitted to DHS, there will

be very little improvement. Among the 21 additional exposed travelers that would be contacted, 70% of them (15 per year) are expected to have measles immunity because they were born before 1957, had history of measles, or received one or more doses of measles vaccine. The remaining 6 travelers per year without proven measles immunity would incur additional costs if they are vaccinated (vaccine costs + vaccine administration, Table 25).

To be conservative, HHS/CDC assumes that all 6 exposed travelers

would be adults and would be vaccinated with the measles-mumps-rubella (MMR) vaccine. The vaccine price for adults is estimated from the Vaccines for Children vaccine price archives (July 2014 and July 2015)<sup>48</sup> based on the public sector price for the vaccine. Vaccine administration costs are estimated from Healthcare Solutions' 2015 Physicians' Fee & Coding Guide (CPT 90471).<sup>49</sup> Total costs resulting from the final rule are summarized in Table 26.

TABLE 26—MARGINAL IMPACT OF FINAL RULE TO IMPROVE CONTACT INVESTIGATIONS

Marginal cost for measles investigations	Additional names provided to health departments	Addition contacts reached by health departments	Number of travelers provided post-exposure prophylaxis	Number of travelers identified earlier	Average probability that contact is infected
\$1,950 .....	8.5	21	6	Unknown .....	0.0035–0.0095

In the absence of interventions by public health departments, travelers infected with measles during international travel would be as likely as any other individuals to spark a measles outbreak. In the absence of HHS/CDC efforts to retrieve and transmit contact data, public health departments would not be able contact travelers to offer post-exposure prophylaxis and/or to recommend self-

monitoring for potential measles symptoms.

For measles in 2011, 16 outbreaks occurred leading to 107 cases. An outbreak was defined based on 3 or more cases in a cluster.<sup>50</sup> The remaining 113 cases reported in 2011 resulted in one or two cases per cluster. Thus, the probability that any individual measles index case leads to an outbreak was between 16/(16+113) = 12.4% and 16/

(16+57) = 20.1%. The lower bound represents an assumption that all of the 113 cases unassociated with outbreaks of 3 or more cases occurred in clusters with just one case each. The upper bound represents a scenario with 56 clusters of two cases each with one cluster with one case. Thus, the probability that any individual measles case could spark an outbreak of 3 or more cases is 12.4% to 20.1%. The

<sup>48</sup> <http://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/price-list/archive.html> Accessed 5/2/2016.

<sup>49</sup> InGauge Healthcare Solutions. 2015 Physicians' Fee & Coding Guide. Atlanta GA2013.

<sup>50</sup> Ortega-Sanchez IR, Vijayaraghavan M, Barskey AE, Wallace GS. The economic burden of sixteen

measles outbreaks on United States public health departments in 2011. *Vaccine*. 2012;32(11).

average cost to public health departments per measles outbreak is \$250,000 and the upper bound cost is \$1 million.<sup>51</sup>

HHS/CDC assumes that the probability that a measles case resulting from exposure during travel and that is not contacted by a public health department is as likely as any other measles case to initiate a measles outbreak of 3 or more cases, which occurs at an approximate probability of 12.4% to 21.9%. The average cost to health departments is \$250,000 for each of these outbreaks and the average outbreak size is about 7 cases (107 cases/16 outbreaks).

The estimated illness costs for measles are \$300 (\$86–\$515) for outpatient cases and \$24,500 (\$3,900–\$45,052) for inpatient cases.<sup>52</sup> The probability of hospitalization is estimated to be 44.3%.<sup>53</sup> A range of hospitalization rates is estimated based on 50% to 150% of this base case estimate (22%–66%). The measles case fatality rate has been estimated to be 0.2%.<sup>54</sup> HHS/CDC assumes that the value of statistical life is \$9.4 million (range \$4.3 million to \$14.2 million). This value is an estimate of the average willingness to pay to reduce one’s mortality risk by a small increment not an estimate of the value of any specific

person’s life. For example if 1,000 people were willing to pay \$1,000 each to reduce their risk of death by 1/1,000, the value of statistical life would be equal to \$1,000/0.001 change in risk of death = \$1 million. Alternatively 1,000 people each experiencing a mortality risk reduction of 0.001 would correspond to 1,000 people × 0.001 mortality risk reduction = 1 statistical life; 1,000 people each willing to pay \$1,000 = 1,000 × \$1,000 = \$1 million to avert that one statistical death. Using these estimates, the average illness costs associated with a measles case (Table 27) is about \$30,000 (\$9,500 to \$58,000).

TABLE 27—ESTIMATED ILLNESS AND MORTALITY COSTS PER MEASLES CASE

	Best estimate	Lower bound	Upper bound
Outpatient cost, a	\$300	\$86	\$515
Inpatient cost, b	\$24,500	\$3,943	\$45,052
Hospitalization rate, c	44.30%	22.0%	66.0%
Case fatality rate, d	0.2%	0.2%	0.2%
VSL, e	\$9,400,000	\$4,300,000	\$14,200,000
Total cost per case (b × c + a × (1 – c) + d × e)	\$29,821	\$9,535	\$58,309

The estimated number of measles cases that will occur in contacts exposed during travel (3.6 to 10.1) can be multiplied by the probability of an outbreak with 3 or more cases (12.4% to 21.7%) to estimate the expected number

of outbreaks in the absence of public health intervention to conduct contact investigations in exposed travelers. For each outbreak, HHS/CDC assumes that an average of 6 additional cases occur with associated morbidity and mortality

costs. The estimated costs of measles outbreaks in the absence of contact investigations for exposed travelers is presented in Table 28.

TABLE 28—ESTIMATED ILLNESS, MORTALITY, PUBLIC HEALTH RESPONSE COSTS ASSOCIATED WITH MEASLES OUTBREAKS

	Best estimate	Lower bound	Upper bound
Estimated number of measles cases among contacts, a	6.85	3.6	10.1
Probability of measles outbreak, b	17	12.4	21.9
Number of additional cases per outbreak, c	6	6	6
Estimated number of outbreaks, d = a × b	1.18	0.45	2.22
Estimated number of outbreak cases, e = a × b × c	7.06	2.68	13.29
Estimated health department costs per outbreak, f	250,000	250,000	250,000
Estimated health department costs, g = f × d	293,989	111,607	553,758
Average cost per case, h	29,821	9,535	58,309
Estimated illness costs, i = h × e	210,406	25,539	774,944
Estimated total costs, g + i	504,395	137,146	1,328,703

HHS/CDC has not received any reports of large measles outbreaks associated with measles cases in patients exposed during travel and contacted by State or local public health departments. As a result, HHS/CDC believes that when measles cases occur in contacts reached by health departments, the probability of an

outbreak is significantly mitigated by pre-warning of exposure before disease outset. Given that HHS/CDC estimates that health departments are able to reach approximately 75% of contacts under the status quo, HHS/CDC assumes that the risk of an outbreak has been reduced by at least 60% under the status quo. Further, HHS/CDC assumes that

the provisions in the final rule further improve health departments’ ability to prevent measles outbreaks in cases that occur among travelers exposed during flights. A modest improvement of 15% is assumed (range 10%–20%) resulting in estimated benefits of about \$45,000 (\$8,000 to \$159,000) in Table 29.

<sup>51</sup> Ortega-Sanchez IR, Vijayaraghavan M, Barskey AE, Wallace GS. The economic burden of sixteen measles outbreaks on United States public health departments in 2011. *Vaccine*. 2012;32(11).

<sup>52</sup> Zhou F, Shefer A, Wenger J, Messonnier M, Wang LY, Lopez A, et al. Economic Evaluation of the Routine Childhood Immunization Program in

the United States, 2009. *Pediatrics*. 2014;133:577–85.

<sup>53</sup> Mason WH, Ross LA, Lanson J, Wright HT. Epidemic measles in the postvaccine era: evaluation of epidemiology, clinical presentation, and complications during an urban outbreak. *Pediatr Infect Dis J*. 1993;12:42–8.

<sup>54</sup> Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases, 13th Edition—Measles* April 2015 <http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/meas.pdf>. Accessed 6/13/2016.

TABLE 29—ESTIMATED BENEFITS ASSOCIATED WITH IMPROVEMENT OF MEASLES CONTACT INVESTIGATIONS AS A RESULT OF THIS FINAL RULE

	Best estimate	Lower bound	Upper bound
Estimated total costs without intervention, $j = g + i$ .....	\$504,395	\$137,146	\$1,328,703
Estimated effectiveness of outbreak prevention baseline, $k$ .....	60%	60%	60%
Estimated cost of measles outbreaks under baseline, $j \times (1 - k)$ .....	\$201,758	\$54,858	\$531,481
Estimated effectiveness of outbreak prevention with final rule, $l$ .....	69%	66%	72%
Estimated cost of measles outbreaks with final rule, $m = j \times (1 - l)$ .....	\$156,363	\$46,630	\$372,037
Estimated benefit associated with final rule, $n = j - m$ .....	\$45,396	\$8,229	\$159,444

Marginal Impact on Tuberculosis Investigations

Although measles is not a quarantinable disease and tuberculosis is a quarantinable disease, HHS/CDC's and health departments' approaches to contact investigations are relatively similar. However, HHS/CDC may issue isolation orders for individuals with active tuberculosis in some situations, but would not have authority to issue isolation (or quarantine orders) for individuals with measles. The expected benefits associated with reduced tuberculosis morbidity and mortality of contact investigations for exposed travelers are based on a previous analysis, which estimated a return on investment of \$1.01 to \$3.20 for the baseline situation in which an estimated 19% of exposed contacts are found to

have latent tuberculosis infection.<sup>55</sup> The contact rate for exposed tuberculosis contacts is probably higher than for measles because the vast majority of tuberculosis contacts are exposed during international travel as exposed to measles contacts, which are approximately evenly divided between interstate and international travel.

The estimated costs to provide testing and treatment to contacts that test positive for latent tuberculosis infection are estimated to be \$1,044 for infected contacts that complete a full course of treatment and \$591 for infected contacts that discontinue treatment after 30 days.<sup>56</sup> Following the assumptions in the article, an estimated 28% of persons who test positive for latent tuberculosis infection do not start treatment. An estimated 46% start and complete

treatment and the remaining 26% start, but do not complete treatment. The authors estimated that the risk of progression to active tuberculosis is reduced by 80% for those that complete treatment. The authors assumed that there is no effect for individuals that start, but do not complete treatment. HHS/CDC assumes that under the status quo that health departments are able to contact 75% of exposed travelers (based on the reported outcomes from measles contact investigations).<sup>57</sup>

The costs to provide treatment for latent tuberculosis infections under the status quo are summarized in Table 30. In total, the costs are almost \$900,000 including about \$720,000 to locate contacts and about \$180,000 to provide treatment to individuals with latent tuberculosis infection.

TABLE 30—BASELINE ESTIMATED COSTS TO CONDUCT TUBERCULOSIS CONTACT INVESTIGATIONS AND TO PROVIDE TREATMENT

	Number of contacts	Estimated cost per contact	Estimated cost	Notes
Estimated cost of contact investigations .....	1,995	\$360	\$718,092	Number of contacts from Table 13 and cost per contact from Table 11.
Estimated number of contacts reached by health departments (75%).	1,496	NA	.....	Estimated at 75% similar to measles from Table 24.
Estimated number of contacts reached by health departments and have latent TB infection (19% of 75%).	284	NA	.....	Estimated 19% of contacts have LTBI (Table 13).
Number of contacts that never start treatment (28%).	79.6	0	0	28% of 284 contacts with LTBI.
Number of contacts that complete treatment (46%).	130.8	1,044	136,506	46% of 284 contacts with LTBI.
Number of contacts that start, but not complete treatment, (26%).	73.9	591	43,677	26% of 284 contacts with LTBI.
Total cost .....	.....	.....	898,275	

The benefits associated with tuberculosis contact investigations are estimated from a published article, which reported a range of \$1.01 to \$3.20. This analysis did not include the potential benefits from reduced onward

transmission of tuberculosis among averted cases, potentially resulting in a conservative estimate of the return on investment. The formula used to derive estimated benefits from the return on investment (ROI) is Estimated Benefits =

Estimated Costs × ROI + Estimated Costs. The estimated benefits are \$2.6 million and are shown in Table 31 (range: \$1.8 million to \$3.8 million).

<sup>55</sup> Coleman M, Marienau K, Marano N, Marks S, Cetron M, Dis TMI. Economics of United States Tuberculosis Airline Contact Investigation Policies. Travel Medicine and Infectious Disease. 2014;12:63–71.

<sup>56</sup> Coleman M, Marienau K, Marano N, Marks S, Cetron M, Dis TMI. Economics of United States Tuberculosis Airline Contact Investigation Policies. Travel Medicine and Infectious Disease. 2014;12:63–71.

<sup>57</sup> Nelson K, Marienau K, Schembri C, Redd S. Measles transmission during air travel, United States, December 1, 2008–December 31, 2011. Travel Med Infect Dis. 2013;11(2):81–9.



TABLE 31—BASELINE ESTIMATED COSTS AND BENEFITS FOR TUBERCULOSIS CONTACT INVESTIGATIONS, 2015 USD

	Best estimate	Lower bound	Upper bound	Notes
Estimate costs for contact investigations and treatment.	\$898,260	\$898,260	\$898,260	Table 30.
Return on investment from tuberculosis contact investigations.	1.91	1.01	3.20	Coleman et al.
Estimated benefits .....	2,613,936	1,805,502	3,772,691	= Cost × ROI + Costs.

The provisions in the final rule should result in a small increase (assumed baseline of 10%, range: 5–15%) in the number of contacts reached by health departments and offered treatment for latent tuberculosis infection. This estimated improvement is less than that assumed for measles because tuberculosis usually involves a

much longer period of latent infection prior to active disease; thus, tuberculosis contact investigations are less time sensitive relative to measles contact investigations. The estimated costs associated with this marginal improvement to reach more contacts can be estimated by multiplying the costs of providing latent tuberculosis (\$180,000)

by this range of improvement (5%–15%) as shown in Table 32. This results in marginal increased costs associated with the final rule of \$18,000 (range: \$9,000 to \$27,000). The estimated benefits (Table 32) associated with the final rule are \$52,000 (range: \$18,000 to \$114,000).

TABLE 32—ESTIMATED COSTS AND BENEFITS FOR TUBERCULOSIS CONTACT INVESTIGATIONS ASSOCIATED WITH THIS FINAL RULE, 2015 USD

	Best estimate	Lower bound	Upper bound	Notes
Baseline contact investigation costs .....	\$718,080	\$718,080	\$718,080	Table 30 costs for latent tuberculosis treatment and testing.
Baseline latent tuberculosis treatment costs ..	\$180,180	\$180,180	\$180,180	
Estimated improvement in health departments' abilities to contact exposed travelers.	10%	5%	15%	Assumed.
Estimated increased cost for latent tuberculosis treatment under final rule.	\$18,018	\$9,009	\$27,027	Estimated cost for improvement in contact rate as result of final rule.
Estimated costs under final rule .....	\$916,278	\$907,269	\$925,287	Estimated baseline cost + increased cost as result of final rule.
Estimated ROI .....	\$1.91	\$1.01	\$3.20	Table 30.
Estimated benefits for final rule .....	\$2,666,368	\$1,823,610	\$3,886,204	= Cost × ROI + Costs.
Estimated costs associated with final rule .....	\$18,018	\$9,009	\$27,027.	Calculated from the difference in costs for the final rule—Baseline costs.
Estimated benefits associated with final rule	\$52,432	\$18,108	\$113,513	Calculated from the difference in benefits for the final rule—Baseline benefits.

Total Costs and Benefits for Measles and Tuberculosis Contact Investigations

The total costs for measles and tuberculosis contact investigation

activities are estimated by summing the costs and benefits of measles contact investigations (Table 29) and tuberculosis contact investigations

(Table 32). The results are summarized in Table 33.

TABLE 33—CHANGES IN MEASLES AND TUBERCULOSIS CONTACT INVESTIGATIONS COSTS AND BENEFITS RELATIVE TO BASELINE, 2015 USD

	Best estimate	Lower bound	Upper bound
Final rule benefits .....	\$97,828	\$26,337	\$272,958
Final rule costs .....	19,968	10,959	28,977

**Note:** This table includes the sum of results in Tables 29 and 32.

Total Annual Benefits Resulting From Codification of Traveler Data Collection (71.4 and 71.5) and Change to Definition of “Ill Person” (70.1 and 71.1) Leading to Improved Contact Investigations and Health Outcomes for Measles and Tuberculosis

The total quantified benefits (Table 34) resulting from the improvement of

the quality and timeliness of traveler contact data or the improvement of illness reporting is summarized by summing the improved efficiency for HHS/CDC to provide contact data to health departments and improved efficiency for health departments to contact exposed travelers (Table 23) and the reductions associated with measles

and tuberculosis morbidity and mortality (Table 33).

TABLE 34—TOTAL ANNUAL COSTS AND BENEFITS ASSOCIATED WITH IMPROVED EFFICIENCY PUBLIC HEALTH RESPONSE ACTIVITIES, 2015 USD

	Best estimate	Lower bound	Upper bound
Final rule benefits .....	\$110,045	\$26,337	\$297,393
Final rule costs .....	19,968	10,959	28,977

The benefits and costs associated with improved effectiveness of contact investigations (Table 34) can be combined with the increased costs to airlines, vessel operators, DOT/FAA, and HHS/CDC to submit and respond to illness reports or to provide more timely and complete traveler contact data for manifest requests (Table 19) to estimate the total annual costs and benefits of the final rule (Table 35).

TABLE 35—TOTAL ANNUAL COSTS AND BENEFITS OF THE FINAL RULE, 2015 USD

	Best estimate	Lower bound	Upper bound
Final rule benefits .....	\$110,045	\$26,337	\$297,393
Final rule costs .....	32,622	10,959	430,839

Other Diseases (Besides Measles and Tuberculosis)

HHS/CDC does not have sufficient data to quantify the health impact of contact investigations for pertussis, rubella, varicella (vessels only), viral hemorrhagic fevers (including Ebola), MERS, or SARS. HHS/CDC attempts to continuously update its contact investigation protocols based on available evidence. In the past few years, HHS/CDC has stopped requesting data to conduct mumps contact investigations<sup>58</sup> and has modified its protocol to reduce the number of tuberculosis contacts investigated.<sup>59</sup>

Experience from interstate flight contact investigations suggest that travelers may want to know when they have been exposed to communicable diseases during flights. The first Ebola contact investigation conducted in the United States occurred in October, 2014, and found that 60 travelers out of 164 had no contact information on the manifest that was provided by the airline. A second request was made to the airline after it was announced to the media that the airline had contacted over 800 travelers, including travelers who had flown on the same plane subsequent to the flight with the Ebola. At that time the airline was able to provide HHS/CDC more complete information for all travelers.

It is likely that the need for CDC to put out media requests for travelers to

contact the Agency created a level of fear in the general population that may not have been necessary if better contact data were available. In addition, this fear may have led to non-health costs (such as fear of airplane travel) that would have been mitigated if the Agency were able to contact all passengers without the media request. However, when HHS/CDC solicited public comment about perceived willingness to pay to be contacted in the event of an exposure to a communicable disease during, HHS/CDC only received a few public comments, all of which indicated that they had zero willingness to pay in the event of an exposure to a communicable disease.

In summary, improved alignment between regulatory text and HHS/CDC's publicly available guidance should reduce compliance costs for airlines and vessel operators while improving HHS/CDC's ability to respond to public health threats associated with international and interstate travel. To the extent that airlines and vessel operators improve responsiveness to HHS/CDC traveler data requests, HHS/CDC may become better able to respond to infectious diseases threats and (1) reduce case-loads during infectious disease outbreaks, (2) reduce public anxiety during disease outbreaks, (3) mitigate economic impacts on businesses as a consequence of reduced public anxiety, and (4) reduce the amount of personnel labor time to conduct large-scale CIs in response to a new infectious disease or one with serious public health and medical consequences like Ebola. HHS/CDC will make all reasonable efforts to work with DHS/CBP via CDC's liaison located at the National Targeting Center, as provided through internal Memorandum of Understanding, to

search and obtain data collected from their APIS and PNR data sets prior to contacting airlines or vessel operators with duplicate data requests.

Analysis of Alternatives

Traveler Contact Data Alternatives

For the less restrictive alternative, HHS/CDC assumes that the process of requesting contact data from airlines and vessel operators would be discontinued. Thus, the cost to provide such data can be modeled as a benefit to airlines and vessel operators equal to their costs under the baseline. For the more restrictive alternative, HHS/CDC assumes that suspension of entry may be implemented for travelers from countries experiencing widespread transmission of quarantinable communicable diseases. HHS/CDC notes that suspension of entry would not be considered for non-quarantinable diseases (refer to Table 4). Specifically, HHS/CDC assumes that persons traveling from affected countries are not permitted entry to the United States unless such persons spend an amount of time equivalent to the incubation period for the target disease at a location where they are not at risk of exposure and are also screened for symptoms of the disease prior to travel to the United States. During the 2014–2016 Ebola epidemic, travelers from Liberia, Sierra Leone or Guinea would not be able to enter until 21 days in another country or within the affected country but separated from others in a manner that excludes the possibility of interaction with potentially infected individuals.

On average, HHS/CDC has conducted about 2.5 contact investigations for viral hemorrhagic fevers and MERS coronavirus over the past six years. HHS/CDC assumes that if suspensions

<sup>58</sup>Nelson KR, Marienau KJ, Barskey AE, Schembri C. No evidence of mumps transmission during air travel, United States, November 1, 2006–October 31, 2010. *Travel Medicine and Infectious Disease*. 2012;10:165–71.

<sup>59</sup>Marienau KJ, Cramer EH, Coleman MS, Marano N, Cetron MS. Flight related tuberculosis contact investigations in the United States: comparative risk and economic analysis of alternate protocols. *Travel Med Infect Dis*. 2014;12(1):54–62.

of entry may be in place, some fraction of these contact investigations may not be conducted.

Thus, the cost to airlines and vessel operators to provide traveler contact data would decrease for the less

restrictive alternative resulting in estimated benefits of \$75,924. For the more restrictive scenario, the costs are relatively similar as for the final rule except for the reduction in cost associated with providing contact data

for 2.5 investigations (\$12,338 vs. \$12,654) and calculating the cost reduction of doing 2.5 fewer contact investigations each year (\$1,898) (Table 36).

TABLE 36—ESTIMATE OF THE COSTS AND BENEFITS TO AIRLINES AND VESSEL OPERATORS TO PROVIDE TRAVELER CONTACT DATA, 2015 USD

	Baseline	Final rule	Less restrictive alternative <sup>a</sup>	More restrictive alternative <sup>b</sup>
Baseline number of contact investigations .....	100	100	0	97.5
<b>Costs</b>				
Best estimate .....	NA	\$12,654	\$0	\$12,338
Lower bound .....	NA	0	0	0
Upper bound .....	NA	25,308	0	24,802
<b>Benefits</b>				
Best estimate .....	NA	\$0	\$75,924	\$1,898
Lower bound .....	NA	0	75,924	1,898
Upper bound .....	NA	0	75,924	1,898

<sup>a</sup> The less restrictive alternative is less expensive than the status quo, because HHS/CDC does not request data from airlines and attempt to provide data to health departments to follow up with exposed travelers.

<sup>b</sup> The more restrictive alternative also could potentially reduce costs to airlines and vessel operators because HHS/CDC would restrict travel to countries undergoing widespread transmission of quarantinable communicable diseases such as viral hemorrhagic fevers, MERS or SARS.

**Illness Reporting Alternatives**

HHS/CDC examines two alternatives: A less restrictive alternative in which HHS/CDC relaxes its regulatory authorities to make illness reporting compliance voluntary rather than compulsory. Under the more restrictive alternative HHS/CDC may enforce the current requirement that airlines report all persons with communicable diseases to local health departments in addition to reporting to HHS/CDC.

The current status quo for illness reporting is summarized in Tables 9 and 10. Reports can be subdivided by illnesses that fit (1) the ill person definition specified in current 42 CFR 71.1, (2) reports based on HHS/CDC's guidance for airlines and vessel operators, or (3) illness reports unrelated to current regulation or guidance. As shown in Table 9, only about 53 out of 175.4 (30%) illness reports during air travel appear to be based on symptoms included in the current definition of an ill person in existing 71.1. The remaining 70% of

reports are based on symptoms currently requested by HHS/CDC, but not required. In addition, only 67% of illness reports during air travel require HHS/CDC response and follow-up. In comparison, illness reports from vessels are much more likely to be based on the definition of ill person as defined in current 71.1 (174.6/218.6 or 80%). In addition, a much greater proportion of reports require an HHS/CDC follow-up (>95%). This may result from differences in the types of illnesses observed on vessels relative to aircraft or because of the presence of medical officers on cruise vessels, who may be better able to identify communicable diseases of public health concern during travel relative to aircraft personnel.

If illness reporting were entirely voluntary, HHS/CDC assumes the number of reports (both info-only and reports requiring response) would decrease by 50% from both airlines and vessel operators (refer to Tables 9 and 10) from the current status quo. HHS/CDC does not have any data to estimate

the magnitude of decrease in reporting. HHS/CDC believes that both HHS/CDC and DOT/FAA would continue to maintain their current infrastructure to effectively respond to public health emergencies either on aircraft or vessels. Thus, relative to the status quo, the primary impact of voluntary reporting would be reduced incremental time costs for pilots in command and masters of vessels, travelers, DOT/FAA, and HHS/CDC, especially for info-only illness reports. This 50% reduction in illness reporting would generate benefits from cost reductions for airlines and vessel operators, HHS/CDC, travelers, and DOT/FAA of approximately \$14,700 (Tables 37 and 38).

The adverse impact for the less restrictive alternative relative to the baseline would be reduced capacity for HHS/CDC to respond quickly to communicable disease threats occurring during travel. This is analyzed in a subsequent section on the health impact of regulated activities.

TABLE 37—LESS RESTRICTIVE ALTERNATIVE FOR ILLNESS REPORTING  
[Effect on info-only reports, 2015 USD]

Employee type	Change in number of info-only reports	Amount of time required per report (min)	Estimated wage rate (per hr.)	Overhead multiplier (%)	Estimated benefit (cost reduction)
Aircraft: Aircraft Pilots or Copilots .....	60	2	\$57.35	100	\$229

TABLE 37—LESS RESTRICTIVE ALTERNATIVE FOR ILLNESS REPORTING—Continued  
[Effect on info-only reports, 2015 USD]

Employee type	Change in number of info-only reports	Amount of time required per report (min)	Estimated wage rate (per hr.)	Overhead multiplier (%)	Estimated benefit (cost reduction)
CDC employee .....	60	60	39.83	100	4,780
DOT/FAA employees .....	60	26	70.57	100	3,670
Traveler .....	60	10	23.23	0	232
Air total .....					8,911
Vessels:					
Captains, Mates, and Pilots of Water Vessels .....	6	2	39.95	100	16
CDC employee .....	6	60	39.83	100	478
Traveler .....	6	10	23.23	0	23
Maritime total .....					517
Total (Air + Maritime) .....					9,428

Assume 50% reduction in reports.

TABLE 38—LESS RESTRICTIVE ALTERNATIVE FOR ILLNESS REPORTING  
[Effect on reports requiring response, 2015 USD]

Employee type	Change in number of info-only reports	Amount of time required per report (min)	Estimated wage rate (per hr.)	Overhead multiplier (%)	Estimated benefit (cost reduction)
Aircraft:					
Aircraft pilots or copilots .....	29	2	\$57.35	100	\$111
CDC employee .....	29	0	39.83	100	
DOT/FAA employee .....	29	26	70.57	100	1,774
Traveler .....	29	60	23.23	0	674
Total .....					2,558
Vessels:					
Captains, mates, and pilots (masters) of vessels ....	104	2	39.95	100	277
CDC employee .....	104	0	39.83	100	
Traveler .....	104	60	23.23	0	2,416
Total .....					2,693
Total (Air + Maritime) .....					5,251

Notes: Assume 50% reduction in air illness reports and 15% of maritime illness reports (response, international and interstate).

Under the more restrictive alternative, HHS/CDC would require duplicate illness reporting both to HHS/CDC and to local health departments with jurisdiction upon arrival for interstate flights and voyages. This alternative is based upon the existing regulatory text under 42 CFR 70.4. HHS/CDC assumes that 50% of illness reports occur during interstate (relative to international) air travel and that 15% of maritime illness

reports occur during interstate travel. The time required for pilots in command and masters of vessels is assumed to be about 4 minutes. This duration is greater than the amount of time estimate for reporting to HHS/CDC because pilots in command and masters of vessels may have to search for contact information for local health departments and because local health departments may have less experience dealing with

illness reports than HHS/CDC. The costs to airlines and vessel operators is estimated to be \$848 per year (Table 39). Since HHS/CDC would coordinate responses to illness reports with local health departments under the status quo, there are no additional costs or benefits to requiring duplicative reports to local health departments. These costs would be added to the costs of the changes resulting from the final rule.

TABLE 39—MORE RESTRICTIVE ALTERNATIVE (ILLNESS REPORTING IN DUPLICATE TO HHS/CDC AND TO LOCAL HEALTH DEPARTMENTS), 2015 USD

Employee type	Change in number of info-only reports	Amount of time required per report (min)	Estimated wage rate (2015 USD per hr.)	Overhead multiplier (%)	Estimated cost (\$2015 USD)
Aircraft pilots or copilots .....	88	4	\$57.35	100	\$673

TABLE 39—MORE RESTRICTIVE ALTERNATIVE (ILLNESS REPORTING IN DUPLICATE TO HHS/CDC AND TO LOCAL HEALTH DEPARTMENTS), 2015 USD—Continued

Employee type	Change in number of info-only reports	Amount of time required per report (min)	Estimated wage rate (2015 USD per hr.)	Overhead multiplier (%)	Estimated cost (\$2015 USD)
Captains, mates, and pilots (masters) of vessels .....	33	4	39.83	100	175
Total .....					848

The total costs and benefits associated with the more and less restrictive illness reporting scenarios as compared to the final rule are summarized in Table 40.

TABLE 40—BEST ESTIMATE, LOWER BOUND AND UPPER BOUND OF THE CHANGES IN ANNUAL MONETIZED BENEFITS AND COSTS AS A RESULT OF THE CHANGE TO THE REPORTABLE ILLNESS DEFINITION, 2015 USD

	Best estimate	Lower bound	Upper bound
<b>Costs</b>			
Final Rule:			
Aircraft .....	\$0	\$0	\$375,751
Vessels .....	0	0	802
Total .....	0	0	376,554
Less Restrictive Alternative: <sup>a</sup>			
Aircraft .....	0	0	0
Vessels .....	0	0	0
Total .....	0	0	0
More Restrictive Alternative:			
Aircraft .....	673	673	376,424
Vessels .....	175	175	978
Total .....	848	848	377,402
<b>Benefits</b>			
Final Rule:			
Aircraft .....	0	0	0
Vessels .....	0	0	0
Total .....	0	0	0
Less Restrictive Alternative: <sup>a</sup>			
Aircraft .....	11,469	11,469	11,469
Vessels .....	3,210	3,210	3,210
Total .....	14,679	14,679	14,679
More Restrictive Alternative:			
Aircraft .....	0	0	0
Vessels .....	0	0	0
Total .....	0	0	0

<sup>a</sup>For the less restrictive scenario, the current reporting requirement is relaxed leading to a reduction in costs.

The total costs of the alternatives compared to the final rule are summarized in Table 41 and include the costs of the change to the definition of an “ill person” and the codification of the requirement for airlines to provide passenger contact data for the final rule, the less restrictive alternative, and the more restrictive alternative.

TABLE 41—TOTAL COSTS AND BENEFITS RESULTING FROM CODIFICATION OF TRAVELER DATA COLLECTION (71.4 AND 71.5) AND CHANGE TO DEFINITION OF “ILL PERSON” (70.1 AND 71.1)

	Best estimate	Lower bound	Upper bound
<b>Costs</b>			
Final Rule:			
71.4 and 71.5 Passenger data collection .....	\$12,654	\$0	\$25,308

TABLE 41—TOTAL COSTS AND BENEFITS RESULTING FROM CODIFICATION OF TRAVELER DATA COLLECTION (71.4 AND 71.5) AND CHANGE TO DEFINITION OF “ILL PERSON” (70.1 AND 71.1)—Continued

	Best estimate	Lower bound	Upper bound
70.1 and 71.1 Change in definition of an “ill person” .....	0	0	376,554
Total costs .....	12,654	0	401,862
Less Restrictive Alternative:			
71.4 and 71.5 Passenger data collection .....	0	0	0
70.1 and 71.1 Change in definition of an “ill person” .....	0	0	0
Total costs .....	0	0	0
More Restrictive Alternative:			
71.4 and 71.5 Passenger data collection .....	12,338	0	24,802
70.1 and 71.1 Change in definition of an “ill person” .....	848	848	377,402
Total costs .....	13,186	848	402,204
<b>Benefits</b>			
Final Rule:			
71.4 and 71.5 Passenger data collection .....	0	0	0
70.1 and 71.1 Change in definition of an “ill person” .....	0	0	0
Total benefits .....	0	0	0
Less Restrictive Alternative:			
71.4 and 71.5 Passenger data collection .....	75,924	75,924	75,924
70.1 and 71.1 Change in definition of an “ill person” .....	14,679	14,679	14,679
Total benefits .....	90,603	90,603	90,603
More Restrictive Alternative:			
71.4 and 71.5 Passenger data collection .....	1,898	1,898	1,898
70.1 and 71.1 Change in definition of an “ill person” .....	0	0	0
Total benefits .....	1,898	1,898	1,898

**Staff Time for Contact Investigations**  
 For the less restrictive alternative, the change relative to baseline is equal to the current cost of performing Cis for travelers exposed on international flights (\$745,000 each for HHS/CDC and local health departments or a total of about \$1.5 million, Table 20). Under the

more restrictive alternative (*i.e.* implementing travel restrictions immediately upon evidence of widespread transmission of viral hemorrhagic fevers, SARS or MERS, the costs of these contact investigations are assumed to be avoided (potential cost reductions of about \$29,000 each to

HHS/CDC and health departments or \$58,000 in total). The benefits of the avoided contacted investigations are then added to the cost savings for the remaining contacts assuming a 0–3% improvement in HHS/CDC efficiency and a 0–2% improvement in PHD efficiency as for the final rule (Table 42).

TABLE 42—ESTIMATED BENEFITS ASSOCIATED WITH REDUCED COSTS TO CONDUCT CONTACT INVESTIGATIONS

	HHS/CDC benefits	PHD benefits	Total
Final Rule:			
Best estimate .....	\$7,331	\$4,887	\$12,218
Lower bound .....	0	0	0
Upper bound .....	14,661	9,774	24,435
Less Restrictive Alternative:			
Best estimate .....	745,380	745,380	1,490,760
Lower bound .....	745,380	745,380	1,490,760
Upper bound .....	745,380	745,380	1,490,760
More Restrictive Alternative:			
Best estimate .....	36,671	34,227	70,898
Lower bound .....	29,340	29,340	58,680
Upper bound .....	44,001	39,114	83,115

**Measles Contact Investigation Health Outcomes—Alternatives**  
 For this analysis, under the less restrictive alternative, HHS/CDC assumes that no contact investigations are performed for measles. As a result,

the probability of onward transmission from 3.6 to 10.1 measles patients exposed each year during travel greatly increases and is modeled based on the estimated costs of measles in the absence of intervention \$504,000 (range:

\$137,000 to \$1.3 million) (Table 28). Measles outcomes for the more restrictive alternative are the same as estimated for the final rule since there is no difference in measles efforts between the final rule and the more

restrictive alternative because measles is not a quarantinable disease. The comparative benefits relative to the status quo baseline are shown in Table 43. For the less restrictive alternative, costs are estimated based on an increase in measles outbreak costs relative to the baseline.

TABLE 43—ESTIMATED BENEFITS ASSOCIATED WITH AVERTED COSTS FROM MEASLES OUTBREAKS RELATIVE TO BASELINE, 2015 USD

	Best estimate	Lower bound	Upper bound
<b>Benefits</b>			
Final Rule .....	\$45,396	\$8,229	\$159,444
Less Restrictive Alternative .....	0	0	0
More Restrictive Alternative .....	45,396	8,229	159,444
<b>Costs</b>			
Final Rule .....	1,950	1,950	1,950
Less Restrictive Alternative <sup>a</sup> .....	201,758	54,858	531,481
More Restrictive Alternative .....	1,950	1,950	1,950

<sup>a</sup>For the less restrictive alternative, contact investigations are not performed so the cost can be estimated based on the estimated public health benefit of contact investigations performed under the baseline (Table 29).

**Tuberculosis Contact Investigations Health Outcomes—Alternatives**

Under the less restrictive alternative, tuberculosis contact investigation are no longer conducted for persons exposed during travel. Relative to the baseline, there are neither costs to conduct such investigations (resulting in benefits of about \$180,000 to forego providing treatment for latent tuberculosis treatment) or benefits associated with reduced tuberculosis morbidity and mortality. Relative to the baseline, the estimated cost of increased tuberculosis morbidity and mortality is estimated to be \$2.6 million (range: \$1.8 million to \$3.8 million). Under the more restrictive alternative in which suspension of entry is enforced in response to quarantinable communicable disease outbreaks, there is no change relative to the final rule results because it is unlikely that a tuberculosis outbreak would cause suspension of entry. Results are summarized in Table 44.

TABLE 44—CHANGES IN TUBERCULOSIS CONTACT INVESTIGATIONS COSTS AND BENEFITS RELATIVE TO BASELINE, 2015 USD

	Best estimate	Lower bound	Upper bound	Notes
<b>Benefits</b>				
Final Rule .....	\$52,432	18,108	113,513	Table 32. Assumed to be the cost to provide LTBI treatment under the baseline (Table 32). The more restrictive alternative has the same effect on TB contact investigations as the final rule.
Less Restrictive Alternative .....	180,180	180,180	180,180	
More Restrictive Alternative .....	52,432	18,108	113,513	
<b>Costs</b>				
Final Rule .....	18,018	9,009	27,027	Table 32. Estimated based on the benefits of avoided TB morbidity and mortality resulting from contact investigations under the baseline. The more restrictive alternative has the same effect on TB contact investigations as final rule.
Less Restrictive Alternative .....	\$2,613,936	\$1,805,502	\$3,772,691	
More Restrictive Alternative .....	18,018	9,009	27,027	

The total costs and benefits of changes in health outcomes associated with the more and less restrictive alternatives compared to the provisions included in the Final Rule are summarized in Table 45. The less restrictive alternative in which contact investigations are no longer pursued shows a large increase in costs relative to the baseline and in comparison to the provisions in the final rule. In addition, there are some benefits, but not enough to offset the costs. The more restrictive alternative does not change health outcomes for tuberculosis and measles in comparison to the final rule.

TABLE 45—CHANGES IN MEASLES AND TUBERCULOSIS CONTACT INVESTIGATIONS COSTS AND BENEFITS RELATIVE TO BASELINE, 2015 USD

	Best estimate	Lower bound	Upper bound
<b>Benefits</b>			
Final Rule .....	\$97,828	\$26,337	\$272,958
Less Restrictive Alternative .....	180,180	180,180	180,180.
More Restrictive Alternative .....	97,828	26,337	272,958
<b>Costs</b>			
Final Rule .....	19,968	10,959	28,977
Less Restrictive Alternative .....	2,815,694	1,860,360	4,304,172
More Restrictive Alternative .....	19,968	10,959	28,977

**Note:** This table includes the sum of results in Tables 43 and 44.

The total quantified costs and benefits (Table 46) resulting from the additional data provision and timeliness of traveler contact data or the improvement of illness reporting for alternatives to the provisions included in the final rule is summarized by summing the improved efficiency for HHS/CDC to provide contact data to health departments and improved efficiency for health departments to contact exposed travelers (Table 42) and the reductions associated with measles and tuberculosis morbidity and mortality (Table 45).

TABLE 46—TOTAL ANNUAL COSTS AND BENEFITS ASSOCIATED WITH IMPROVED EFFICIENCY PUBLIC HEALTH RESPONSE ACTIVITIES, 2015 USD

	Best estimate	Lower bound	Upper bound
<b>Benefits</b>			
FR .....	\$110,045	\$26,337	\$297,393
Less Restrictive Alternative .....	1,670,940	1,670,940	1,670,940
More Restrictive Alternative .....	168,725	85,017	356,073
<b>Costs</b>			
FR .....	19,968	10,959	28,977
Less Restrictive Alternative .....	2,815,694	1,860,360	4,304,172
More Restrictive Alternative .....	19,968	10,959	28,977

The total annual costs and benefits for the alternatives compared to the final rule are summarized in Table 47. Although the benefits for the more restrictive alternative in which suspensions of entry would be implemented for countries experiencing outbreaks of quarantinable communicable diseases are greater than the quantified annual benefits of the final rule, the costs are underestimated. HHS/CDC does not have sufficient data to quantify the long term costs of implementing suspensions of entry for countries experiencing outbreaks of quarantinable diseases; however, such costs would probably exceed the \$100,000 in estimated benefits associated with suspensions of entry that may result in fewer contact investigations for quarantinable diseases such as Ebola and MERS. Refer to the appendix for some details of potential costs associated with hypothetical suspensions of entry for the countries with widespread Ebola transmission during the 2014–2016 global Ebola epidemic.

TABLE 47—TOTAL ANNUAL COSTS AND BENEFITS OF THE FINAL RULE, LESS RESTRICTIVE AND MORE RESTRICTIVE ALTERNATIVES, 2015 USD

	Best estimate	Lower bound	Upper bound
<b>Benefits</b>			
Final Rule .....	\$110,045	\$26,337	\$297,393
Less Restrictive Alternative .....	1,780,524	1,780,524	1,780,524
More Restrictive Alternative .....	170,623	86,915	357,971
<b>Costs</b>			
Final Rule .....	32,622	10,959	430,839
Less Restrictive Alternative .....	2,815,694	1,860,360	4,304,172
More Restrictive Alternative .....	33,154	11,807	431,181



### Codification of Current Practice (Multiple Provisions in Final Rule)

HHS/CDC does not expect that most of the provisions included in the final rule will result in measurable changes relative to the economic baseline. The primary purpose of the provisions summarized in list below is to explain how HHS/CDC interprets its current statutory and regulatory authority under the Public Health Service Act (42 U.S.C. 264, 265) and regulations at 42 CFR parts 70 and 71. HHS/CDC is grouping the complementary provisions in part 70 and part 71 in the list below, when they align, to facilitate public review of the current provisions as well as those included in the final rule. These changes are intended to clarify the agency's standard operating procedures and policies, and due process rights for individuals. HHS/CDC believes that such clarity is an important qualitative benefit of the provisions in this final rule, but is not able to monetize this impact in a significant way.

- New Provisions: § 70.5

Requirements relating to travelers under a Federal order of isolation, quarantine, or conditional release.

- Baseline and Current Regulatory Provision: § 70.5 Certain communicable disease; special requirements.

- Without the final rule, HHS/CDC may issue Federal orders to restrict travel for persons infected or exposed to quarantinable communicable diseases. However, this process is less transparent and efficient than allowing travel (*i.e.* issue travel permits to allow interstate travel to persons under Federal orders for diseases not currently identified under existing 42 CFR 70.5.) Under current practice, HHS/CDC issues approximately one Federal order per year, most frequently for tuberculosis, which is a disease not included in the current 70.5.

- Change relative to baseline as result of final rule

- With the final rule, HHS/CDC is aligning the list of diseases for which individuals under Federal orders may be allowed to travel with the quarantinable communicable diseases specified in Executive Order. A potential future qualitative benefit would be to reduce uncertainty by the individual subject to the order, carrier operators, and cooperating health and law enforcement entities about whether HHS/CDC could issue a travel permit to an individual under a Federal order and quantifiable benefit would be the avoided cost of potential legal challenge.

- Qualitative benefit/cost of final rule

- Improved transparency for HHS/CDC's ability to allow individuals under

Federal orders to issue travel permits to allow individuals to travel (interstate). HHS/CDC may allow persons under Federal orders to travel interstate for whom there is greater uncertainty regarding HHS/CDC restricting their travel.

- Monetized benefit/cost of final rule
  - Increased clarity around due process may result in fewer resources and time expended by individuals under orders and HHS/CDC in disagreements over HHS/CDC's authority to issue Federal public health orders that limit an individual's movement. This includes the potential costs of litigation and associated activities.

- New provisions: § 70.6 Apprehension and detention of persons with specific diseases; § 71.32 Persons, carriers, and things (no change to title)

- Baseline and Current Regulatory Provision:

- Under current 42 CFR 70.6 and § 71.32, HHS/CDC has regulatory authority to apprehend and detain individuals with quarantinable communicable diseases.

- Change relative to baseline as result of final rule

- As a result of these new provisions, the major change would be improved transparency of HHS/CDC's regulatory authority with regard to the issuance of Federal quarantine, isolation, or conditional release orders of individuals traveling interstate.

- Qualitative benefit/cost of final rule
  - Improved transparency and compliance with Federal orders.

- Monetized benefit/cost of final rule

- Increased clarity around due process may result in fewer resources and time expended by individuals under orders, cooperating entities, and CDC in disagreements over HHS/CDC's authority to issue Federal public health orders that limit an individual's movement. This includes the potential costs of litigation and associated activities.

- New Provisions: § 70.10 Public health prevention measures to detect communicable disease; § 71.20 Public health prevention measures to detect communicable disease.

- Baseline and Current Regulatory Provisions: No explicit regulatory provision.

- In the absence of the final rule and under existing statutory authority provided in the Public Health Service Act and regulatory authority provided by 42 CFR 70.2 and 71.32(b), HHS/CDC could still implement public health measures at locations where individuals may gather for interstate travel or at U.S. ports of entry. However, without more

transparent regulatory authority to require such measures, travelers may be less likely to comply, either by refusing to answer risk assessment questions or providing false information. This lack of compliance may require that HHS/CDC, if it reasonably believes that the individual is infected with or has been exposed to a quarantinable communicable disease, to quarantine, isolate, or place the individual under surveillance under 42 CFR 70.6 or 71.32 and 71.33. HHS/CDC has not implemented public health measures at locations where individuals may congregate for the purposes of interstate travel in at least 50 years and cannot predict if or how often it may implement measures in the future.

- Change relative to baseline as result of final rule

- Improved transparency and potentially improved compliance in the event that HHS/CDC implements such measures in the future.

- Qualitative benefit/cost of final rule

- Improved transparency and public understanding of HHS/CDC's rationale and authority to conduct such measures and require individuals to comply.

- Monetized benefit/cost of final rule

- Increased clarity around due process procedures may result in fewer resources and time expended by individuals under orders and HHS/CDC in disagreements over HHS/CDC's authority to issue Federal public health orders that limit an individual's movement. This includes the potential costs of litigation and associated activities.

- New Provisions: § 70.12 Medical examinations; § 71.36 Medical Examinations

- Baseline and Current Regulatory Provisions: 71.33 Persons: Isolation and Surveillance.

- This is carried out under statutory authority and under the regulatory authorities in 42 CFR 70.6 and 71.32(a), 71.33, which would allow for medical examinations of individuals under Federal orders.

- Change to baseline as result of final rule

- With the final rule, the major change would be an alignment between the statutory language in the Public Health Service Act and improved transparency of HHS/CDC's regulatory authority.

- Qualitative benefit/cost of final rule

- Improved transparency and public understanding of HHS/CDC's rationale and authority to conduct such measures and require individuals to comply.

- Monetized benefit/cost of final rule

- Increased clarity around due process procedures may result in fewer

resources and time expended by individuals under orders, cooperating entities, and HHS/CDC in disagreements over HHS/CDC's authority to issue Federal public health orders that limit an individual's movement. This includes the potential costs of litigation and associated activities.

- New Provisions: § 70.13 Payment for Care and Treatment; § 71.30 Payment for Care and Treatment

- Baseline and Current Regulatory Provisions: No current explicit regulatory provision.

- This addition is not expected to lead to a change in HHS/CDC policy under which HHS/CDC may act as the payer of last resort for individuals subject to medical examination, quarantine, isolation, and conditional release under Federal orders. The provisions included in the final rule are similar to a Memorandum of Agreement between a number of hospitals and HHS/CDC. Under the terms of the Memorandum of Agreement, the hospital can be reimbursed for incurred medical expenses subject to HHS/CDC's discretion, availability of appropriations, and limited to what a hospital would bill Medicare. The Memorandum of Agreement also indicates that HHS/CDC should be the payer of last resort.

- HHS/CDC issued 12 isolation orders between Jan 1, 2005 and May 10, 2016, which would correspond to an average of about 1 order per year over the past 11.3 years. HHS/CDC has information on payments made for 3 of the 12 cases. In most cases, HHS/CDC makes payment directly to healthcare facilities, sometimes in lieu of payments that would be made by State or local health departments. Among the three instances for which HHS/CDC has some data on payments for treatment, care, and transportation of individuals under Federal orders:

- HHS/CDC's expected annual payments for care and treatment are estimated to be between \$0 and \$1,000,000 in any given year under the current baseline. This upper bound cost would correspond to a year in which HHS/CDC would have to incur the costs of two patients at \$500,000 per patient. This roughly corresponds to the average cost to treat an extremely drug-resistant tuberculosis case (XDR-TB). Alternatively, this could represent a situation in which HHS/CDC may have to pay a significant fraction of the total costs for one very complicated illness associated with a quarantinable communicable disease not endemic to the United States (e.g., Ebola).

- HHS/CDC has not incurred any costs for the care and treatment of any

individuals besides for those under Federal isolation orders.

- Change to baseline as result of final rule

- Improved transparency around HHS/CDC's authority for, and requirements and processes related to payment for care and treatment.

- Qualitative benefit/cost of final rule
- Improved transparency and public knowledge of HHS/CDC's procedures and regulatory requirements.

- Monetized benefit/cost of final rule
- None. This is a clarification of HHS/CDC's current practice. (For more details, please refer to separate RIA Appendix)

- New Provisions: § 70.14 Requirements relating to the issuance of a Federal order for quarantine, isolation, or conditional release; § 71.37

- Requirements relating to the issuance of a Federal order for quarantine, isolation, or conditional release

- Baseline and Current Regulatory Provisions: No current explicit regulatory provision

- Without the final rule, HHS/CDC can under current statutory provided by the Public Health Service Act and regulatory authority under 42 CFR 70.6 and 71.32(a), 71.33 continue to issue Federal quarantine, isolation, or condition release orders. However, the issuance of federal orders is implemented through internal policies and standard operating procedures that are not as transparent to the public as detailed regulations outlining requirements.

- Change to baseline as result of final rule

- Improved transparency around HHS/CDC's authority for, and requirements and processes related to, the issuance of Federal quarantine, isolation, and conditional release orders.

- Qualitative benefit/cost of final rule
- Improved transparency and public knowledge of HHS/CDC's procedures and regulatory requirements.

- Monetized benefit/cost of final rule
- None. This is a clarification of HHS/CDC's current practice.

- New Provisions: § 70.15 Mandatory reassessment of a Federal order for quarantine, isolation, or conditional release; § 71.38 Mandatory reassessment of a Federal order for quarantine, isolation, or conditional release

- Baseline and Current Regulatory Provisions: No current explicit regulatory provision.

- Without the final rule, HHS/CDC can under current statutory authority provided by the Public Health Service Act and regulatory authority under 42 CFR 70.6 and 71.32(a), 71.33 continue to

issue Federal quarantine, isolation, or conditional release orders. However, the process for reassessing a Federal order is implemented through internal policy and standard operating procedures that are not as transparent to the public as detailed regulations outlining requirements.

- Change to baseline as result of final rule:

- With the final rule, individuals under Federal order may be more aware of the mandatory reassessment of a Federal quarantine, isolation, or conditional release order.

- Qualitative benefit/cost of final rule
- Improved transparency and understanding of due process protections under a Federal public health order.

- Monetized benefit/cost of final rule
- Increased clarity around due process protections may result in fewer resources and time expended by individuals under orders and HHS/CDC in disagreements over HHS/CDC's authority to issue Federal public health orders that limit an individual's movement. This includes the potential costs of litigation and associated activities.

- New Provisions: § 70.16 Medical review of a Federal order for quarantine, isolation, or conditional release; § 71.39 Medical review of a Federal order for quarantine, isolation, or conditional release

- Baseline and Current Regulatory Provisions: No current explicit regulatory provision.

- Without the final rule, HHS/CDC can under current statutory authority provided by the Public Health Service Act and regulatory authority under 42 CFR 70.6 and 71.32, 71.33 continue to issue Federal quarantine, isolation, or conditional release orders. However, the process for a medical review of a Federal order is outlined in internal policy and standard operating procedures that are not as transparent to the public as detailed regulations outlining requirements.

- Change to baseline as result of final rule:

- With the final rule, individuals under Federal order may become aware of their right to a medical review, and exercise that right, under this due process provision.

- Qualitative benefit/cost of final rule
- Improved transparency and understanding of due process afforded to individuals under a Federal order

- Monetized benefit/cost of final rule
- Increased clarity around due process protections may result in fewer resources and time expended by individuals under orders and HHS/CDC

in disagreements over HHS/CDC's authority to issue Federal public health orders that limit an individual's movement. This includes the potential costs of litigation and associated activities.

- One potential change that could have an economic effect is the requirements to appoint medical and legal representatives for individuals that qualify as "indigent". The status of "indigent" is self-reported as HHS/CDC will not require access to an individual's financial records. Those who self-identify as indigent may be required to sign an affidavit or declaration under penalty of perjury stating they meet the threshold of at least 200% of the applicable poverty guidelines. HHS/CDC notes that in practice it has never denied a request for a representative. HHS/CDC estimates the cost of providing one medical representative and one legal representative based on the average hourly wage for physicians and surgeons (\$97.33, occupation code 29–1060) and lawyers (\$65.51, occupation code 23–1011) as reported from the Bureau of Labor Statistics' May 2015 National Occupational Employment and Wage Estimates. Assuming that it takes about 40 hours of physician time and 40 hours of lawyer time per review and an overhead cost multiplier of 100%, the expected cost is about \$13,000 per review. HHS/CDC notes that public health orders are issued on average once per year. The need for HHS/CDC to pay for medical and legal representatives will depend on the income level for persons placed under federal orders, but should not exceed this \$13,000 estimate in most years and will be \$0 in many years. Without the new regulatory provision, as part of current practice, HHS/CDC would still attempt to appoint legal and medical representatives if requested for the medical review by individuals unable to afford the cost of such representation. Thus, relative to current practice, there should be minimal costs associated with this provision.

- New Provisions: § 70.17 Administrative records relating to Federal quarantine, isolation, or conditional release; § 71.29 Administrative records relating to Federal quarantine, isolation, or conditional release

- Baseline and Current Regulatory Provisions: No current explicit regulatory provision.

- Without the final rule, HHS/CDC can issue under current statutory provided by the Public Health Service Act and regulatory authority under 42 CFR 70.6 and 71.32(a), 71.33 continue to

issue Federal quarantine, isolation, or conditional release orders. However, the process for documenting the administrative record is implemented internal policy and standard operating procedures that are not as transparent to the public as a detailed regulation outlining this requirement.

- Change to baseline as result of final rule

- The requirement, with which HHS/CDC is already complying, will clarify for the public that certain documents must be retained for the administrative record.

- Qualitative benefit/cost of final rule

- Improved transparency

- Monetized benefit/cost of final rule

- Not applicable. This is a

codification of an administrative activity within HHS/CDC.

- New Provisions: § 70.18 Penalties/ § 71.2 Penalties

- Baseline and Current Regulatory Provision: § 71.2 Penalties. Part 70 currently has no penalties provision.

- Without the final rule, individuals may not be aware that 18 U.S.C. 3559 and 3571 increased the maximum penalties for violations of regulations under 42 CFR part 70 and part 71. And it may not be clear to individuals that violating quarantine regulation under 42 CFR part 70 may result in criminal penalties.

- Change to baseline as result of final rule

- With the NRPM, there will be less confusion about the maximum criminal penalties for a violation of regulations under 42 CFR 70 and 71.

- Qualitative benefit/cost of final rule

- Improved transparency and alignment with current law under 18 U.S.C. 3559 and 3571.

- Monetized benefit/cost of final rule
- No individual or organization has been assessed criminal penalties for violating these regulations, so monetizing this benefit or cost is not feasible. This is simply an effort to align the domestic and foreign quarantine penalties provisions, and updates outdated regulatory language so that it reflects current statutory language concerning criminal penalties.

- New Provisions: § 71.63 Suspension of entry of animals, articles, or things from designated foreign countries and places into the United States

- Baseline and Current Regulatory Provision: § 71.32(b) has previously been used to justify the temporary embargo of imported African rodents prior to the codification of this as a requirement in existing 42 CFR 71.56.

- Without the final rule, individuals may not be aware that HHS/CDC's authority to temporarily suspend entry

of animals, articles or things from designated foreign countries and places into the United States based on existing 42 CFR 71.32(b).

- Change to baseline as result of final rule

- With the NRPM, there will be less confusion about HHS/CDC's ability to temporarily restrict importations associated with communicable disease risks.

- Qualitative benefit/cost of final rule

- Improved transparency.

- Monetized benefit/cost of final rule

- Refer to the appendix for an analysis of the temporary embargo of African rodents implemented in 2003.

## B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), agencies are required to analyze regulatory options to minimize significant economic impact of a rule on small businesses, small governmental units, and small not-for-profit organizations. We have analyzed the costs and benefits of the final rule, as required by Executive Order 12866, and a preliminary regulatory flexibility analysis that examines the potential economic effects of this rule on small entities, as required by the Regulatory Flexibility Act. Based on the cost benefit analysis, we expect the rule to have little or no economic impact on small entities.

## C. The Paperwork Reduction Act

HHS/CDC has determined that this final rule contains proposed information collections that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). A description of these proposed provisions is given below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information. Comments are invited on the following subjects.

- Whether the proposed collection of information is necessary for the proper performance of the functions of HHS/CDC, including whether the information will have practical utility.

- The accuracy of HHS/CDC's estimate of the burden of the collection of information.

- Ways to enhance the quality, utility, and clarity of the information to be collected.

• Ways to minimize the burden of the collection of information on respondents, including by using information technology.

While HHS/CDC currently has approval to collect certain information concerning illnesses and travelers under OMB Control Numbers 0920–0134 (*Foreign Quarantine Regulations*, expiration date 05/31/2019) and 0920–0488 (*Restrictions on Interstate Travel of Persons*, expiration date 05/31/2019), CDC is requesting updates to certain information collections within these control numbers.

In another information collection request associated with this final rule, CDC is also requesting approval to require that airlines and vessels provide certain data elements to CDC, as described in proposed 71.4 and 71.5, for the purposes of contact tracing. This information is used to locate individuals, both passengers and crewmembers, who may have been exposed to a communicable disease during travel and to provide them with appropriate public health follow-up.

Written comments should be received within 30 days of the publication of this final rule. Please send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806.

#### Proposed Projects

(1) Foreign Quarantine Regulations (42 CFR part 71) (OMB Control No. 0920–0134)—Nonmaterial/non-substantive change—National Center for Emerging, and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

(2) Restrictions on Interstate Travel of Persons (42 CFR part 70) (OMB Control No. 0920–0488)—Nonmaterial/non-substantive change—National Center for Emerging, and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC)

(3) Airline and Vessel and Traveler Information Collection (42 CFR and 71)—New Information Collection Request—National Center for Emerging, and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

#### Description

Section 361 of the Public Health Service (PHS) Act (42 U.S.C. 264) 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 and interstate. Legislation and existing regulations governing foreign and

interstate quarantine activities (42 CFR parts 70 and 71) authorize quarantine officers and other personnel to inspect and undertake necessary control measures in order to protect the public health. Currently, with the exception of the CDC's Vessel Sanitation Program, inspections are performed only on those vessels and aircraft that report illness before arriving or when illness is discovered upon arrival. Other inspection agencies assist quarantine officers in public health risk assessment and management of persons, pets, and other importations of public health importance. These practices and procedures ensure protection against the introduction and spread of communicable diseases into the United States with a minimum of recordkeeping and reporting as well as a minimum of interference with trade and travel. The information collection burden is associated with these recordkeeping and reporting requirements.

At present, HHS/CDC has approval from OMB to collect certain information and impose recordkeeping requirements related to foreign quarantine responsibilities under OMB Control Number 0920–0134 (expiration 05/31/2019). The specific provisions within 42 CFR part 71 that include information collection under are as follows:

42 CFR 71.21(a), (b), and (c) Report of death and illness.

42 CFR 71.33(c) Report of persons held in isolation or surveillance.

42 CFR 71.35 Report of death or illness on carrier during stay in port.

42 CFR 71.51 Dogs and cats.

42 CFR 71.52 Turtles, terrapins, tortoises.

42. CFR 71.56 African Rodents

HHS/CDC has also used its authority under 42 CFR 71.32 to require importers to submit statements or documentation of non-infectiousness for those items that may constitute a public health risk if not rendered non-infectious.

Finally, HHS/CDC has approval from OMB to collect from importers/filers certain documents and data elements to identify and clear HHS/CDC regulated imports via the Automated Commercial Environment and the International Trade Data System using the Document Imaging System and Partner Government Agency Message Sets. These CDC Partner Government Agency Message Sets are currently limited to: CDC PGA Message Set for Importing Cats and Dogs, CDC PGA Message Set for Importing African Rodents, CDC PGA Message Set for Importing African Rodent and All Family *Viverridae* Products.

In this final rule, CDC is requesting approval from OMB for 4 non-substantive changes to OMB Control Number 0920–0134 Foreign Quarantine Regulations (42 CFR part 71):

(1) Updating the definition of “ill person,” which relates to the illness reporting requirements under 42 CFR 71.21(a), (b), and (c) for airlines and vessels arriving into the United States. CDC is updating the definition of “ill person” by implementing current practice with the anticipated effect of better facilitating identification of communicable diseases of concern and quarantinable communicable diseases aboard flights and maritime voyages to the United States, diseases such as measles, viral hemorrhagic fevers, active tuberculosis, and influenza caused by novel or re-emergent influenza viruses that are causing or have the potential to cause a pandemic. CDC is also including a provision to allow the Director to add new symptoms to the definition of ill person to respond to unknown communicable diseases that may emerge as future concerns.

The final rule updates the current definition of ill person to better focus on the signs and symptoms of communicable diseases of public health concern and quarantinable communicable diseases. The changes define an ill person in the context of the medical resources available to the operator of an airline or vessel.

CDC already requests from pilots in command of aircraft and commanders of vessels several of the symptoms included in the revised definition of ill person through publicly available guidance to airlines and vessels. Moreover, for airlines, the updated definition also better aligns with symptoms reporting guidelines published by ICAO in Note 1 to paragraph 8.15 of Annex 9 to the Convention on International Civil Aviation, and the definition of “acute gastroenteritis” is used by the WHO and is currently included in reporting guidance from CDC's Vessel Sanitation Program. Therefore, CDC does not anticipate additional burden on airlines or vessel operators to respond to these information collections.

(2) CDC is requesting a change in the title of the information collection pertaining to reports of death and illness from vessels to CDC. The former title is *Radio Report of death or illness*—illness reports from ships. CDC sought a change to remove “Radio” from the title. This change reflects the fact that reports to CDC primarily via means other than radio, such as the Maritime Illness and Death Reporting System, managed by CDC's Vessel Sanitation Program. CDC

did not receive any public comments to this change, and it is therefore finalized as proposed.

(3) CDC is seeking a change in the title of a specific information collection pertaining to reports of gastro-intestinal illness to CDC. CDC is updating the definition of ill person and is replacing the term “gastro-intestinal” with “acute gastroenteritis”; therefore, the title change is requested to align with the definition.

(4) CDC is seeking a change in title of respondents from “Maritime Conveyance Operator” to “Maritime Vessel Operator” and from “Airline

Commander or Operator” to “Pilot in Command.”

Table 1 below presents estimates of annual burden (in hours) associated with each reporting and recordkeeping requirement under this OMB control number, accounting for the rule changes.

*Description of Respondents.* Respondents to this data collection include pilots in command of aircraft, maritime vessel operators, importers/filers, and travelers/general public. The nature of the response to HHS/CDC dictates which forms are completed and by whom. The total requested burden hours are 82,779.

There is no burden to respondents other than the time taken to complete the reports to CDC, maintain recordkeeping of illness aboard vessels and records of sickness or death in imported cats and dogs, as outlined in the table below. If a cat or dog is ill upon arrival, or dies prior to arrival, an exam is required, the initial exam fee may be between \$100 and \$200. Rabies testing on a dog that dies may be between \$50 and \$100. The expected number of ill or dead dogs arriving into the United States for which CDC may require an examination is estimated at less than 30 per year.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN 0920–0134

Type of respondent	Regulatory provision or form name	No. of respondents	No. of responses per respondent	Average burden per response (in hours)	Total burden hours
Maritime Vessel Operators .....	42 CFR 71.21(a) Report of illness or death from ships—Maritime Vessel Illness or Death Investigation Form/Cumulative Influenza/Influenza-Like Illness (ILI) Form/Radio report or transcribed email.	2,000	1	2/60	67
Pilot in Command .....	42 CFR 71.21 (b) Death/Illness reports from aircraft ....	1,700	1	2/60	57
Maritime Vessel Operators .....	42 CFR 71.21(c) (MIDRS) Acute Gastro-Enteritis reports (24 and 4 hours before arrival).	17,000	1	3/60	850
Maritime Vessel Operators .....	42 CFR 71.21 (c) Recordkeeping-Medical logs .....	17,000	1	3/60	850
Isolated or Quarantined individuals.	42 CFR 71.33 Report by persons in isolation or surveillance.	11	1	3/60	1
Maritime Vessel Operators .....	42 CFR 71.35 Report of death/illness during stay in port.	5	1	30/60	3
Importer .....	42 CFR 71.51(c)(1), (d)—Valid Rabies Vaccination Certificates.	245,310	1	15/60	61,328
Importer .....	CDC Form 75.37 Notice To Owners And Importers Of Dogs: Requirement for Dog Confinement.	1,400	1	10/60	233
Importer .....	42 CFR 71.51(c)(i), (ii), and (iii) exemption criteria for the importation of a dog without a rabies vaccination certificate.	43,290	1	15/60	10,823
Importer .....	42 CFR 71.51(c)(2), (d) Application for a Permit to Import A Dog Inadequately Immunized Against Rabies.	1,400	1	15/60	350
Importer .....	42 CFR 71.51(b) (3) Dogs/cats: Record of sickness or deaths.	20	1	15/60	5
Importer/Filer .....	42 CFR 71.51_CDC Requested Data on Regulated Imports: Domestic Dogs and Cats (PGA Message Set).	30,000	1	15/60	7,500
Importer .....	42 CFR 71.52(d) Turtle Importation Permits .....	5	1	30/60	3
Importers .....	42 CFR 71.55, 42 CFR 71.32 Dead Bodies—Death certificates.	5	1	1	5
Importer .....	42 CFR 71.56 (a)(2) African Rodents—Request for exemption.	20	1	1	20
Importer .....	42 CFR 71.56(a)(iii) Appeal .....	2	1	1	2
Importer/Filer .....	42 CFR 71.56 CDC Requested Data on Regulation Imports: Live African Rodents (PGA Message Set).	60	1	15/60	15
Importer/Filer .....	42 CFR 71.32 Statements or documentation of non-infectiousness.	2,000	1	5/60	167
Importer/Filer .....	42 CFR 71.56, 42 CFR 71.32 CDC Requested Data on Regulated Imports: Products of African Rodents; Products of all Family Viverridae (PGA Message Set).	2,000	1	15/60	500
Total .....	.....	.....	.....	.....	82,779

The estimates are based on experience to date with current recordkeeping and reporting requirements of 42 CFR part 71, with additional burden included to

account for the potential for increased reports of illness during an outbreak and for reports of disease that may have

been missed by airlines or vessels and are reported to CDC after travel.

Under this final rule, CDC is also requesting a nonmaterial/non-

substantive change to Restrictions on Interstate Travel of Persons (42 CFR part 70) (OMB Control No. 0920-0488). The regulations at 42 CFR part 70 are intended to prevent the interstate spread of disease, and include a requirement that the master of vessel or person in charge of conveyance to report the occurrence on board of communicable disease. Under this regulation and control number, CDC has approval to collect the following information:

- 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.

Through this final rule, CDC is adding the provision 70.11 *Report of death or illness onboard aircraft operated by airline*, which specifies that the pilot in command of an aircraft operating on behalf of an airline who conducts a commercial passenger flight in interstate traffic under a regular schedule shall report as soon as practicable to HHS/CDC the occurrence onboard of any deaths or ill persons among passengers or crew and take such measures as HHS/CDC may direct to prevent the potential spread of the communicable disease. HHS/CDC notes that it is changing the existing regulatory requirement at 42 CFR 70.4, which states that the master of a vessel or person in charge of any conveyance engaged in interstate traffic

on which a case or suspected case of communicable disease develops shall, as soon as practicable, notify the local health authority.

Under the final rule, pilots in command of an aircraft, operating on behalf of an airline, that submit the ill person or death report to HHS/CDC under new 70.11 will not be required to also submit a report to the local health authority under current 70.4. HHS/CDC will continue to share public health information with State and local health departments through electronic disease reporting networks. It is unlikely that HHS/CDC would request follow-up reports of illnesses that are reported to the local health authorities, unless there was an urgent public health need. Therefore, CDC does not anticipate any additional burden to the respondents; however, the accounting for burden in Table 2 will add 70.11 *Report of death or illness onboard aircraft operated by airline*.

As a result of this final rule, CDC does not anticipate a change in total burden. CDC is instead allocating 95% of the reports of illness or death within the proposed 70.11 *Report of death or illness onboard aircraft operated by airline*. The remains 5% will remain within 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, in the event that some reports are still made to State health authorities.

In addition to the requirement to report directly to HHS/CDC, HHS/CDC is updating the definition of “ill person” for the purposes of illness reports to HHS/CDC in 42 CFR part 70. HHS/CDC has, as a matter of agency guidance, communicated with airlines that the same current set of required and requested signs and symptoms of disease, as well as any death, apply to domestic as well as international flights. This guidance is similar to that of the guidelines issued by ICAO under *Note 1 to paragraph 8.15 of Annex 9 to the Convention on International Civil Aviation*. Therefore, the new proposed definition of ill person should not affect standard practice, and no change in burden is anticipated.

Table 2 below presents estimates of annual burden (in hours) associated with each reporting and recordkeeping requirement under this OMB control number, accounting for the rule changes.

Description of Respondents

Respondents to this data collection include masters of vessels or persons in charge of conveyance and pilots in command of aircraft.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN 0920-0488

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 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.	10	1	7/60	1
Total .....	.....	200	.....	.....	23

The total requested burden hours are 23. There is no burden to respondents other than the time taken to complete the reports. The estimates are based on experience to date with current recordkeeping and reporting requirements of 42 CFR part 70, and take into account the potential for additional burden from increased reports of illness during an outbreak and for reports of disease that may have been missed by respondents during travel and are reported to CDC by other means.

Finally, under this final rule HHS/CDC is requesting approval for a new information collection, Airline and Vessel and Traveler Information Collection (42 CFR part 71). This information collection request accompanies the codification of issuing orders to airlines and vessel operators for the provision to CDC of airline and vessel and traveler information (aka manifests) in the event that a quarantinable communicable disease or a communicable disease of public health concern, or a death caused by a quarantinable communicable disease or

communicable disease of public health concern, occurs during travel to the United States and public health follow-up is warranted. These proposed provisions are found in 42 CFR 71.4 for airlines and 71.5 for vessels.

The ordering of manifests from airlines and vessel operators arriving into the United States is an ongoing activity executed under CDC’s broad regulatory authority found at 42 CFR 71.32 *Persons, carriers, and things*. To increase transparency with regard to CDC’s authorities and manifest order process, CDC is proposing specific

regulatory provisions that outline the particular data elements CDC requires to perform contact tracing investigations. As stated in the final rule, CDC is not mandating the collection of additional data. Only that if the airlines or maritime operators have the data elements listed in 71.4 and 71.5 in their

possession, they must be provided to CDC within 24 hours. Table 3 below presents estimates of annual burden (in hours) associated with each reporting and recordkeeping requirement under this OMB control number, accounting for the final rule changes.

Description of Respondents

Respondents to this data collection include the Airline Medical Officer or Equivalent and a Computer and Information Systems Manager.

TABLE 3—ESTIMATE OF ANNUAL BURDEN AIRLINE AND VESSEL MANIFEST ORDERS

Type of respondent	Form name	No. of respondents	No. of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Airline Medical Officer or Equivalent/Computer and Information Systems Manager.	International TB Manifest Template .....	67	1	360/60	402
Airline Medical Officer or Equivalent/Computer and Information Systems Manager.	International Non-TB Manifest Template. ....	29	1	360/60	174
Total .....	.....	96	.....	.....	576

The total requested burden hours included in this final rule is 576. There is no burden to respondents other than the time taken to complete the manifest information and send to CDC. The estimates are based on experience to date with current manifest order process.

*D. National Environmental Policy Act (NEPA)*

HHS/CDC has determined that the amendments to 42 CFR parts 70 and 71 will not have a significant impact on the human environment.

*E. Executive Order 12988: Civil Justice Reform*

HHS/CDC has reviewed this rule under Executive Order 12988 on Civil Justice Reform and determines that this final rule meets the standard in the Executive Order.

*F. Executive Order 13132: Federalism*

Under Executive Order 13132, a Federalism analysis is required if a rulemaking has Federalism implications, would limit or preempt State or local law, or impose substantial direct compliance costs on State or local governments. Under such circumstances, a Federal agency must consult with State and local officials. Federalism implications is defined as having substantial direct effects on State or local governments, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Under 42 U.S.C. 264(e), Federal public health regulations do not preempt State or local public

health regulations, except in the event of a conflict with the exercise of Federal authority. Other than to restate this statutory provision, this rulemaking does not alter the relationship between the Federal government and State/local governments as set forth in 42 U.S.C. 264. The longstanding provision on preemption in the event of a conflict with Federal authority (42 CFR 70.2) is left unchanged by this rulemaking. Additionally, there are no provisions in these regulations that impose direct compliance costs on State and local governments. Therefore, HHS/CDC believes that the rule does not warrant additional consultation under Executive Order 13132.

*G. The Plain Language Act of 2010*

Under 63 FR 31883 (June 10, 1998), Executive Departments and Agencies are required to use plain language in all proposed and final rules. HHS/CDC received several comments suggesting that the proposed regulation was not written in plain language and was therefore difficult to understand. Prior to publication, this final rule was reviewed by specialists in health communication and education to ensure the content and intention, as well as substance, were clear and accurate.

**List of Subjects in 70.1, 70.5, 70.6, 70.10–70.18, 71.1, 71.2, 71.4, 71.5, 71.12, 71.20, 71.29, 71.30, 71.36–71.39, 71.63**

Apprehension, Communicable diseases, Conditional release, CDC, Ill person, Isolation, Non-invasive, Public health emergency, Public health prevention measures, Qualifying stage,

Quarantine, Quarantinable Communicable Disease.

For the reasons discussed in the preamble, we amend 42 CFR parts 70 and 71 as follows:

**PART 70—INTERSTATE QUARANTINE**

- 1. The authority citation for part 70 continues to read as follows:
  - Authority:** Secs. 215 and 311 of the Public Health Service (PHS) Act, as amended (42 U.S.C. 216, 243) section 361–369, PHS Act, as amended (42 U.S.C. 264–272); 31 U.S.C. 9701.
- 2. Amend § 70.1 by—
  - a. Adding in alphabetical order definitions for “Airline”, “Apprehension”, and “Communicable stage”;
  - b. Revising the definition of “Conditional release”;
  - c. Adding in alphabetical order a definitions for “Contaminated environment”;
  - d. Revising the definition of “Conveyance”;
  - e. Adding in alphabetical order definitions for “Electronic or Internet-based monitoring” and “Ill person”;
  - f. Revising the definition of “Incubation period”;
  - g. Adding in alphabetical order a definition for “Indigent”;
  - h. Revising the definition of “Interstate traffic”;
  - i. Revising the definition of “Master or operator”;
  - j. Adding in alphabetical order definitions for “Medical examination”, “Medical reviewer”, “Non-invasive”, “Precommunicable stage”, “Public health emergency”, “Public health

prevention measures”, “Qualifying stage”, “Reasonably believed to be infected, as applied to an individual”, and “Representatives”.

The additions and revisions read as follows:

#### § 70.1 General definitions.

*Airline* means any air carrier or foreign air carrier providing air transportation as that term is defined in 49 U.S.C. 40102(a)(2), (a)(5), and (a)(21).

*Apprehension* means the temporary taking into custody of an individual or group for purposes of determining whether Federal quarantine, isolation, or conditional release is warranted.

\* \* \* \* \*

*Communicable stage* means the stage during which an infectious agent may be transmitted either directly or indirectly from an infected individual to another individual.

*Conditional release* means the temporary supervision by a public health official (or designee) of an individual or group, who may have been exposed to a quarantinable communicable disease to determine the risk of disease spread and includes public health supervision through in-person visits, telephone, or through electronic or Internet-based monitoring.

*Contaminated environment* means the presence of an infectious agent on a surface, including on inanimate articles, or in a substance, including food, water, or in the air.

*Conveyance* means an aircraft, train, road vehicle, vessel (as defined in this section) or other means of transport, including military.

\* \* \* \* \*

*Electronic or Internet-based monitoring* means mechanisms or technologies allowing for the temporary public health supervision of an individual under conditional release and may include communication through electronic mail, SMS texts, video or audio conference, webcam technologies, integrated voice-response systems, entry of information into a Web-based forum, wearable tracking technologies, and other mechanisms or technologies as determined by the Director or supervising health authority.

*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**.

*Incubation period* means the time from the moment of exposure to an infectious agent that causes a communicable disease until signs and symptoms of the communicable disease appear in the individual or, if signs and symptoms do not appear, the latest date signs and symptoms could reasonably be expected to appear. For a quarantinable communicable disease, incubation period means the precommunicable stage.

*Indigent* means an individual whose annual family income is below 200% of the applicable poverty guidelines updated periodically in the **Federal Register** by the U.S. Department of Health and Human Services under the authority of 42 U.S.C. 9902(2) or, if no income is earned, liquid assets totaling less than 15% of the applicable poverty guidelines.

*Interstate traffic* (1) Means:

(i) The movement of any conveyance or the transportation of persons or property, including any portion of such movement or transportation that is entirely within a State or possession—

(ii) From a point of origin in any State or possession to a point of destination in any other State or possession; or

(iii) Between a point of origin and a point of destination in the same State or possession but through any other State, possession, or contiguous foreign country.

(2) Interstate traffic does not include the following:

(i) The movement of any conveyance which is solely for the purpose of unloading persons or property transported from a foreign country, or loading persons or property for transportation to a foreign country.

(ii) The movement of any conveyance which is solely for the purpose of effecting its repair, reconstruction, rehabilitation, or storage.

\* \* \* \* \*

*Master or operator* with respect to a vessel, means the sea crew member with responsibility for vessel operation and navigation, or a similar individual with responsibility for a conveyance. Consistent with the definition of “operate” in 14 CFR 1.1, “operator” means, with respect to aircraft, any person who uses, causes to use, or authorizes to use an aircraft, for the

purpose (except as provided in 14 CFR 91.13) of air navigation including the piloting of an aircraft, with or without the right of legal control (as owner, lessee, or otherwise).

*Medical examination* means the assessment of an individual by an authorized and licensed health worker to determine the individual’s health status and potential public health risk to others and may include the taking of a medical history, a physical examination, and collection of human biological samples for laboratory testing as may be needed to diagnose or confirm the presence or extent of infection with a quarantinable communicable disease.

*Medical reviewer* means a physician, nurse practitioner, or similar medical professional qualified in the diagnosis and treatment of infectious diseases who is appointed by the Secretary or Director to conduct medical reviews under this part and may include an HHS or CDC employee, provided that the employee differs from the CDC official who issued the Federal order for quarantine, isolation, or conditional release.

*Non-invasive* means procedures conducted by an authorized public health worker (*i.e.*, an individual with education and training in the field of public health) or another individual with suitable public health training and includes the visual examination of the ear, nose, and mouth; temperature assessments using an ear, oral, cutaneous, or noncontact thermometer, or thermal imaging; and other procedures not involving the puncture or incision of the skin or insertion of an instrument or foreign material into the body or a body cavity excluding the ear, nose, and mouth.

\* \* \* \* \*

*Precommunicable stage* means the stage beginning upon an individual’s earliest opportunity for exposure to an infectious agent and ending upon the individual entering or reentering the communicable stage of the disease or, if the individual does not enter the communicable stage, the latest date at which the individual could reasonably be expected to have the potential to enter or reenter the communicable stage.

*Public health emergency* as used in this part means:

(1) Any communicable disease event as determined by the Director with either documented or significant potential for regional, national, or international communicable disease spread or that is highly likely to cause death or serious illness if not properly controlled; or

(2) Any communicable disease event described in a declaration by the



Secretary pursuant to 319(a) of the Public Health Service Act (42 U.S.C. 247d (a)); or

(3) Any communicable disease event the occurrence of which is notified to the World Health Organization, in accordance with Articles 6 and 7 of the International Health Regulations, as one that may constitute a Public Health Emergency of International Concern; or

(4) Any communicable disease event the occurrence of which is determined by the Director-General of the World Health Organization, in accordance with Article 12 of the International Health Regulations, to constitute a Public Health Emergency of International Concern; or

(5) Any communicable disease event for which the Director-General of the World Health Organization, in accordance with Articles 15 or 16 of the International Health Regulations, has issued temporary or standing recommendations for purposes of preventing or promptly detecting the occurrence or reoccurrence of the communicable disease.

*Public health prevention measures* means the assessment of an individual through non-invasive procedures and other means, such as observation, questioning, review of travel documents, records review, and other non-invasive means, to determine the individual's health status and potential public health risk to others.

*Qualifying stage* is statutorily defined (42 U.S.C. 264(d)(2)) to mean:

(1) The communicable stage of a quarantinable communicable disease; or

(2) The precommunicable stage of the quarantinable communicable disease, but only if the quarantinable communicable disease would be likely to cause a public health emergency if transmitted to other individuals.

\* \* \* \* \*

*Reasonably believed to be infected, as applied to an individual*, means specific articulable facts upon which a public health officer could reasonably draw the inference that an individual has been exposed, either directly or indirectly, to the infectious agent that causes a quarantinable communicable disease, as through contact with an infected person or an infected person's bodily fluids, a contaminated environment, or through an intermediate host or vector, and that as a consequence of the exposure, the individual is or may be harboring in the body the infectious agent of that quarantinable communicable disease.

*Representatives* means a physician, nurse practitioner, or similar medical professional qualified in the diagnosis and treatment of infectious diseases,

and an attorney who is knowledgeable of public health practices, who are appointed by the Secretary or Director and may include HHS or CDC employees, to assist an indigent individual under Federal quarantine, isolation, or conditional release with a medical review under this part.

\* \* \* \* \*

*Secretary* means the Secretary of Health and Human Services (HHS) or any other officer or employee of that Department to whom the authority involved has been delegated.

\* \* \* \* \*

■ 3. Revise § 70.5 to read as follows:

**§ 70.5 Requirements relating to travelers under a Federal order of isolation, quarantine, or conditional release.**

(a) The following provisions are applicable to any individual under a Federal order of isolation, quarantine, or conditional release with regard to a quarantinable communicable disease or to any individual meeting the requirements of paragraph (d), (e), or (f) of this section:

(1) Except as specified under the terms of a Federal conditional release order, no such individual shall travel in interstate traffic or from one State or U.S. territory to another without a written travel permit issued by the Director.

(2) Requests for a travel permit must state the reasons why the travel is being requested, mode of transportation, the places or individuals to be visited, the precautions, if any, to be taken to prevent the potential transmission or spread of the communicable disease, and other information as determined necessary by the Director to assess the individual's health condition and potential for communicable disease spread to others.

(3) The Director will consider all requests for a permit and, taking into consideration the risk of introduction, transmission, or spread of the communicable disease, may condition the permit upon compliance with such precautionary measures as the Director shall prescribe. The Director shall respond to a request for a permit within 5 business days.

(4) An individual to whom a permit has been issued shall retain it in his/her possession throughout the course of his/her authorized travel and comply with all conditions prescribed therein, including presentation of the permit to the operators of conveyances, as required by its terms.

(5) An individual who has had his/her request for a permit denied, or who has had a travel permit suspended or

revoked, may submit a written appeal to the Director (excluding the CDC official who denied, suspended, or revoked the permit). The appeal must be in writing, state the factual basis for the appeal, and be submitted to the Director (excluding the CDC official who denied, suspended, or revoked the permit) within 10 calendar days of the denial, suspension, or revocation of the permit. The Director (excluding the CDC official who denied, suspended, or revoked the permit) will issue a written response to the appeal within 3 business days, which shall constitute final agency action.

(b) The operator of any conveyance operating in interstate traffic shall not:

(1) Accept for transportation any individual whom the operator knows, or reasonably should know, to be under a Federal order of isolation, quarantine, or conditional release, unless such an individual presents a permit issued by the Director or a copy of the Federal conditional release order authorizing such travel;

(2) Transport any individual whom the operator knows, or reasonably should know, to be under a Federal order of isolation, quarantine, or conditional release in violation of any of the terms or conditions prescribed in the travel permit or conditional release order issued by the Director.

(c) Whenever a conveyance operating in interstate traffic transports an individual under a Federal order or travel permit, the Director may require that the operator of the conveyance submit the conveyance to inspection, sanitary measures, and other measures, as the Director deems necessary to prevent the possible spread of communicable disease.

(d) The Director may additionally apply the provisions in paragraphs (a) through (c) of this section to individuals traveling entirely intrastate and to conveyances that transport such individuals upon the request of a State or local health authority of jurisdiction. The Director shall consider the State or local health authority's request for assistance and taking into consideration the risk of introduction, transmission, or spread of the communicable disease, grant or deny, in his/her discretion, the request for assistance.

(e) The Director may additionally apply the provisions in paragraphs (a) through of this section (c) to individuals traveling interstate or entirely intrastate and to conveyances that transport such individuals whenever the Director makes a determination under 42 CFR 70.2 that based on the existence of inadequate local control such measures are needed to prevent the spread of any

of the communicable diseases from such State or U.S. territory to any other State or U.S. territory.

(f) The Director may additionally apply the provisions in paragraphs (a) through (c) of this section to individuals under a State or local order, or written agreement, for quarantine, isolation, or conditional release and to conveyances that may transport such individuals, upon the request of a State or local health authority of jurisdiction or whenever the Director makes a determination of inadequate local control under 42 CFR 70.2. The Director shall consider the State or local health authority's request for assistance and taking into consideration the risk of introduction, transmission, or spread of the communicable disease, grant or deny, in his/her discretion, the request for assistance.

(g) The Director may exempt individuals and non-public conveyances, such as ambulances, air ambulance flights, or private vehicles, from the requirements of this section.

■ 4. Revise § 70.6 to read as follows:

**§ 70.6 Apprehension and detention of persons with quarantinable communicable diseases.**

(a) The Director may authorize the apprehension, medical examination, quarantine, isolation, or conditional release of any individual for the purpose of preventing the introduction, transmission, and spread of quarantinable communicable diseases, as specified by Executive Order, based upon a finding that:

(1) The individual is reasonably believed to be infected with a quarantinable communicable disease in a qualifying stage and is moving or about to move from a State into another State; or

(2) The individual is reasonably believed to be infected with a quarantinable communicable disease in a qualifying stage and constitutes a probable source of infection to other individuals who may be moving from a State into another State.

(b) The Director will arrange for adequate food and water, appropriate accommodation, appropriate medical treatment, and means of necessary communication for individuals who are apprehended or held in quarantine or isolation under this part.

■ 5. Add §§ 70.10 through 70.18 to read as follows:

Sec. \* \* \* \* \*

70.10 Public health prevention measures to detect communicable disease.

70.11 Report of death or illness onboard aircraft operated by an airline.

70.12 Medical examinations.

70.13 Payment for care and treatment.

70.14 Requirements relating to the issuance of a Federal order for quarantine, isolation, or conditional release.

70.15 Mandatory reassessment of a Federal order for quarantine, isolation, or conditional release.

70.16 Medical review of a Federal order for quarantine, isolation, or conditional release.

70.17 Administrative records relating to Federal quarantine, isolation, or conditional release.

70.18 Penalties.

**§ 70.10 Public health prevention measures to detect communicable disease.**

(a) The Director may conduct public health prevention measures at U.S. airports, seaports, railway stations, bus terminals, and other locations where individuals may gather to engage in interstate travel, through non-invasive procedures determined appropriate by the Director to detect the presence of communicable diseases.

(b) As part of the public health prevention measures, the Director may require individuals to provide contact information such as U.S. and foreign addresses, telephone numbers, email addresses, and other contact information, as well as information concerning their intended destination, health status, known or possible exposure history, and travel history.

**§ 70.11 Report of death or illness onboard aircraft operated by an airline.**

(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.

**§ 70.12 Medical examinations.**

(a) The Director may require an individual to undergo a medical examination as part of a Federal order for quarantine, isolation, or conditional release for a quarantinable communicable disease.

(b) The Director shall promptly arrange for the medical examination to

be conducted when one is required under this section and shall as part of the Federal order advise the individual that the medical examination shall be conducted by an authorized and licensed health worker, and with prior informed consent.

(c) As part of the medical examination, the Director may require an individual to provide information and undergo such testing as may be reasonably necessary to diagnose or confirm the presence or extent of infection with a quarantinable communicable disease.

(d) Individuals reasonably believed to be infected based on the results of a medical examination may be isolated, or if such results are inconclusive or unavailable, individuals may be quarantined or conditionally released in accordance with this part.

**§ 70.13 Payment for care and treatment.**

(a) The Director may authorize payment for the care and treatment of individuals subject to medical examination, quarantine, isolation, and conditional release, subject to paragraphs (b) through (h) of this section.

(b) Payment for care and treatment shall be in the CDC's sole discretion and subject to the availability of appropriations.

(c) Payment shall be secondary to the obligation of the United States or any third-party (*i.e.*, any State or local governmental entity, private insurance carrier, or employer), under any other law or contractual agreement, to pay for such care and treatment, and shall be paid by the Director only after all third-party payers have made payment in satisfaction of their obligations.

(d) Payment may include costs for providing ambulance or other medical transportation when such services are deemed necessary by the Director for the individual's care and treatment.

(e) Payment shall be limited to those amounts the hospital, medical facility, or medical transportation service would customarily bill the Medicare system using the International Classification of Diseases, Clinical Modification (ICD-CM), and relevant regulations promulgated by the Centers for Medicare and Medicaid Services in existence at the time of billing.

(f) For quarantinable communicable diseases, payment shall be limited to costs for services and items reasonable and necessary for the care and treatment of the individual or group for the time period beginning when the Director refers the individual or group to the hospital or medical facility and ends when, as determined by the Director,

the period of apprehension, quarantine, isolation, or conditional release expires.

(g) For diseases other than those described in paragraph (f) of this section, such payment shall be limited to costs for services and items reasonable and necessary for care and treatment of the individual for the time period that begins when the Director refers the individual to the hospital or medical facility and ends when the individual's condition is diagnosed, as determined by the Director, as an illness other than a quarantinable communicable disease.

(h) For ambulance or other medical transportation, payment shall be limited to the costs for such services and other items reasonable and necessary for the individual's safe medical transport.

**§ 70.14 Requirements relating to the issuance of a Federal order for quarantine, isolation, or conditional release.**

(a) A Federal order authorizing quarantine, isolation, or conditional release shall be in writing, signed by the Director, and contain the following information:

(1) The identity of the individual or group subject to the order;

(2) The location of the quarantine or isolation or, in the case of conditional release, the entity to who and means by which the individual shall report for public health supervision;

(3) An explanation of the factual basis underlying the Director's reasonable belief that the individual is in the qualifying stage of a quarantinable communicable disease;

(4) An explanation of the factual basis underlying the Director's reasonable belief that the individual is moving or about to move from one State into another or constitutes a probable source of infection to others who may be moving from one State into another;

(5) An explanation that the Federal order will be reassessed no later than 72 hours after it has been served and an explanation of the medical review of the Federal order pursuant to this part, including the right to request a medical review, present witnesses and testimony at the medical review, and to be represented at the medical review by either an advocate (*e.g.*, an attorney, family member, or physician) at the individual's own expense, or, if indigent, to have representatives appointed at the government's expense;

(6) An explanation of the criminal penalties for violating a Federal order of quarantine, isolation, or conditional release; and

(7) An explanation that if a medical examination is required as part of the Federal order that the examination will

be conducted by an authorized and licensed health worker, and with prior informed consent.

(b) A Federal order authorizing quarantine, isolation, or conditional release shall be served on the individual no later than 72 hours after the individual has been apprehended, except that the Federal order may be published or posted in a conspicuous location if the Federal order is applicable to a group of individuals and individual service would be impracticable.

(c) The Director shall arrange for translation or interpretation services of the Federal order as needed.

(d) Nothing in this section shall affect the constitutional or statutory rights of individuals to obtain judicial review of their Federal detention.

**§ 70.15 Mandatory reassessment of a Federal order for quarantine, isolation, or conditional release.**

(a) The Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall reassess the need to continue the quarantine, isolation, or conditional release of an individual no later than 72 hours after the service of the Federal order.

(b) As part of the reassessment, the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall review all records considered in issuing the Federal order, including travel records, records evidencing exposure or infection with a quarantinable communicable disease, as well as any relevant new information.

(c) As part of the reassessment, and where applicable, the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall consider and make a determination regarding whether less restrictive alternatives would adequately serve to protect the public health.

(d) At the conclusion of the reassessment, the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall promptly issue and serve a written Federal order directing that the quarantine, isolation, or conditional release be continued, modified, or rescinded.

(e) In the event that the Director orders that the quarantine, isolation, or conditional release be continued or modified, the written Federal order shall explain the process for requesting a medical review under this part.

(f) The Director's written Federal order shall be promptly served on the

individual, except that the Federal order may be served by publication or by posting in a conspicuous location if the Federal order is applicable to a group of individuals and individual service would be impracticable.

(g) The Director shall arrange for translation or interpretation services of the Federal order as needed.

**§ 70.16 Medical review of a Federal order for quarantine, isolation, or conditional release.**

(a) The Director shall, as soon as practicable, arrange for a medical review upon a request by an individual under Federal quarantine, isolation, or conditional release.

(b) A request for a medical review may only occur after the Director's mandatory reassessment under section 70.15 and following the service of a Federal order continuing or modifying the quarantine, isolation, or conditional release.

(c) The medical review shall be for the purpose of ascertaining whether the Director has a reasonable belief that the individual is infected with a quarantinable communicable disease in a qualifying stage.

(d) The Director shall notify the individual in writing of the time and place of the medical review.

(e) The Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall designate a medical reviewer to review the medical or other evidence presented at the review, make medical or other findings of fact, and issue a recommendation concerning whether the Federal order for quarantine, isolation, or conditional release should be rescinded, continued, or modified.

(f) The individual under Federal quarantine, isolation, or conditional release may authorize an advocate (*e.g.*, an attorney, family member, or physician) at his or her own expense to submit medical or other evidence and, in the medical reviewer's discretion, be allowed to present a reasonable number of medical experts. The Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall appoint representatives at government expense to assist the individual for purposes of the medical review upon a request and certification, under penalty of perjury, by that individual that he or she is indigent.

(g) Prior to the convening of the review, the individual or his/her authorized advocate or representatives shall be provided a reasonable opportunity to examine the available medical and other records involved in

the medical review that pertain to that individual.

(h) The Director shall take such measures that he/she determines to be reasonably necessary to allow an individual under Federal quarantine or isolation to communicate with any authorized advocate or representatives in such a manner as to prevent the possible spread of the quarantinable communicable disease.

(i) The medical reviewer may order a medical examination of an individual when, in the medical reviewer's professional judgment, such an examination would assist in assessing the individual's medical condition.

(j) As part of the review, and where applicable, the medical reviewer shall consider and accept into the record evidence concerning whether less restrictive alternatives would adequately serve to protect public health.

(k) The medical review shall be conducted by telephone, audio or video conference, or through other means that the medical reviewer determines in his/her discretion are practicable for allowing the individual under quarantine, isolation, or conditional release to participate in the medical review.

(l) At the conclusion of the review, the medical reviewer shall, based upon his or her review of the facts and other evidence made available during the medical review, issue a written report to the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) concerning whether, in the medical reviewer's professional judgment, the Federal quarantine, isolation, or conditional release should be rescinded, continued, or modified. The written report shall include a determination regarding whether less restrictive alternatives would adequately serve to protect public health. The written report shall be served on the individual and the individual's authorized advocate or representatives.

(m) The Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall, as soon as practicable, review the written report and any objections that may be submitted by the individual or the individual's authorized advocate or representatives that contest the findings and recommendation contained in the medical reviewer's written report. Upon conclusion of the review, the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall promptly issue a written Federal order directing that the quarantine, isolation, or conditional

release be continued, modified, or rescinded. In the event that the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) continues or modifies the Federal quarantine, isolation, or conditional release, the Director's written order shall include a statement that the individual may request that the Director rescind the Federal quarantine, isolation, or conditional release, but based only on a showing of significant, new or changed facts or medical evidence that raise a genuine issue as to whether the individual should continue to be subject to Federal quarantine, isolation, or conditional release. The written Federal order shall be promptly served on the individual and the individual's authorized advocate or representatives, except that the Federal order may be served by publication or by posting in a conspicuous location if applicable to a group of individuals and individual service would be impracticable.

(n) The Director's written order shall not constitute final agency action until it has been served on the individual and the individual's authorized advocate or representatives, or alternatively, if applicable to a group of individuals and individual service would be impracticable, it is published or posted.

(o) The Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) may order the consolidation of one or more medical reviews if the number of individuals or other factors makes the holding of individual medical reviews impracticable.

(p) The Director may issue additional instructions as may be necessary or desirable governing the conduct of medical reviews.

(q) The Director shall arrange for translation or interpretation services as needed for purposes of this section.

#### **§ 70.17 Administrative records relating to Federal quarantine, isolation, or conditional release.**

(a) The administrative record of an individual under Federal quarantine, isolation, or conditional release shall, where applicable, consist of the following:

(1) The Federal order authorizing quarantine, isolation, or conditional release, including any subsequent Federal orders continuing or modifying the quarantine, isolation or conditional release;

(2) Records of any available medical, laboratory, or other epidemiologic information that are in the agency's possession and that were considered in issuing the Federal quarantine, isolation, or conditional release order;

or any subsequent Federal orders;

(3) Records submitted by the individual under quarantine, isolation, or conditional release, or by an authorized advocate or representatives, as part of a request for rescission of the Federal quarantine, isolation, or conditional release or as part of a medical review;

(4) The written findings and report of the medical reviewer, including any transcripts of the medical review and any written objections submitted by the individual under Federal quarantine, isolation, or conditional release, or by any authorized advocate or representatives;

(b) An individual subject to a Federal public health order shall upon request be served with a copy of his or her own administrative record in its entirety.

#### **§ 70.18 Penalties.**

(a) Persons in violation of this part are subject to a fine of no more than \$100,000 if the violation does not result in a death or one year in jail, or both, or a fine of no more than \$250,000 if the violation results in a death or one year in jail, or both, or as otherwise provided by law.

(b) Violations by organizations are subject to a fine of no more than \$200,000 per event if the violation does not result in a death or \$500,000 per event if the violation results in a death or as otherwise provided by law.

### **PART 71—FOREIGN QUARANTINE**

■ 6. The authority citation for part 71 continues to read as follows:

**Authority:** Secs. 215 and 311 of the Public Health Service (PHS) Act, as amended (42 U.S.C. 216, 243) section 361–369, PHS Act, as amended (42 U.S.C. 264–272).

■ 7. Amend § 71.1, paragraph (b), by—

■ a. Adding in alphabetical order definitions for “Airline” and “Apprehension”;

■ b. Revising the definition of “Commander”;

■ c. Adding in alphabetical order definitions for “Conditional release”, “Contaminated environment”, and “Electronic or Internet-based monitoring”;

■ d. Revising the definition of “Ill person”;

■ e. Adding in alphabetical order a definition for “Indigent”;

■ f. Revising the definition of “International voyage”;

■ g. Adding in alphabetical order definitions for “Master or operator”, “Medical examination”, “Medical reviewer”, “Non-invasive”, “Public health prevention measures”, “Representatives”, and “Secretary”.

The additions and revisions read as follows:

§ 71.1 General definitions.

\* \* \* \* \*

(b) \* \* \*

Airline means any air carrier or foreign air carrier providing air transportation, as that term is defined in 49 U.S.C. 40102(a)(2), (a)(5), and (a)(21).

Apprehension means the temporary taking into custody of an individual or group for purposes of determining whether quarantine, isolation, or conditional release is warranted.

\* \* \* \* \*

Commander means the pilot in command of an aircraft as defined in 14 CFR 1.1.

\* \* \* \* \*

Conditional release means surveillance as defined under this part and includes public health supervision through in-person visits by a health official or designee, telephone, or through any electronic or internet-based means as determined by the Director.

Contaminated environment means the presence of an infectious agent on a surface, including on inanimate articles, or in a substance, including food, water, or in the air.

\* \* \* \* \*

Electronic or internet-based monitoring means mechanisms or technologies allowing for the temporary public health supervision of an individual under conditional release and may include communication through electronic mail, SMS texts, video or audio conference, webcam technologies, integrated voice-response systems, entry of information into a web-based forum, wearable tracking technologies, and other mechanisms or technologies as determined by the Director.

Ill person means an individual:

(i) Who if onboard an aircraft:

(A) 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

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

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

(ii) Who if onboard a vessel:

(A) 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 or suspected or confirmed pneumonia, persistent cough or cough with bloody sputum, decreased consciousness or confusion of recent onset, new unexplained bruising or bleeding (without previous injury), persistent vomiting (other than sea sickness), headache with stiff neck; or

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

(C) Has acute gastroenteritis, which means either diarrhea, defined as three or more episodes of loose stools in a 24-hour period or what is above normal for the individual, or vomiting accompanied by one or more of the following: One or more episodes of loose stools in a 24-hour period, abdominal cramps, headache, muscle aches, or fever (temperature of 100.4 °F [38 °C] or greater); or

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

Indigent means an individual whose annual family income is below 200% of the applicable poverty guidelines updated periodically in the Federal Register by the U.S. Department of Health and Human Services under the authority of 42 U.S.C. 9902(2) or, if no income is earned, liquid assets totaling less than 15% of the applicable poverty guidelines.

\* \* \* \* \*

International voyage means:

(i) In the case of a carrier, a voyage between ports or airports of more than one country, or a voyage between ports or airports of the same country if the ship or aircraft stopped in any other country on its voyage; or

(ii) In the case of a person, a voyage involving entry into a country other than the country in which that person begins his/her voyage.

\* \* \* \* \*

Master or operator with respect to a vessel, means the sea crew member with responsibility for vessel operation and navigation, or a similar individual with responsibility for a carrier. Consistent with the definition of "operate" in 14 CFR 1.1, "operator" means, with respect to aircraft, any person who uses, causes to use or authorizes to use aircraft, for the purpose (except as provided in 14 CFR 91.13) of air navigation including the piloting of aircraft, with or without

the right of legal control (as owner, lessee, or otherwise).

Medical examination means the assessment of an individual by an authorized and licensed health worker to determine the individual's health status and potential public health risk to others and may include the taking of a medical history, a physical examination, and collection of human biological samples for laboratory testing as may be needed to diagnose or confirm the presence or extent of infection with a quarantinable communicable disease.

Medical reviewer means a physician, nurse practitioner, or similar medical professional qualified in the diagnosis and treatment of infectious diseases who is appointed by the Secretary or Director to conduct medical reviews under this part and may include an HHS or CDC employee, provided that the employee differs from the CDC official who issued the Federal order for quarantine, isolation, or conditional release.

\* \* \* \* \*

Non-invasive means procedures conducted by an authorized public health worker (i.e., an individual with education and training in the field of public health) or another individual with suitable public health training and includes the visual examination of the ear, nose, and mouth; temperature assessments using an ear, oral, cutaneous, or noncontact thermometer, or thermal imaging; and other procedures not involving the puncture or incision of the skin or insertion of an instrument or foreign material into the body or a body cavity excluding the ear, nose, and mouth.

\* \* \* \* \*

Public health prevention measures means the assessment of an individual through non-invasive procedures and other means, such as observation, questioning, review of travel documents, records review, and other non-invasive means, to determine the individual's health status and potential public health risk to others.

Representatives means a physician, nurse practitioner, or similar medical professional qualified in the diagnosis and treatment of infectious diseases, and an attorney who is knowledgeable of public health practices, who are appointed by the Secretary or Director and may include HHS or CDC employees, to assist an indigent individual under Federal quarantine, isolation, or conditional release with a medical review under this part.

\* \* \* \* \*

Secretary means the Secretary of Health and Human Services (HHS) or

any other officer or employee of that Department to whom the authority involved has been delegated.

\* \* \* \* \*

■ 8. Revise § 71.2 to read as follows:

**§ 71.2 Penalties.**

(a) Persons in violation of this part are subject to a fine of no more than \$100,000 if the violation does not result in a death or one year in jail, or both, or a fine of no more than \$250,000 if the violation results in a death or one year in jail, or both, or as otherwise provided by law. (b) Violations by organizations are subject to a fine of no more than \$200,000 per event if the violation does not result in a death or \$500,000 per event if the violation results in a death or as otherwise provided by law.

■ 9. Add 71.4 to subpart A to read as follows:

**§ 71.4 Requirements relating transmission of airline passenger, crew and flight information for public health purposes.**

(a) Any airline with a flight arriving into the United States, including any intermediate stops between the flight's origin and final destination, shall make the data elements in paragraph (b) of this section available to the Director for passengers or crew who, as determined by the Director, may be at risk of exposure to a communicable disease, to the extent that such data are already available and maintained by the airline, within 24 hours of an order by the Director and in a format available and acceptable to both the airline and the Director.

(b) The data elements referred to in paragraph (a) of this section include:

- (1) Full name (last, first, and, if available, middle or others);
- (2) Date of birth;
- (3) Sex;
- (4) Country of residence;
- (5) If a passport is required: Passport number, passport country of issuance, and passport expiration date;
- (6) If a travel document other than a passport is required: Travel document type, travel document number, travel document country of issuance and travel document expiration date;
- (7) Address while in the United States (number and street, city, State, and zip code), except that U.S. citizens and lawful permanent residents will provide address of permanent residence in the U.S. (number and street, city, State, and zip code);
- (8) Primary contact phone number to include country code;
- (9) Secondary contact phone number to include country code;
- (10) Email address;
- (11) Airline name;

- (12) Flight number;
- (13) City of departure;
- (14) Departure date and time;
- (15) City of arrival;
- (16) Arrival date and time; and
- (17) Seat number.

(c) No later than February 18, 2019, the Secretary or Director will publish and seek comment on a report evaluating the burden of this section on affected entities and duplication of activities in relation to mandatory passenger data submissions to DHS/CBP. The report will specifically recommend actions that streamline and facilitate use and transmission of any duplicate information collected.

■ 10. Add § 71.5 to subpart A to read as follows:

**§ 71.5 Requirements relating transmission of vessel passenger, crew, and voyage information for public health purposes.**

(a) The operator of any vessel carrying 13 or more passengers (excluding crew) and, which is not a ferry as defined under 46 U.S.C. 2101 and U.S. Coast Guard (USCG) regulations (46 CFR 2.10–25), shall make the data elements in paragraph (b) of this section available to the Director for passengers or crew who, as determined by the Director, may be at risk of exposure to a communicable disease, to the extent that such data are already in the operator's possession, within 24 hours of an order by the Director and in a format available and acceptable to both the operator and the Director.

(b) The data elements referred to in paragraph (a) of this section include:

- (1) Full name (last, first, and, if available middle or others);
- (2) Date of birth;
- (3) Sex;
- (4) Country of residence;
- (5) If a passport is required: Passport number, passport country of issuance, and passport expiration date;
- (6) If a travel document other than a passport is required: Travel document type, travel document number, travel document country of issuance and travel document expiration date;
- (7) Address while in the United States (number and street, city, State, and zip code), except that U.S. citizens and lawful permanent residents will provide address of permanent residence in the United States (number and street, city, State, and zip code; as applicable);
- (8) Primary contact phone number to include country code;
- (9) Secondary contact phone number to include country code;
- (10) Email address;
- (11) Vessel operator;
- (12) Vessel name;
- (13) Voyage number;

- (14) Embarkation port and date;
- (15) Disembarkation port and date;
- (16) All port stops; and
- (17) Cabin number.

(c) No later than February 21, 2019, the Secretary or Director will publish and seek comment on a report evaluating the burden of this section on affected entities and duplication of activities in relation to mandatory passenger data submissions to DHS/CBP. The report will specifically recommend actions that streamline and facilitate use and transmission of any duplicate information collected.

■ 11. Add § 71.20 to subpart C to read as follows:

**§ 71.20 Public health prevention measures to detect communicable disease.**

(a) The Director may conduct public health prevention measures, at U.S. ports of entry or other locations, through non-invasive procedures as defined in section 71.1 to detect the potential presence of communicable diseases.

(b) As part of the public health prevention measures, the Director may require individuals to provide contact information such as U.S. and foreign addresses, telephone numbers, email addresses, and other contact information, as well as information concerning their intended destination, health status, known or possible exposure history, and travel history.

■ 12. Add §§ 71.29 and 71.30 to subpart D to read as follows:

**§ 71.29 Administrative records relating to quarantine, isolation, or conditional release.**

(a) The administrative record of an individual under quarantine, isolation, or conditional release shall, where applicable, consist of the following:

(1) The Federal order authorizing quarantine, isolation, or conditional release, including any subsequent Federal orders continuing or modifying the quarantine, isolation or conditional release;

(2) Records of any available medical, laboratory, or other epidemiologic information that are in the agency's possession and that were considered in issuing the Federal quarantine, isolation, or conditional release order, or any subsequent Federal orders;

(3) Records submitted by the individual under quarantine, isolation, or conditional release, or by an authorized advocate or representatives, as part of a request for rescission of the quarantine, isolation, or conditional release or as part of a medical review;

(4) The written findings and report of the medical reviewer, including any transcripts of the medical review and any written objections submitted by the

individual under Federal quarantine, isolation, or conditional release, or by an authorized advocate or representatives;

(b) An individual subject to a Federal public health order shall, upon request, be served with a copy of his or her own administrative record in its entirety.

**§ 71.30 Payment for care and treatment.**

(a) The Director may authorize payment for the care and treatment of individuals subject to medical examination, quarantine, isolation, and conditional release, subject to paragraphs (b) through (h) of this section.

(b) Payment for care and treatment shall be in the Director's sole discretion and subject to the availability of appropriations.

(c) Payment shall be secondary to the obligation of the United States or any third-party (including any State or local governmental entity, private insurance carrier, or employer), under any other law or contractual agreement, to pay for such care and treatment, and shall be paid by the Director only after all third-party payers have made payment in satisfaction of their obligations.

(d) Payment may include costs for providing ambulance or other medical transportation when such services are deemed necessary by the Director for the individual's care and treatment.

(e) Payment shall be limited to those amounts the hospital, medical facility, or medical transportation service would customarily bill the Medicare system using the International Classification of Diseases, Clinical Modification (ICD-CM), and relevant regulations promulgated by the Centers for Medicare and Medicaid Services in existence at the time of billing.

(f) For quarantinable communicable diseases, payment shall be limited to costs for services and items reasonable and necessary for the care and treatment of the individual for the time period beginning when the Director refers the individual to the hospital or medical facility and ends when, as determined by the Director, the period of apprehension, quarantine, isolation, or conditional release expires.

(g) For diseases other than those described in paragraph (f) of this section, such payment shall be limited to costs for services and items reasonable and necessary for care and treatment of the individual for the time period that begins when the Director refers the individual to the hospital or medical facility and ends when the individual's condition is diagnosed, as determined by the Director, as an illness

other than a quarantinable communicable disease.

(h) For ambulance or other medical transportation, payment shall be limited to the costs for such services and other items reasonable and necessary for the safe medical transport of the individual.

■ 13. Amend § 71.33 by revising paragraphs (a) and (c) to read as follows:

**§ 71.33 Persons: Isolation and surveillance.**

(a) The Director will arrange for adequate food and water, appropriate accommodation, appropriate medical treatment, and means of necessary communication for persons who are apprehended or held in isolation or quarantine under this subpart.

\* \* \* \* \*

(c) Every person who is placed under surveillance by authority of this subpart shall, during the period of surveillance:

(1) Give information relative to his/her health and his/her intended destination and submit to surveillance, including electronic and internet-based monitoring as required by the Director or by the State or local health department having jurisdiction over the areas to be visited, and report for such medical examinations as may be required.

(2) Inform the Director prior to departing the United States or prior to traveling to any address other than that stated as the intended destination.

\* \* \* \* \*

■ 14. Add §§ 71.36 through 71.39 to subpart D to read as follows:

Sec.

\* \* \* \* \*

- 71.36 Medical examinations.
- 71.37 Requirements relating to the issuance of a Federal order for quarantine, isolation, or conditional release.
- 71.38 Mandatory reassessment of a Federal order for quarantine, isolation, or conditional release (surveillance).
- 71.39 Medical review of a Federal order for quarantine, isolation, or conditional release.

**§ 71.36 Medical examinations.**

(a) The Director may require that an individual arriving into the United States undergo a medical examination as part of a Federal order for quarantine, isolation, or conditional release.

(b) The Director shall promptly arrange for the medical examination to be conducted when one is required under this section and shall as part of the Federal order advise the individual that the medical examination shall be conducted by an authorized and licensed health worker, and with prior informed consent.

(c) As part of the medical examination, the Director may require

that an individual provide information and undergo such testing, as may be reasonably necessary, to diagnose or confirm the presence, absence, or extent of infection with a quarantinable communicable disease.

(d) Individuals reasonably believed to be infected, based on the results of a medical examination, may be isolated, or if such results are inconclusive or unavailable, individuals may be quarantined or conditionally released in accordance with this part.

**§ 71.37 Requirements relating to the issuance of a Federal order for quarantine, isolation, or conditional release.**

(a) A Federal order authorizing quarantine, isolation, or conditional release shall be in writing, signed by the Director, and contain the following information:

- (1) The identity of the individual or group subject to the order;
- (2) The location of the quarantine or isolation or, in the case of conditional release, the entity to who and means by which the individual shall report for public health supervision;
- (3) An explanation of the factual basis underlying the Director's reasonable belief that the individual is exposed to or infected with a quarantinable communicable disease;

(4) An explanation that the Federal order will be reassessed no later than 72 hours after it has been served and an explanation of the medical review of the Federal order pursuant to this part, including the right to request a medical review, present witnesses and testimony at the medical review, and to be represented at the medical review by either an advocate (e.g., an attorney, family member, or physician) at the individual's own expense, or, if indigent, to have representatives appointed at the government's expense;

(5) An explanation of the criminal penalties for violating a Federal order of quarantine, isolation, or conditional release; and

(6) An explanation that if a medical examination is required as part of the Federal order that the examination will be conducted by an authorized and licensed health worker, and with prior informed consent.

(b) A Federal order authorizing quarantine, isolation, or conditional release shall be served on the individual no later than 72 hours after the individual has been apprehended, except that the Federal order may be published or posted in a conspicuous location if applicable to a group of individuals and individual service would be impracticable.



(c) The Director shall arrange for translation or interpretation services of the Federal order as needed.

(d) Nothing in these regulations shall affect the constitutional or statutory rights of individuals to obtain judicial review of their federal detention.

**§ 71.38 Mandatory reassessment of a Federal order for quarantine, isolation, or conditional release (surveillance).**

(a) The Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall reassess the need to continue the quarantine, isolation, or conditional release of an individual no later than 72 hours after the service of the Federal order.

(b) As part of the reassessment, the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall review all records considered in issuing the Federal order, including travel records, records evidencing exposure or infection with a quarantinable communicable disease, as well as any relevant new information.

(c) As part of the reassessment, and where applicable, the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall consider and make a determination regarding whether less restrictive alternatives would adequately serve to protect the public health.

(d) At the conclusion of the reassessment, the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall promptly issue a written Federal order directing that the quarantine, isolation, or conditional release be continued, modified, or rescinded.

(e) In the event that the Director orders that the quarantine, isolation, or conditional release be continued or modified, the written Federal order shall explain the process for requesting a medical review under this part.

(f) The Director's written Federal order shall be promptly served on the individual, except that the Federal order may be served by publication or by posting in a conspicuous location if applicable to a group of individuals and individual service would be impracticable.

(g) The Director shall arrange for translation or interpretation services of the Federal order as needed.

**§ 71.39 Medical review of a Federal order for quarantine, isolation, or conditional release.**

(a) The Director shall, as soon as practicable, arrange for a medical review

upon a request by an individual under Federal quarantine, isolation, or conditional release.

(b) A request for a medical review may only occur after the Director's mandatory reassessment under 71.38 and following the issuance and service of a Federal order continuing or modifying the quarantine, isolation, or conditional release.

(c) The medical review shall be for the purpose of ascertaining whether the Director has a reasonable belief that the individual is infected with a quarantinable communicable disease.

(d) The Director shall notify the individual in writing of the time and place of the medical review.

(e) The Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall designate a medical reviewer to review the medical or other evidence presented at the review, make medical or other findings of fact, and issue a recommendation concerning whether the Federal order for quarantine, isolation, or conditional release should be rescinded, continued, or modified.

(f) The individual subject to Federal quarantine, isolation, or conditional release may authorize an advocate (e.g., an attorney, family member, or physician) at his or her own expense to submit medical or other evidence and, in the medical reviewer's discretion, be allowed to present a reasonable number of medical experts. The Director shall appoint representatives at government expense to assist the individual for purposes of the medical review upon a request and certification, under penalty of perjury, by that individual that he/she is indigent.

(g) Prior to the convening of the review, the individual or his/her authorized advocate or representatives shall be provided a reasonable opportunity to examine the available medical and other records involved in the medical review pertaining to that individual.

(h) The Director shall take such measures that he/she determines to be reasonably necessary to allow an individual under Federal quarantine or isolation to communicate with any authorized advocate or representatives in such a manner as to prevent the possible spread of the quarantinable communicable disease.

(i) The medical reviewer may order a medical examination of an individual when, in the medical reviewer's professional judgment, such an examination would assist in assessing the individual's medical condition.

(j) As part of the review, and where applicable, the medical reviewer shall

consider and accept into the record evidence concerning whether less restrictive alternatives would adequately serve to protect public health.

(k) The medical review shall be conducted by telephone, audio or video conference, or through other means that the medical reviewer determines in his/her discretion are practicable for allowing the individual under quarantine, isolation, or conditional release to participate in the medical review.

(l) At the conclusion of the review, the medical reviewer shall, based upon his or her review of the facts and other evidence made available during the medical review, issue a written report to the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) concerning whether, in the medical reviewer's professional judgment, the Federal quarantine, isolation, or conditional release should continue. The written report shall include a determination regarding whether less restrictive alternatives would adequately serve to protect public health. The written report shall be served on the individual and the individual's authorized advocate or representatives.

(m) The Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall, as soon as practicable, review the written report and any objections that may be submitted by the individual or the individual's advocate or representatives that contest the findings and recommendation contained in the medical reviewer's written report. Upon conclusion of the review, the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall promptly issue a written Federal order directing that the quarantine, isolation, or conditional release be continued, modified, or rescinded. In the event that the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) continues or modifies the Federal quarantine, isolation, or conditional release, the Director's written order shall include a statement that the individual may request that the Director rescind the Federal quarantine, isolation, or conditional release, but based only on a showing of significant, new or changed facts or medical evidence that raise a genuine issue as to whether the individual should continue to be subject to Federal quarantine, isolation, or conditional release. The written Federal order shall be promptly served on the individual and the individual's authorized advocate or



representatives, except that the Federal order may be served by publication or by posting in a conspicuous location if applicable to a group of individual's and individual service would be impracticable.

(n) The Director's written order shall not constitute final agency action until it has been served on the individual or the individual's authorized advocate or representatives, or alternatively, if applicable to a group of individuals and individual service would be impracticable, it is published or posted.

(o) The Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) may order the consolidation of one or more medical reviews if the number of individuals or other factors makes the holding of individual medical reviews impracticable.

(p) The Director may issue additional instructions as may be necessary or

desirable governing the conduct of medical reviews.

(q) The Director shall arrange for translation or interpretation services as needed for purposes of this section.

■ 15. Add § 71.63 to subpart F to read as follows:

**§ 71.63 Suspension of entry of animals, articles, or things from designated foreign countries and places into the United States.**

(a) The Director may suspend the entry into the United States of animals, articles, or things from designated foreign countries (including political subdivisions and regions thereof) or places whenever the Director determines that such an action is necessary to protect the public health and upon a finding that:

(1) There exists in a foreign country (including one or more political subdivisions and regions thereof) or place a communicable disease the introduction, transmission, or spread of

which would threaten the public health of the United States; and

(2) The entry of imports from that country or place increases the risk that the communicable disease may be introduced, transmitted, or spread into the United States.

(b) The Director shall designate the foreign countries or places and the period of time or conditions under which the introduction of imports into the United States shall be suspended. The Secretary or Director will coordinate in advance with other Federal agencies that have overlapping authority in the regulation of entry of animals, articles, or other things, as may be necessary to implement and enforce this provision.

Dated: January 9, 2017.

**Sylvia M. Burwell,**  
*Secretary.*

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