

# Questions and Answers about the Final Rule for Control of Communicable Diseases: Interstate (Domestic) and Foreign Quarantine

# Overview

The Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC) published the final rule for the Control of Communicable Diseases on January 19th, 2017 which includes amendments to the current domestic (interstate) and foreign quarantine regulations for the control of communicable diseases. The final rule is published on the Office of the Federal Register's website .

These amendments have been made to better protect the public health of the United States and reflect public comments received regarding the Notice of Proposed Rulemaking (NPRM) published on August 15, 2016. This final rule improves CDC's ability to protect against the introduction, transmission, and spread of communicable diseases while ensuring due process. This rule became effective on March 21<sup>st</sup>, 2017.

## Public Comments to the NPRM

HHS/CDC published a Notice of Proposed Rulemaking on August 15, 2016, and received 15,800 public comments from individuals, stakeholders, and other interested parties during the 60-day comment period. We note that many commenters raised concerns about forced vaccinations or compulsory medical treatment. We emphasize that this final rule does not authorize compulsory medical testing, vaccinations, or medical treatment.

Other comments covered a range of topics, including: proposed agreements entered into between the CDC and persons subject to public health orders, CDC's constitutional and statutory authority for carrying out its public health activities, data collection from airline and vessel operators, communicable diseases subject to federal isolation and quarantine, due process concerns, concerns about electronic monitoring and surveillance of persons subject to public health orders, the proposed definition and requirements for airline and vessel operators to report an "ill person," concerns about public health assessments being made by non-medically trained personnel, payment for hospital and other expenses for persons subject to public health orders, the proposed definition of "indigent," and concerns about CDC's description of existing criminal penalties that appear in statute.

As a result of these comments, CDC made many significant changes from the NPRM to the final rule. Changes are described in detail below.

What has CDC changed in the final rule as a result of public comment?

After reviewing and carefully considering the comments on the Notice of Proposed Rulemaking, HHS/CDC made the following changes to the rule:

- Removed the proposed provision, definition, and references to "Agreements."
- Added a requirement that CDC serve an individual with a public health order within 72 hours after apprehending the individual.
- Added a requirement for CDC to advise an individual subject to a medical examination that the examination will be conducted by an authorized, licensed health worker and with prior informed consent.
- Added a requirement that CDC provide for translation or interpretation services as needed for federal orders and during the medical review.
- 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 federal guarantine or isolation.
- Clarified how CDC considers and determines how to use the least restrictive means in quarantining or isolating an individual to protect the public's health.
- Added a right to counsel by changing the definition of Medical Representative to "Representatives" and added the
  additional appointment of "an attorney who is knowledgeable of public health practices" for an indigent individual
  who requests a medical review.
- Increased the threshold for those who may be considered "indigent" to 200% of the federal poverty level (the NPRM proposed a 150% threshold), so that more individuals may qualify for appointment of a medical representative and an attorney.
- Further explained that the definitions of both "representatives" and "medical reviewer" 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 federal quarantine or isolation order.
- Modified the definition of "electronic or internet-based monitoring" by clarifying that this definition pertains to the means by which CDC may communicate with an individual (e.g., Skype, email, cellular phone calls).
- Added a requirement that the Director must respond to a request for a travel permit within 5 business days and must respond to an appeal of a denial of a travel permit within 3 business days.
- Modified the definition of non-invasive to (1) replace "physical inspection" with "visual inspection," (2) specify that the individual performing the assessment must be a "public health worker" and (3) remove "auscultation, external palpation, external measurement of blood pressure." The definition has also been clarified to explain that the public health worker who conducts the public health risk assessment is "an individual with education and training in the field of public health."

### Who is affected by CDC's new foreign and domestic communicable disease regulations?

These regulations generally apply to persons (regardless of citizenship or nationality) arriving into the United States from foreign countries or traveling between U.S. states or territories. Certain provisions of these regulations also apply to conveyance operators (e.g., the operator of an airplane, ship, bus, or train) or persons attempting to import an animal or other product into the United States.

### Does this rule authorize mandatory vaccination without informed consent?

No, this final rule does not authorize compulsory vaccination, medical testing, or medical treatment. When a medical examination is ordered as part of an isolation or quarantine order, the medical exam is conducted by trained clinical staff at a hospital who are responsible for obtaining informed consent. The final rule now requires that the CDC Director, as part of the Federal order authorizing a medical examination, advise the individual that the medical examination will be conducted by an authorized, licensed health worker and with prior informed consent.

### How does CDC protect data it collects about travelers?

CDC is committed to protecting the privacy of personally identifiable information collected and maintained under the Privacy Act of 1974. On December 13, 2007, HHS/CDC published a notice of a new system of records (SORN) under the Privacy Act of 1974 for activities covered under this final rule.

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. 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, CDC will make disclosures from the system only with the consent of the subject individual, in accordance with the routine uses published in its SORN, or as allowed under an exception to the Privacy Act. Furthermore, CDC will apply the protections of the SORN to all travelers regardless of citizenship or nationality.

### How does CDC store the data provided by airlines and/or vessels?

This data is currently stored in the Quarantine Activity Reporting System (QARS) and data is kept in accordance with the records retention schedule. The National Archives and Records Administration (NARA) maintains the official Records Control Schedule (RCS) repository . The repository contains scanned versions of approved records schedules, or Standard Forms 115, Request for Records Disposition Authority.

# Protecting People's Rights

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The final rule is a significant improvement over previous regulations that contained no explicit due process protections. In response to public comment, the final rule added many strong due process protections for individuals subject to federal public health orders. These protections include:

- The right to a written order that explains the reasons why the CDC considers quarantine or isolation to be necessary and your rights if held in federal quarantine or isolation;
- The right to have this written order served on you within 72 hours after being apprehended;
- The right to adequate food and water, appropriate accommodation, appropriate medical treatment, and means of necessary communication while apprehended or if held in federal quarantine or isolation;
- The right to have CDC reassess its written order within 72 hours after it is served on you to ensure that the CDC has not made a mistake, that there is a continued public health need for federal quarantine or isolation, and that the CDC is using the least restrictive means to protect the public's health;
- The right to request a medical review after the CDC has reassessed its written order and if the CDC has determined that quarantine or isolation is still necessary;
- The right to have a medical review conducted by a medical reviewer (a medical professional other than the person who issued the quarantine or isolation order) and to have the medical reviewer make findings of fact, issue a report and recommendation to the CDC Director, and make his/her own determination as to whether the CDC is using the least restrictive means to protect the public's health;
- The right to 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 your own expense, or, if indigent, to have representatives (i.e., a medical professional and an attorney) appointed at the government's expense.
- Acknowledgement that you still have the right to go to court.

### Can the "medical reviewer" and "representatives" be people from outside the CDC?

The final rule defines both "representatives" and "medical reviewer" in a manner that would allow for the appointment of non-HHS/CDC employees in these capacities at the Director's discretion. For individuals qualifying as indigent, CDC generally intends to provide independent legal counsel from outside of the agency. However, to maintain flexibility and ensure that medical reviews are conducted in a timely fashion, CDC has retained language in the final rule stating that representatives and the medical reviewer, "may include an HHS or CDC employee."

#### Does the final rule require CDC to use the least restrictive means to protect the public's health?

Yes, CDC will carry out its authorities for isolation and quarantine consistent with principles of using the least restrictive means to protect the public's health. In general, this means that the CDC will attempt to obtain voluntary compliance with public health measures and explore options such as the appropriateness of a home environment if quarantine or isolation is necessary.

### Does the final rule preserve people's right to go to court?

Yes, the final rule explicitly states that it does not affect the constitutional or statutory rights of individuals to obtain judicial review of their federal detention. Individuals who are detained in federal isolation or quarantine may file a petition for a writ of habeas corpus as appropriate 

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#### Is the final rule consistent with the International Health Regulations?

Yes, the final rule is consistent with U.S. obligations under the IHR. In addition to implementing the final rule consistent with U.S. constitutional requirements, CDC's implementation will also be consistent with IHR Article 32 which, among other things, requires provision of basic necessities, protection of baggage and other possessions, appropriate accommodation, arranging for appropriate medical treatment, and means of communication for international travelers subject to public health orders.

# CDC's Authority Under this Rule

### Does the final rule expand CDC's authority?

No, the final rule does not expand the authority granted to the CDC by Congress to place individuals into quarantine or isolation, nor does it change the formal list of diseases subject to federal isolation or quarantine, which is established only by an Executive Order of the President.

### What communicable diseases are subject to federal isolation and quarantine?

CDC's authority to order isolation or quarantine is limited to people who the CDC reasonably believes to be infected with a quarantinable communicable disease as defined by Executive Order of the President. The final rule does not change the list of quarantinable communicable diseases; the list may only be changed by Executive Order of the President. The current list of these diseases is available here.

This list currently includes cholera, diphtheria, infectious tuberculosis, plague, smallpox, yellow fever, viral hemorrhagic fevers (Lassa, Marburg, Ebola, Crimean-Congo, South American, and others not yet isolated or named), severe acute respiratory syndromes (e.g., SARS, MERS), and influenza caused by novel or reemergent influenza viruses that are causing, or have the potential to cause, a pandemic.

If an individual does not have, or is not suspected of having, one of these illnesses, CDC cannot hold the individual for quarantine or isolation.

#### When does CDC use its federal authority?

CDC generally uses its federal authority to isolate a sick person or quarantine an exposed person only in rare situations where states do not have jurisdiction or are otherwise unable to use their authority. For example, CDC has used its isolation authority at international airports and land border crossings. CDC may also use its authority if a state or local authority requests assistance from CDC or in the event of inadequate local control.

### What about a State's responsibility for isolation or quarantine?

CDC acknowledges that the States have primary authority for quarantine and isolation within their borders. The final rule is consistent with U.S. principles of federalism (the relationship between the federal government and state/local governments). By statute, 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. The final rule does not change the long-standing provision at 42 C.F.R. 70.2 authorizing CDC to take measures to prevent the interstate spread of communicable diseases in the event of inadequate local control. The final rule recognizes that CDC by statute has a primary role at ports of entry and in other time-sensitive situations where state and local public health authorities may not be present or where measures taken by these authorities are inadequate to prevent communicable disease spread.

### Why does CDC use the term "apprehension" in the final rule?

CDC uses the term "apprehension" because this term aligns with the statutory language written by Congress in the Public Health Service Act at 42 U.S.C. 264. The final rule defines an apprehension as "the temporary taking into custody of an individual or group for purposes of determining whether quarantine, isolation, or conditional release is warranted." Please see the response below for more details regarding apprehension and public health risk assessments.

### How does CDC determine if someone should be apprehended?

Before issuing a quarantine or isolation order, CDC conducts a public health risk assessment that takes into account symptoms and possible exposures.

CDC may apprehend, detain, examine, or conditionally release an individual if it reasonably believes that he/she may be infected with or exposed to a quarantinable communicable disease.

The final rule defines reasonable belief as the existence of "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."

### How long can someone be apprehended and detained?

Under the final rule, CDC must serve an individual with a federal order for quarantine, isolation, or conditional release within 72 hours after taking that person into custody. CDC notes that historically, the issuance of federal orders is rare (i.e. 1 to 2 orders issued per year).

Isolation would last for the period of communicability of the illness, which varies by disease and the availability of specific treatment. Quarantine lasts only as long as necessary to protect the public by (1) providing public health care (such as voluntary immunization or drug treatment, as required) and (2) ensuring that quarantined persons do not infect others if they have been exposed to a contagious disease.

The final rule does not expand CDC's authority to quarantine or isolate individuals or eliminate the formal list of diseases subject to federal isolation or quarantine. By statute, CDC authority to apprehend, detain, or examine an individual is limited to those quarantinable communicable diseases that are specified in an Executive Order of the President and cannot be changed by the CDC.

The final rule defines "public health emergency" because by statute CDC may only apprehend and detain an individual who is moving between U.S. states if the individual is in the "qualifying stage" of a quarantinable communicable disease. The "qualifying stage" is defined by statute as the "communicable stage" of the disease or a "precommunicable stage, if the disease would be likely to cause a public health emergency if transmitted to other individuals." The final rule defines "public health emergency" so that people will better understand CDC's processes and procedures around quarantine and isolation.

# Using Effective Public Health Measures

### Are the public health measures described in this final rule effective?

Yes, the final rule is consistent with scientific principles and best practices of modern isolation and quarantine. Modern isolation and quarantine lasts only as long as necessary to protect the public by (1) providing a public health intervention (such as voluntary testing or drug treatment, as appropriate and with the informed consent of the patient) and (2) ensuring that persons under isolation and quarantine do not infect others if they have been exposed to or are capable of spreading a quarantinable communicable disease.

# Protecting Travelers through Illness Reporting

### If someone is reported as being "ill" under the definition in the final rule, what will happen?

The final rule does not expand CDC's authority to quarantine or isolate individuals or eliminate the formal list of diseases subject to federal isolation or quarantine. By statute, CDC authority to apprehend, detain, or examine an individual is limited to quarantinable communicable diseases that are specified in an Executive Order of the President. The final rule defines an "ill person" for purposes of determining when a public health investigation of an ill traveler onboard a flight or ship may be required. An "ill person" is not automatically subject to federal isolation and quarantine.

Airline pilots and ship operators are required to report all deaths on board, and certain overt and common signs and symptoms of sick travelers to the CDC and before arriving into the United States. HHS/CDC has also requested that other symptoms of communicable diseases be routinely reported to the CDC. This rule makes these commonly requested symptoms (already routinely and voluntarily reported to CDC) required reporting.

This final rule does not change any current operations of CDC's Vessel Sanitation Program or make any substantive changes in gastrointestinal illness (i.e. diarrheal) reporting for vessels. Updated lists of the additional required signs and symptoms are in the table below.

### **Airlines**

(1) Fever (defined as measured temperature of 100.4°F [38°C] or greater, feels warm to the touch, or gives a history of feeling feverish)

#### **AND one** of the following:

- Skin rash
- Difficulty breathing
- Persistent cough
- Decreased consciousness or recent onset of confusion
- New unexplained bleeding or bruising
- Persistent diarrhea
- Persistent vomiting (other than airsickness)
- Headache with stiff neck
- Appearing obviously unwell; OR
- (2) Fever that has persisted for more than 48 hours; **OR**
- (3) Other signs or symptoms of communicable disease CDC is concerned about and has announced in the Federal Register.

### Ships

(1) Fever (defined as measured temperature of 100.4°F [38°C] or greater, feels warm to the touch, or gives a history of feeling feverish)

### **AND one** of the following:

- Skin rash
- Difficulty breathing or suspected or confirmed pneumonia
- Persistent cough or cough with bloody sputum
- Decreased consciousness or recent onset of confusion
- New unexplained bruising or bleeding
- Persistent vomiting (other than seasickness)
- Headache with stiff neck
- Appearing obviously unwell; OR
- (2) Fever that has persisted for more than 48 hours; **OR**
- (3) Acute gastroenteritis (inflammation of stomach or intestines or both), defined as:
  - Diarrhea, defined as within a 24-hour period, 3 or more episodes of loose stools or an occurrence of loose stools that is above normal for the person, or
  - Vomiting and one or more of the following additional symptoms: 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
- (4) Other signs or symptoms of communicable disease CDC is concerned about and has announced in the Federal Register.

### Why has HHS/CDC updated the definition of "ill person"?

The updated definition includes additional signs and symptoms that might be expected in a person who has a quarantinable communicable disease or another serious communicable disease that could spread through travel. By giving airlines and ships this updated definition, CDC is increasing the likelihood that a sick person with a communicable disease will be recognized by the CDC. The new definition also more closely matches international standards for disease reporting published by the International Civil Aviation Organization (ICAO, the United Nations specialized agency for air travel). Finally, the new definition allows the CDC Director to update the definition through notice in the Federal Register if new information suggests that additional signs or symptoms should be reported to limit the risk of disease spread through travel.

### Why is the definition of "ill person" different for airline and ship operators?

The "ill person" definition is different for airlines and ships because in general, travelers spend more time on ships than they do on a plane. As a result, there is more time to monitor travelers on ships for signs and symptoms of disease. Cruise ships usually have a medical provider on board who can complete a medical examination of the sick traveler, and both cruise and cargo ships can request a consultation from CDC long before the ship arrives at a port of entry.

### What is the updated reporting requirement for domestic airlines? Is this a new procedure?

With these updates, airline crews flying between states must report directly to CDC any deaths occurring on board and certain signs and symptoms of sick travelers. This requirement will mirror the current reporting requirement for flights arriving into the United States from a foreign country. CDC will then coordinate a response with state and local public health authorities. This update will streamline reporting and response to sick travelers on flights between states by providing a single point of contact.

The regulations continue to allow flight crews to report sick travelers to the local health authority in addition to CDC. Airlines may choose to report to CDC or to CDC and the local or state health department. Most chose to report to only to CDC for convenience. The update to the regulations allows airlines to report to CDC, instead of the local health authority. CDC will then notify the state or local health authority, as needed, satisfying any federal requirement to report to the local health authority. The updated requirements also more closely match guidance and standards issued to airlines by the International Civil Aviation Organization (ICAO).

#### How will airline and ship crews know what to report to CDC?

CDC provides training and guidance to our airline, cruise line, and shipping partners to make sure they are aware of how and what to report, and of any situations such as outbreaks that might require special precautions.

This guidance can be found on the CDC Quarantine and Isolation Web page.

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# **Additional Information**

### When are these changes effective?

These changes became effective on March 21, 2017.

### Can I make comments on the final rule?

No. The comment period for this rulemaking ended on October 14, 2016. 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.

### Where can I view comments made to the Notice of Proposed Rulemaking?

Comments may be viewed at www.regulations.gov ☑, docket number CDC-2016-0086 ☑.

### Where can I find more information about this final rule?

The final rule is published at the Office of the Federal Register's website.

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