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Department of Health and Human Services

42 CFR Parts 70 and 71

Control of Communicable Diseases; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Parts 70 and 71

RIN 0920–AA03

Control of Communicable Diseases

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

ACTION: Notice of proposed rulemaking.

SUMMARY: CDC is committed to protecting the health and safety of the American public by preventing the introduction of communicable disease into the United States. Having updated regulations in place is an important measure to ensure swift response to public health threats. CDC proposes to update existing regulations related to preventing the introduction, transmission, or spread of communicable diseases from foreign countries into the U.S. and from one State or possession into another.

DATES: Written comments must be received on or before January 30, 2006. Written comments on the proposed information collection requirements should also be submitted on or before January 30, 2006. Comments received after January 30, 2006 will be considered to the extent practicable.

ADDRESSES: You may submit written comments to the following address: Centers for Disease Control and Prevention, Division of Global Migration and Quarantine, ATTN: Q Rule Comments, 1600 Clifton Road, NE., (E03), Atlanta, GA 30333. Comments will be available for public inspection Monday through Friday, except for legal holidays, from 9 a.m. until 5 p.m. at 1600 Clifton Road, NE., Atlanta, GA 30333. Please call ahead to 1–866–694–4867 and ask for a representative in the Division of Global Migration and Quarantine to schedule your visit. Comments also may be viewed at *http://www.cdc.gov/ncidod/dq.* You may submit written comments electronically via the Internet at *http://www.regulations.gov* or via e-mail to *qrulepubliccomments@cdc.gov.* To download an electronic version of the rule, you may access *http://www.regulations.gov.*

Mail written comments on the proposed information collection requirements to the following address: Office of Information and Regulatory Affairs, OMB, New Executive Office Building, 725 17th Street, NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for CDC.

FOR FURTHER INFORMATION CONTACT: Jennifer Brooks, Centers for Disease Control and Prevention, Division of Global Migration and Quarantine,1600 Clifton Road, NE., (E03), Atlanta, GA 30333; telephone (404) 498–2395.

SUPPLEMENTARY INFORMATION: The Preamble to this notice of proposed rulemaking is organized as follows:

I. Legal Authority

These regulations are proposed under the authority of 25 U.S.C. 198, 231, and 1661; 42 U.S.C. 243, 248, 249, 264–272, and 2001.

II. Background and Purpose

The primary authorities supporting this rulemaking are §§ 361–368 of the Public Health Service Act (42 U.S.C. 264–271). Section 361 authorizes the Secretary to make and enforce regulations as are necessary to prevent the introduction, transmission or spread of communicable diseases from foreign countries into the United States and from one State or possession into another.

Recent experiences with emerging infectious diseases such as West Nile Virus, SARS, and monkeypox have illustrated the rapidity with which disease may spread throughout the world and the impact communicable diseases, when left unchecked, may have on the global economy. As noted by the Institute of Medicine, National Academy of Sciences in a recent study, ‘‘Whether naturally occurring or intentionally inflicted, infections can cause illness, disability, and death in persons while disrupting whole populations, economies, and governments. And because national borders offer trivial impediment to such threats, especially in the highly interconnected and readily traversed ‘‘global village’’ of our time, one nation's problem soon becomes every nation's problem.’’ (Microbial Threats to Health: Emergence, Detection and Response’’, Institute of Medicine, March, 2003). As diseases evolve naturally or as a result of human intervention, it is important to ensure that containment procedures reflect new threats and uniform ways to respond to them.

Stopping an outbreak—whether it is naturally occurring or intentionally caused—requires the use of the most rapid and effective public health tools available. These tools include basic public health practices such as disease reporting requirements and identification and notification of contacts who may have been exposed to a communicable disease so that they may receive preventive measures. Quarantine is defined as the restriction of the movement of persons exposed to infection to prevent them from infecting others, including family members, friends, and neighbors. Quarantine of exposed persons may be the best initial way to prevent the uncontrolled spread of highly dangerous biologic agents such as smallpox, plague, and Ebola fever—especially when combined with other health strategies such as vaccination, prophylactic drug treatment, patient isolation, and other appropriate infection control measures. Quarantine may be particularly important if a biologic agent has been rendered contagious, drug-resistant, or vaccine-resistant through bioengineering, making other disease control measures less effective.

The Secretary's authority to quarantine persons is limited to those communicable diseases published in an Executive Order of the President. This list currently includes cholera, diphtheria, infectious tuberculosis, plague, smallpox, yellow fever, and viral hemorrhagic fevers, such as

Marburg, Ebola and Congo-Crimean, Severe Acute Respiratory Syndrome, and influenza caused by novel or reemergent influenza viruses that are causing or have the potential to cause a pandemic (see Executive Order 13295, as amended by Executive Order 13375 on April 1, 2005).

Regulations that implement federal quarantine authority are currently promulgated in 42 CFR parts 70 and 71. Part 71 deals with foreign arrivals and part 70 deals with interstate matters. The Secretary has delegated to the Director of the Centers for Disease Control and Prevention the authority for implementing 42 CFR part 71, which was last substantively updated in 1985. On August 16, 2000, the Secretary transferred the authority for interstate quarantine over persons from FDA to CDC, which became 42 CFR part 70. FDA retained, pursuant to 21 CFR part 1240, regulatory authority over animals and other products that may transmit or spread communicable diseases. The Secretary took this action in order to consolidate regulations designed to control the spread of communicable diseases, thereby increasing the agencies' efficiency and effectiveness. This proposed rule is not intended to have any effect upon FDA's authority in 21 CFR part 1240. In 2003, in response to the emergence of Severe Acute Respiratory Syndrome (SARS), Health and Human Services (HHS) amended 42 CFR 70.6 and 71.3 to incorporate by reference the Executive Order listing the communicable diseases subject to quarantine, thereby eliminating the administrative delay involved in separately publishing the list of diseases through rulemaking. Also in 2003, CDC published an interim final rule that added § 71.56 African rodents and other animals that may carry the monkeypox virus. Finally, on January 25, 2005, the Secretary added section 70.9 to establish vaccination clinics and a user fee in connection with administration of vaccine services and vaccine.

The intent of the proposed updates to 42 CFR parts 70 and 71 is to clarify and strengthen existing procedures to enable CDC to respond more effectively to current and potential communicable disease threats.

III. Legal Basis of Federal Quarantine Authority

The primary statutory authority to enact regulations for the purpose of communicable disease control is found at section 361 (42 U.S.C. 264) of the Public Health Service Act. Section 361 is divided into four subsections. Subsection (a) authorizes the Secretary [1] to make and enforce such regulations ''as in his judgment are necessary to prevent the introduction, transmission, and spread of communicable diseases'' from foreign countries and from one state or possession into any other state or possession. Subsection (a) also authorizes a variety of public health measures, including destruction of articles determined to be sources of communicable disease. Subsection (b) authorizes the ''apprehension, detention, or conditional release'' of individuals to prevent the spread of communicable diseases as specified in Executive Orders of the President. Subsection (c) provides the basis for foreign quarantine of persons, while subsection (d) provides the basis for interstate quarantine of persons.

As prescribed in 42 U.S.C. 271 and 18 U.S.C. 3559 and 3571(c), criminal sanctions exist for violating regulations enacted under section 361. Specifically, individuals in violation of such regulations are subject to a fine of no more than $250,000 or one year in jail, or both. Violations by organizations are currently subject to a fine no greater than $500,000 per event. Federal district courts also have jurisdiction to enjoin individuals and organizations from violating regulations implemented under section 361. *See* 28 U.S.C. 1331. Furthermore, section 311 (42 U.S.C. 243) of the PHSA, authorizes the Secretary to accept state and local assistance in the enforcement of quarantine regulations and to assist states and their political subdivisions in the control of communicable diseases.

Prevention of communicable diseases has long been the subject of federal regulation. In 1796, Congress enacted the first federal quarantine law in response to a yellow fever epidemic, which gave federal officials the authority to assist states in the enforcement of quarantine laws. In 1799, Congress repealed the 1796 Act and replaced it with one establishing the first federal inspection system for maritime quarantines. In 1878, Congress amended the Quarantine Act to assign responsibilities to the Marine Hospital Service, which had been established in 1798 to provide for the health needs of merchant seaman. The 1878 Quarantine Act, however, was extremely limited and provided that federal quarantine regulations could not conflict with those of state or municipal authorities.

In 1893, Congress expanded the role of the Marine Hospital Service by enacting ''An Act Granting Additional Quarantine Powers and Imposing Additional Duties upon the Marine Hospital Service.'' *See Compagnie Francaise de Navigation a Vapeur* v. *State Board of Health, Louisiana,* 186 U.S. 380, 395–96 (1902). While the 1893 Act did not abrogate the role of the states, it nonetheless granted the Secretary of the Treasury the authority to enact additional rules and regulations to prevent the introduction of diseases, both foreign and interstate, where state and municipal ordinances were deemed insufficient. *Id.* at 396. The Act also authorized direct federal enforcement of communicable disease regulations where state and municipal authorities refused to act. *Id.* Section 361 was enacted in 1944, and last amended in 2002.

Acknowledging the critical importance of protecting the public's health, long-standing court decisions uphold the ability of Congress and the States to enact quarantine and other public health laws, and to have them executed by public health officials. *United States* v. *Shinnick,* 219 F.Supp.789 E.D.N.Y. (1963). *Kroplin* v. *Truax,* 165 N.E. 498 (1929); *Jacobson* v. *Massachusetts,* 197 U.S. 11 (1905); *North American Cold Storage Co.* v. *City of Chicago,* 211 U.S. 306 (1908); *Compagnie Francaise de Navigation a Vapeur* v. *Board of Health,* 186 U.S. 380 (1902). Whereas the States derive public health authorities from the police power reserved to them by the 10th Amendment to the U.S. Constitution, the authority of the federal government to enact quarantine rules and regulations is based on the Commerce Clause, which grants to Congress the exclusive authority to regulate foreign and interstate commerce. *See* U.S. Const. Art. I, section 8, cl.3 (granting to Congress the power ''to regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes.'').

In addition to Congress' authority to regulate foreign commerce, the U.S. Supreme Court has identified three broad categories of interstate activity that Congress may regulate under its Commerce Clause authority: (1) The use of the channels of interstate commerce (e.g., prohibitions on the shipment in interstate commerce of noxious articles or kidnapped persons); (2) the instrumentalities of interstate commerce, or persons or things in interstate commerce, even though the threat to interstate commerce may come only from intrastate activities (e.g., regulations on railway rates); and (3)

[1] The Office of the Surgeon General was abolished by section 3 of the 1966 reorganization plan, effective June 25, 1966, 31 FR 8855. Accordingly, statutory references to the Surgeon General should be understood as referring to the Secretary.

activities that substantially affect interstate commerce (e.g., labor standards). *United States* v. *Lopez,* 514 U.S. 549, 558–559 (1995). The proposed regulation is consistent with the scope of the federal government's commerce power because it seeks to regulate the uses of the channels of foreign and interstate commerce (i.e., by protecting against the introduction, transmission, and spread of communicable diseases) and the instrumentalities of foreign and interstate commerce (e.g., airlines with flights arriving into the U.S. or traveling from one state or possession into another).

The proposed regulation also is consistent with the ''search and seizure'' requirements of the Fourth Amendment. Authority to ''search and seize'' in the form of inspections, detentions, and quarantine has long existed under the Public Health Service Act and the current regulations. The Fourth Amendment to the U.S. constitution provides that ''[t]he right of the people to be secure in their persons, houses, papers, and effects, shall not be violated, and no warrants shall issue, but upon probable cause. * * *'' Courts have held, however, that not all types of searches and seizures necessarily require probable cause and a warrant. Searches and seizures conducted with the consent of an authorized person and those searches and seizures that are conducted to avert an imminent threat to health or safety do not run afoul of the Fourth Amendment even when conducted without probable cause and a warrant. *See Lenz* v. *Winburn,* 51 F.3d 1540, 1548 (11th Cir. 1995) (''Anyone who possesses common authority over or other sufficient relationship to the premises or effects sought to be inspected may consent to the search of another's property.'') (internal quotations marks omitted); *North American Cold Storage,* 211 U.S. at 315 (upholding seizure of food unfit for human consumption). Similarly, individuals at points of entry and who are in transit have a substantially reduced expectation of privacy concerning their persons and effects and thus courts have not required that searches and seizures be conducted pursuant to probable cause and a warrant. *See United States* v. *McDonald,* 100 F.3d 1320, 1324–25 (7th Cir. 1996) (noting that it is generally recognized that people who are in transit on common thoroughfares, i.e., on a bus, train, or airplane, have a substantially reduced expectation of privacy compared to persons in a fixed dwelling); *United States* v. *Berisha,* 925 F.2d 791, 795 (5th Cir. 1991) (noting that both incoming and outgoing border searches have features in common including the need to protect U.S. citizens, the likelihood of smuggling contraband, and the fact that individuals are placed on notice that their privacy may be invaded when they cross the border).

The U.S. Supreme Court has also recognized a reduced expectation of privacy concerning commercial industries that are ''closely regulated'' and thus searches and seizures of such commercial industries do not require probable cause and a warrant. *See New York* v. *Burger,* 482 U.S. 691, 702 (1987) (noting that the warrant and probable-cause requirements of the Fourth Amendment have lessened application in this context); *Lesser* v. *Espy,* 34 F.3d 1301, 1308 (1994) (upholding warrantless inspections of rabbit farms by the Animal Plant Health Inspection Program pursuant to the Animal Welfare Act). Specifically, warrantless inspections of ''closely regulated'' businesses are deemed reasonable provided that (1) there is a substantial government interest that informs the regulatory scheme pursuant to which the inspection is made; (2) the warrantless inspection is necessary to further the regulatory scheme; and (3) the inspection program, in terms of the certainty and regularity of its application, provides an adequate substitute for a warrant. *Burger,* 482 U.S. at 702–703.

Section 361(a) of the PHS Act (42 U.S.C. 264(a)) provides that regulations enacted by the Secretary may provide for inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated to be sources of dangerous infection to human beings, and other measures that in the Secretary's judgment may be necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States or from one state or possession into another. The statute also authorizes the apprehension, detention, and conditional release of persons reasonably believed to be infected with specified communicable diseases and arriving into the United States or traveling from one state into another. In carrying out this statutory authority, the proposed regulations authorize the Director to detain and inspect carriers and articles on board carriers for purposes of determining whether they may require the application of sanitary measures to prevent the introduction, transmission, or spread of communicable diseases.

The Director's delegated authority under section 361 is distinct from legal authority afforded to other federal agencies, such as USDA, which, among other things, includes the legal authority to prohibit or restrict the importation or entry of any animal, article, or means of conveyance, or the use of any means of conveyance or facility, if the USDA Secretary determines that the prohibition or restriction is necessary to prevent the introduction into or dissemination within the United States of any pest or disease of livestock. See 7 U.S.C. 8303. In implementing measures necessary to prevent the introduction, transmission, and spread of communicable diseases that affect both human and livestock health, e.g., avian influenza, CDC would work collaboratively with USDA.

As previously noted, there are circumstances where courts have held that the Fourth Amendment does not require probable cause and a warrant, including searches conducted upon the consent of the individual and those necessary to avert an imminent threat to human health or safety. Inspections conducted by quarantine officers at ports of entry and other locations will most often fall into one of these two categories. In addition, under the proposed regulations, the Director may compel inspections of carriers and the application of sanitary measures through written order. Furthermore, the proposed regulations provide the owners with an opportunity for a written appeal in the event that the Director orders the detention of a carrier or the destruction of animals, articles, or things, on board the carrier. Regarding individuals, the proposed regulation authorizes the provisional quarantine of persons arriving into the United States reasonably believed to be infected with or exposed to a quarantinable disease and persons who the Director reasonably believes to be in the qualifying stage of a quarantinable disease and traveling from one state into another or who are a probable source of infection to others who may be traveling from one state into another.

The routine inspection of persons or property for purposes of determining the presence of communicable disease is authorized by statute and does not run afoul of the Fourth Amendment because of the reduced expectation of privacy inherent in travel and at border crossings. *See United States* v. *Flores-Montano,* 541 U.S. 149, 152 (2004) (noting that the Government's interest in preventing the entry of unwanted persons and effects is at its zenith at the international border and that border searches conducted pursuant to the longstanding right of the sovereign to protect itself by stopping and examining persons and property crossing into this country are reasonable simply by virtue of the fact that they occur at the border); *McDonald,* 100 F.3d at 1324 n.5 (''This diminished interest derives from, among other factors, the myriad legitimate safety concerns that pertain to those who travel by common carrier.''). Air travel and shipping are also closely regulated industries in the United States because these industries must comply with myriad regulatory requirements relating to safety, immigration, and homeland security. *See United States* v. *Dominguez-Prieto,* 923 F.2d 464, 468 (6th Cir. 1991) (holding that common carriers in the trucking industry are pervasively regulated industries for purposes of warrantless inspections because of extensive federal and state regulations). Courts have also long recognized a substantial government interest in preventing the introduction, transmission, and spread of communicable diseases. *See Jacobson,* 197 U.S. at 11. Unsanitary carriers, as well as contaminated goods, may pose a threat to human health or safety, as well as lead to further contamination of other articles, if not immediately inspected and sanitized. The issuance of a written order by the Director, when necessary to compel compliance, accompanied by an opportunity for a written appeal, in the case of carriers ordered detained or animals, articles, or things ordered destroyed, also provides protections analogous to those of a warrant. *See Burger,* 482 U.S. at 711 (ruling that the administrative inspection program provided an adequate substitute for a warrant because it placed appropriate restraints on the discretion of the inspecting officers).

It is well recognized that freedom from physical restraint is a ''liberty'' interest protected by the Due Process Clause of the 14th Amendment to the U.S. Constitution. *See Kansas* v. *Hendricks,* 521 U.S. 346, 356 (1997) (noting that while freedom from physical restraint is at the core of the liberty protected by the Due Process Clause, that liberty interest is not absolute). In circumstances where due process is required, courts determine the process that is due by balancing the private interest affected by the official action against the government's asserted interest and the burdens that the government would face in providing greater process. *See Hamdi* v. *Rumsfeld,* 124 S.Ct. 2633, 2646 (2004) (relying on *Mathews* v. *Eldridge,* 424 U.S. 319, 335 (1976)). Due process is a flexible concept requiring that the level of process granted be commensurate with the degree of deprivation and the circumstances of the event. *See Parham* v. *J.R.,* 442 U.S. 584, 608 (1979) (''What process is constitutionally due cannot be divorced from the nature of the ultimate decision that is being made.''). Furthermore, due process does not always require judicial-type hearings or quasi-criminal proceedings before curtailing an individual's physical liberty for public health purposes. *See id.* at 609 (''Although we acknowledge the fallibility of medical and psychiatric diagnosis, we do not accept the notion that the shortcomings of specialists can always be avoided by shifting the decision from a trained specialist using the traditional tools of medical science to an untrained judge or administrative hearing officer after a judicial-type hearing.'') (internal citation omitted); *Addington* v. *Texas,* 441 U.S. 418, 431 (1979) (holding that states need not apply the strict criminal standard of proof beyond a reasonable doubt before committing the mentally ill); *Morales* v. *Turman,* 562 F.2d 993, 998 (5th Cir. 1977) (noting *in dicta* that ''[a] state should not be required to provide the procedural safeguards of a criminal trial when imposing a quarantine to protect the public against a highly communicable disease.''). The basic elements of due process include: Reasonable and adequate notice of the action that the government is purporting to take (typically through a written order); an opportunity to be heard in a reasonable time and manner; access to legal counsel; and review of the government's actions by an impartial decision-maker. *See Goldberg* v. *Kelly,* 397 U.S. 254, 267–268 (1970) (discussing due process in the context of terminating welfare benefits). Because quarantine implicates an individual's liberty interest to remain free from physical restraint, CDC in carrying out quarantine actions is obliged to act in a manner consistent with these basic elements of due process.

The proposed regulation establishes administrative procedures that afford individuals with due process commensurate with the degree of deprivation and the circumstances of controlling the spread of communicable disease. CDC quarantine officers are typically the first line of defense in preventing the importation of communicable diseases into the United States. Quarantine officers routinely conduct rapid assessments of ill passengers at airports and other ports of entry to assess the presence of communicable disease. Such assessments generally occur on a voluntary basis with the consent of the ill passenger. Where the quarantine officer reasonably believes that an ill passenger has a quarantinable disease, and the passenger is otherwise non-compliant, the quarantine officer may order the provisional quarantine of the passenger by serving the passenger with a written order, verbally ordering that the passenger be provisionally quarantined, or by ordering that actual restrictions be placed on a non-compliant passenger. The quarantine officer's reasonable belief would be informed by objective scientific evidence such as clinical criteria indicative of one of the specified quarantinable diseases, e.g., high fever, respiratory distress, and/or chills, accompanied by epidemiologic criteria such as travel to or from an affected area and/or contact with known cases. Provisionally quarantined individuals are provided with a written order in support of the agency's determination at the time that provisional quarantine commences or as soon thereafter as the circumstances reasonably permit. The written provisional quarantine order provides the individual with notice regarding the legal and scientific basis for their provisional quarantine, the location of detention, and the suspected quarantinable disease. Under the proposed regulations, CDC may provisionally quarantine an individual for up to three business days unless the Director determines that the individual should be released or served with a quarantine order. CDC does not intend to provide individuals with administrative hearings during this initial three-day period of provisional quarantine, but rather will afford an opportunity for a full administrative hearing in the event that the individual or group of individuals is served with a quarantine order, which potentially would involve a longer period of detention.

While there are no federal cases establishing a specific time period for holding persons in quarantine-type detentions, there are several analogous federal cases dealing with ''alimentary canal'' smugglers, i.e., persons who smuggle drugs in their intestines by swallowing balloons. In *United States* v. *Montoya de Hernandez,* 473 U.S. 531 (1985), the U.S Supreme Court analogized holding a suspected alimentary canal smuggler to detaining someone for suspected tuberculosis, noting that ''both are detained until their bodily processes dispel the suspicion that they will introduce a harmful agent into this country.''

Federal courts have upheld detention periods ranging from 16 hours to 20 days based on ''reasonable suspicion'' for suspected alimentary canal smugglers. CDC believes that the provisional quarantine of individuals for up to three business days without an administrative hearing is reasonable because such a time frame is necessary to determine whether the individual has one of the specified quarantinable diseases. A provisional quarantine order is likely to be premised on the need to investigate based on reasonable suspicion of exposure or infection, whereas a quarantine order is more likely to be premised on a medical determination that the individual actually has one of the quarantinable diseases. Thus, during this initial three business day period, there may be very little for a hearing officer to review in terms of factual and scientific evidence of exposure or infection. Three business days may be necessary to collect medical samples, transport such samples to laboratories, and conduct diagnostic testing, all of which would help inform the Director's determination that the individual is infected with a quarantinable disease and that further quarantine is necessary. In addition, because provisional quarantine may last no more than three business days, allowing for a full hearing, with witnesses, almost guarantees that no decision on the provisional quarantine will actually be reached until after the provisional period has ended, thus making such a hearing virtually meaningless in terms of granting release from the provisional quarantine. In the event that further quarantine or isolation is necessary, the Director would issue an additional order based on scientific principles such as clinical manifestations, diagnostic or other medical tests, epidemiologic information, laboratory tests, physical examination, or other available evidence of exposure or infection. The length of quarantine or isolation would not exceed the period of incubation and communicability for the communicable disease as determined by the Director.

Under 28 U.S.C. 2241, an opportunity for judicial review of the agency's decision exists via the filing of a petition for a writ of habeas corpus. This judicial review mechanism affords individuals under quarantine with the full panoply of due process rights typical of a court hearing. A petition for a writ of habeas corpus is the traditional mechanism by which individuals may contest their detention by the federal government. *See Hamdi*, 124 S.Ct. at 2644 (noting that absent suspension, the writ of habeas corpus remains available to all individuals detained within the United States); *United States* v. *Shinnick,* 219 F.Supp.789 (E.D.N.Y. 1963) (upholding the U.S. Public Health Service's medical isolation of an arriving passenger because she had been in Stockholm, Sweden, a city declared by the World Health Organization to be a smallpox infected local area and could not show proof of vaccination).

In addition to this judicial review mechanism, as previously mentioned, the proposed regulations establish a procedure for individuals under quarantine to request an administrative hearing. The purpose of the administrative hearing is not to review any legal or constitutional issues that may exist, but rather only to review the factual and scientific evidence concerning the agency's decision, e.g., whether the individual has been exposed to or infected with a quarantinable disease. Such an administrative hearing would comport with the basic elements of due process. Under the proposed regulations, the Director would notice the hearing and designate a hearing officer to review the available evidence of exposure or infection and make findings as to whether the individual should be released or remain in quarantine. The proposed regulations authorize the Director to take such measures as the Director determines to be reasonably necessary to allow an individual in quarantine to communicate with their authorized representative to participate in the hearing.

In addition to section 361 of the PHS Act (42 U.S.C. 264), HHS also relies on the following legal authorities with respect to this notice of proposed rulemaking: 25 U.S.C. 198, 231, and 1661; 42 U.S.C. 243, 248, 249, 265–272, and 2001. 25 U.S.C. 198, 231, 1661 and 42 U.S.C. 2001 contain legal authorities primarily relevant to public health measures taken with respect to Indian country. 42 U.S.C. 265–272 contain legal authorities primary relevant to HHS operations and activities with respect to quarantine and other public health measures. These authorities are discussed in depth in Section IV.

IV. Summary of Proposed Changes to 42 CFR Part 70

Several new sections have been added to 42 CFR Part 70. Most of these sections are provided to update and streamline practices to reflect modern quarantine practice. Imposition of quarantine needs to be based on clear legal authorities and applied safely and effectively while according respect to the individual.

The following is a section-by-section analysis:

Section 70.1 Scope and Definitions

Section 70.1 is renamed scope and definitions. Section 70.1 explains that, except where otherwise stated, regulations to prevent the spread of disease among possessions or from a possession to a State are contained in 42 CFR Part 71.

A number of terms have been added or modified to be consistent with modern quarantine concepts and current medical principles and practice. Specifically, definitions for ''aircraft commander,'' ''airline,'' ''airline agent,'' ''business day,'' ''carrier,'' ''detention,'' ''emergency contact information,'' ''flight information,'' ''hearing officer,'' ''Indian country,'' ''Indian tribe,'' ''infectious agent,'' ''interstate traffic,'' ''medical monitoring,'' ''military service,'' ''possession,'' ''provisional quarantine'', ''public health emergency,'' ''qualifying stage,'' ''quarantine,'' ''quarantinable disease,'' ''sanitary measure,'' ''Secretary,'' ''State'' and ''vector'' have been added or modified. The definition of an ill person has been modified to include the signs or symptoms commonly associated with diseases for which provisional quarantine or quarantine may be necessary. This definition is of particular importance because it determines the scope of the reporting requirement specified in § 70.2. Because reporting is dependent on recognition of an ill passenger by non-medical personnel and without the benefit of a medical examination, such as by the flight crew, this definition relies on descriptive terms that are overt and commonly understood by lay persons. The definition is broad by design for two reasons: (1) To ensure that all situations for which the Director must take action in order to prevent the introduction and spread of communicable diseases are reported, and (2) the reporting of ill passengers relies on personnel without medical training. While a narrower definition might reduce the number of situations reported for which action by the Director is unnecessary, such a definition would necessarily include findings or terms that cannot be accurately assessed by those without medical training. Moreover, a narrower definition would likely exclude situations of public health significance thus circumventing the very purpose for which the reporting requirement is designed. Therefore, the more prudent course has been chosen, whereby reporting is required for a broad range of signs and symptoms, allowing the

Director to use her professional judgment to determine which situations require additional action.

Section 70.2 Report of Death or Illness on Board Flights

As noted previously, the Director has a responsibility to prevent the spread of communicable diseases between states. The purpose of the disease reporting requirement is to ensure that CDC can mobilize appropriate personnel to respond efficiently to the arrival of an ill person with a communicable disease. This response may require evaluation of the ill passenger by trained medical personnel, evaluation of other passengers who may have been exposed to the disease en route, and secure transport of individuals to a designated isolation facility where they may receive appropriate care while minimizing the risk of transmission to others. Because the entire panel of responders may not be onsite at the airport it is imperative that notification be received by CDC as soon as the illness is identified and, whenever possible, at least one hour prior to arrival.

Under current regulations (§ 70.4), the person in charge of any carrier engaged in interstate traffic on which a case or suspected case of a communicable disease develops, as soon as practicable, is required to notify the local health authorities at the next port of call, station, or stop and take such measures as the local health authority directs. Paragraph (a) of § 70.2 in the proposed revision eliminates the requirement that carriers report to local health authorities, requiring instead that reports be made to the Director. By providing a single point of contact for disease reports, the burden on carriers to identify and maintain points of contact with local health authorities is significantly reduced. The Director would assume responsibility for notifying local health authorities as indicated. It is common, but not universal, that FAA officials (e.g., air traffic control) are included among those notified by the airline of an ill passenger. Current CDC procedure dictates that FAA personnel and other emergency response personnel are notified by Quarantine Station staff of the impending arrival of a plane carrying a passenger with other than routine illness. However, this notification is contingent on CDC awareness of the situation prior to flight arrival, as this provision requires.

The regulation was drafted to afford the carrier maximum flexibility in establishing a system to ensure that the advance reporting requirement is met. We do not intend to mandate a particular pathway of communication as long as a report is made by the designated airline official within the specified time frames. Individuals typically involved in the notification process include the crew, including the pilot or captain, flight operations on the ground, air traffic controllers, other ground personnel, and other airline representatives.

Paragraph (b) of this section enables the Director to order airlines engaged in interstate traffic to distribute to passengers and crew, at a time specified by the Director, public health notices and other materials that describe recommended measures for preventing spread of communicable diseases. During SARS and in the time since the outbreak was controlled, CDC has distributed Health Alert Notices to advise passengers on international flights who may have been exposed to a communicable disease as to how to monitor their health and how to proceed should certain symptoms develop. These notices were an important component of the CDC response to SARS. The effectiveness of this measure, however, was limited by CDC's inability to ensure that all passengers received the notices, a goal that was particularly difficult if distribution occurred after passengers already had entered the terminal and were focused on getting to distant gates or their final destinations. The routine delay in passenger dispersal following disembarkation that accompanies international arrivals (i.e., while they undergo immigration and customs processing) is absent from interstate arrivals, thereby making distribution of this information post-disembarkation even more challenging. By requiring airline staff to distribute these materials prior to disembarkation, for example, Director can better ensure that potentially exposed passengers have access to information critical to maintaining their own health and to preventing spread in the community. CDC expects to exercise this requirement in situations where a significant outbreak of a quarantinable disease is detected abroad and there is the potential for exposure among interstate travelers. CDC might also require airlines to distribute notices in the period between the outbreak of a new communicable disease and the addition of the disease to the list of quarantinable diseases.

Section 70.3 Written Plan for Reporting of Deaths or Illness on Board Flights and Designation of an Airline Agent

In order to ensure that all parties are aware of the appropriate lines of communication between airlines and CDC for reporting, and that policies and procedures are in place to facilitate such communication, this section requires airlines engaged in interstate travel to develop a written plan sufficient to ensure the reporting of ill passengers and deaths on board flights and submit it to the Director within 90 days of the final publication of this rule. Airlines that intend to commence operation of flights in interstate traffic after this effective date shall submit a written plan to the Director before commencing operations.

The plan may be submitted electronically to an e-mail address or permanent address that will be provided in the final rule. This plan would identify the designated airline ''point of contact'' or ''agent'' for issues related to reporting of any deaths or ill passengers. In addition, the plan would identify the members of the flight team (e.g., cabin crew, captain, airline flight operations, flight controllers, or other airline-designated agent for reporting) who will be responsible for making the required report to the Director.

The plan must be implemented within 180 days of the final publication of the rule. CDC believes that a 90-day time frame for development of a written plan and an additional 90 days for implementation to be appropriate because airlines should already have such procedures in place to satisfy the existing ill passenger reporting requirement currently contained in 42 CFR 70.4. Airlines commencing operations after the rule is in effect must implement their written plans by the later of the following: 180 days after the final publication of the rule or upon commencement of operations. CDC solicits comment on whether these timeframe are appropriate. During the phase-in period established in this section, airlines are still expected to comply with the reporting requirements contained in current § 70.4.

Airlines are required to review the plan one year after implementation and annually thereafter and make revisions as necessary. Airlines that have not reported ill passengers or deaths on board a flight under the requirements in 70.2 in the prior 365 days are required to conduct drills or exercises to test and evaluate the effectiveness of the plan. Any revisions as a result of the annual review or the drills or exercises must be submitted to the Director within 60 days.

Section 70.4 Passenger Information

Among the fundamental components of the public health response to the report of a person with a communicable disease is the identification and evaluation of those who may have been exposed. Public health authorities may then offer these individuals treatment, vaccination, or other preventive measures as may be available. These treatments, by preventing the development or progress of the disease, serve the dual purpose of providing direct benefit to those exposed along with benefit to the community at large by preventing further person-to-person spread. Thus, in order to carry out her delegated responsibility to control spread of communicable diseases between states, the Director must, for a limited time, be able to efficiently identify and locate persons who may have been exposed to a communicable disease during travel. The identification and notification of those exposed is an essential first step in providing the exposed access to potentially life-saving medical follow-up and disease prevention measures, including vaccination. Preventing secondary cases among contacts, in turn, helps prevent further propagation and spread of disease within the community. As such, travelers and the public at large derive direct benefit from a system, such as is proposed, that ensures that, if an exposure has occurred, affected passengers can be identified, located, and notified within the incubation period of the disease. If notification does not occur by the conclusion of the incubation period, the effectiveness of medical follow-up and disease prevention measures and, therefore, the benefit to the public is severely reduced.

The worldwide outbreak of SARS, an illness that was originally reported in Asia in late 2002 and quickly spread to North America and Europe, provided a clear example of the rapidity with which an infectious disease may spread through air travel, while exposing clear limitations in the current system of identifying and notifying those who may have been exposed during travel. During this outbreak, CDC attempted to gather contact information on persons exposed and received significant cooperation from the airlines. CDC met flights containing suspected contagious passengers and obtained location and contact data from both passengers and crew members before disembarkation. Ill passengers on planes from affected areas were met by CDC staff members for evaluation and referred for medical care when appropriate. However, if a suspected case of SARS was identified after disembarkation, CDC staff had to manually gather, compile, and process data from flight manifests, customs declarations, and any other available sources relevant to the case.

Utilizing this manual process, CDC staff encountered the following difficulties:

- Manifests provided by carriers contained only the name and the seat number.
- Custom declarations were completed by the passenger by hand and were often illegible.
- Names on the customs declarations did not necessarily match those on the manifests.
- Phone numbers were not included on customs forms, and only one customs form was filled out per family.

Since the data gathered from manifests and customs declarations were only available in hard copy, it often took several days to obtain. Photocopies were sent by express mail to CDC where the data were keyed into a database. Entering the data and verifying the addresses usually took several more days. The time required to track passengers was routinely longer than the incubation period of the SARS virus.

While CDC received good cooperation from the industry, the primary responsibility for locating passengers rests with public health authorities as recognized by International Air Transport Association (IATA) Recommended Practices 1788, as shown in the following excerpts:

> When a Member is advised by a health authority that it may have transported a passenger with an infectious disease, it shall co-operate with such health authority, with the understanding that it is not the Member's responsibility to trace and notify other passengers who may have been exposed to the infectious disease.
>
> If the health authority requests a list of other passengers who may have been exposed to the infectious disease, the health authority should be advised to first utilize immigration records of the arriving passengers, such as landing cards, in order to determine the names and addresses of such passengers. If the health authority advises the Member that it was unable to determine from immigration records, the names of other passengers who may have been exposed to the infectious disease, the Member should ask the health authority to make a formal request for a list of passengers.

In the aftermath of SARS, CDC has continued to enjoy good overall cooperation from airline industry partners. However, citing information privacy concerns, some airlines have increasingly required that CDC accompany its request for passenger information with a written order explaining CDC's legal authority for requesting such information.

In November 2003, the University of Louisville School of Medicine prepared a report entitled ''Quarantine and Isolation: Lessons Learned from SARS,'' that recommended:

> In the event that an international traveler develops an infectious disease, there is an urgent need to be able to locate crew members and other passengers from the same flight or ship. Public health officials must have immediate access to passenger manifests or be able to require all arriving passengers to complete a public health form containing, for example, the individual's health status, seat number, countries visited, and contact information. This information must be in electronic form.

Collection of this information finds strong support in public opinion. While a significant number of air passengers expressed concerns with increased reservation or check-in time, a Harvard School of Public Health study, Project on the Public and Biological Security, finds that 94% of air travelers would want public health authorities to contact them if they might have been exposed to a serious contagious disease on an airplane. In addition, 93% of domestic air travelers and 89% of international air travelers expressed a willingness to provide some type of contact information.

In its April 2004 report on Emerging Diseases, GAO–04–564, the U.S. Government Accountability Office concluded:

> The Centers for Disease Control and Prevention * * * tried to contact passengers from flights and ships on which a traveler was diagnosed with SARS after arriving in the United States. However, these efforts were hampered by airline concerns and procedural issues.

On the basis of that conclusion, the GAO recommended that the

> Secretary of HHS complete steps to ensure that the agency can obtain passenger contact information in a timely manner, including, if necessary, the promulgation of specific regulations.

This provision seeks to address this recommendation by GAO.

As stated previously, under 42 U.S.C. 264, the Secretary of HHS is authorized to make and enforce regulations necessary to prevent the introduction, transmission, and spread of communicable diseases from foreign countries into the United States and from one state or possession into another. The Director has been delegated the responsibility for carrying out these regulations. The Director's authority to investigate suspected cases and potential spread of communicable disease among foreign and interstate travelers is thus not limited to those known or suspected of having a quarantinable disease (any of the communicable diseases listed in an Executive Order, as provided under Section 361 of the Public Health Service Act (42 U.S.C. 264). Executive Order 13295, of April 4, 2003, as amended by Executive Order 13375 of April 1, 2005, contains the current revised list of quarantinable diseases, and may be obtained at *http://www.cdc.gov* and *http://www.archives.gov/federal_register).* Rather, the authority encompasses all communicable diseases that may necessitate a public health response. An order for transmission of passenger information is more likely to follow exposure to a non-quarantinable communicable disease than to one listed as quarantinable under the current Executive Order as the former occur much more commonly. Examples of situations where manifest data may be requested for communicable diseases would be following exposure to an individual with suspected measles or bacterial meningitis. When to order transmission of data from airlines would, by necessity, have to be decided on a case-by-case basis depending on the facts and circumstances of the particular disease occurrence. However, any order to transmit passenger information to CDC would be done so when necessary for the protection of the vital interests of an individual or other persons, in regard to significant health risks.

The proposed regulation requires that airlines operating interstate flights arriving in or departing from any of the airports listed in Appendix A to request certain information from passengers, maintain it in an electronic database for 60 days from the end of the flight, and transmit the information to CDC within 12 hours of a request. This information includes, as specified in paragraph (e), full name (first, last, middle initial, suffix); current home address (street, apartment number, city, state/province, postal code); at least one of the following current phone numbers in order of preference: (mobile, home, pager, or work); e-mail address; passport or travel document, including the issuing country or organization; traveling companions or group; flight information; returning flight (date, airline number, and flight number); and emergency contact information as defined in § 70.1. The following table summarizes the data elements that would be collected under the proposed NPRM, those items currently collected by airlines and the frequency of collection, and items which the Department of Homeland Security collects under its Advanced Passenger Information System (APIS). Based on CDC's experience with previous contact tracing efforts using passenger data, the data elements are ordered according to the relative utility of each piece of data with respect to contract tracing.

Data elements required by CDC NPRM	Currently collected by airlines	Required by DHS/APIS for international flights
Name	Yes	Yes.
Emergency contact	Intermittent to rarely for domestic flights, more frequently for international flights.	No.
Flight information	Yes	Yes.
Phone number	Intermittent	No.
Email address	Intermittent—usually only for Internet, phone, or travel agent reservations.	No.
Current home address	Intermittent—usually only for Internet or travel agent reservations.	No.
Passport or travel document number and country (for foreign nationals for domestic and international flights).	Only for international flights	Yes.
Traveling companions	No	No.
Returning flight information	Usually only if booked at same time or with same airline	No.

The data are to be collected from each crewmember and passenger or head of household if the passenger is a minor and must be maintained by the airline for 60 days from the end of the voyage. Upon request of the Director, the data are to be transmitted to CDC within 12 hours. This time period is considered longer than will actually be necessary once the plan for data transmission developed pursuant to § 70.5 has been implemented. In addition, paragraph (f) enables the Director to compel, through order, transmittal of additional information in the airline's possession that may be necessary to prevent the introduction, transmission, or spread of communicable diseases. For example, information regarding the airline's food service provider may be relevant to an investigation of a foodborne outbreak on board an airline.

The provision does not require airlines to verify the accuracy of the information collected from passengers. Airlines, however, are expected to accurately transmit information collected from passengers. Based in part on data from a public opinion survey, it is believed likely that passengers will voluntarily provide this information so that CDC could contact the passenger in the case of that passenger's exposure to a communicable disease. However, passengers who decline to provide contact information will not be prohibited from traveling.

CDC invites comments on any and all aspects of this data collection. Specifically, CDC solicits comments on the following subjects:

- Although we assume travelers will be willing to provide accurate information in the interest of being contacted for public health reasons, we are interested in further strategies that may increase the likelihood of receiving accurate information from travelers
- Whether a shorter list of contact data would improve the willingness to provide information or the accuracy of the information provided.
- The degree to which airlines and shiplines currently collect each proposed data element, the feasibility and cost of collecting each data element, and the extent that the additional data collection would require changes in IT systems or operating procedures.
- The utility of each proposed data element for the purposes of contact tracing.

Information and records provided to CDC will be maintained and stored in accordance with HHS and CDC policies and in accordance with Privacy Act (5 U.S.C. 552a) and its implementing regulations (45 CFR Part 5b), which require that the records only be used for authorized purposes by authorized personnel. Paper records will be kept in locked storage containers and access will only be allowed for authorized personnel; electronic records will be inaccessible to all CDC employees except those that are authorized to use them in accordance with Federal law. After the legal retention period for these records has expired, they will be destroyed (shredding or maceration for paper files; wiping of electronic files) to ensure that the information is not recoverable and to ensure the privacy and confidentiality of those involved. CDC has a long history of managing sensitive data in a manner that protects the confidentiality and privacy of the public. This positive track record will continue with the management of these records.

The Federal Records Management retention guidelines require that we develop a specific approved records control schedule through the established records disposition process. CDC intends to propose a records control schedule for these records that would establish a legal retention period of one year. This would allow CDC to properly respond to outbreaks, and to ensure the health of airline passengers and the American public. The review process (as defined in 36 CFR part 1228) will involve significant internal CDC review (including substantive legal review), a review by HHS and the National Archives and Records Administration (NARA), and finally the publishing of a proposed retention schedule for these records in the **Federal Register** for public comment. CDC anticipates that this process will take 12–18 months. We are confident that after this process all relevant interests and concerns from health, privacy and legal perspectives, and those representing the interests of passengers, the airline industry, and the general public will be taken into consideration. Current standard records retention policy requires that we keep data for 10 years. Until we can create a new records schedule for these data, CDC will follow this policy.

Airlines are expected to safeguard the confidentiality of the information collected. Under the proposed regulation, information collected solely in order to comply with this rule may only be used for the purposes for which it is collected. Airlines shall ensure that passengers are informed of the purposes of this information collection at the time passengers arrange their travel. CDC solicits comments on the privacy aspects of collecting information to be used solely in order to comply with this rule, including the practicality of informing passengers of the purposes of the information collection and the safeguarding of passenger information.

The airports listed in Appendix A are derived from a list that the Federal Aviation Administration uses to apportion its Airport Improvement Program grants base. As part of this program, FAA assigns the status of airport hubs based upon that airport's passenger boardings as a percent of total U.S. passenger boardings. CDC has listed in Appendix A the 67 large and medium hubs assigned by FAA in 2004, which is the latest list published by FAA. CDC is focusing upon the 67 large and medium hubs because this captures a majority (approximately 90%) of annual passenger boardings without burdening airlines that operate only in small hubs where passenger boardings are considerably lighter. CDC may revise this list in the future through notice and comment rulemaking.

Section 70.5 Written Plan for Passenger Information and Designation of an Airline Agent

This provision as outlined in paragraph (a) requires airlines engaged in interstate commerce to designate an agent as a CDC single point of contact for communications related to passenger manifests. In addition, airlines must develop, within six months of the final publication of this rule, a written plan sufficient to ensure the electronic transmission to the Director of data that are collected from passengers and crew pursuant to § 70.4. Paragraph (f) explains that airlines meeting the provisions in (a) that intend to commence operations after the effective date in (a) shall submit a written plan to the Director prior to commencing operations.

The plan may be submitted electronically to an e-mail address or permanent address that will be provided in the final rule. The written plan must include policies and procedures for the transmission of the data in an electronic format available to both the airline and the Director using industry standards for data encoding, transmission, and security. Airlines are required to submit their written plans for transmission of passenger manifest information to the Director and implement the plan within 2 years of the final publication of this rule. Airlines commencing operations after the effective date in (a) are required to implement the plan on the later of these two dates: 2 years after the final publication of this rule or upon commencement of operations. CDC is soliciting comments specifically in regard to these timeframes.

Upon implementation of the plan, airlines are required to conduct drills or exercises to test and evaluate the effectiveness of the plan. Airlines are required to review the plan one year after implementation and annually thereafter. The review shall include drills or exercises to test and evaluate the effectiveness of the written plan unless the airline has transmitted passenger and crewmember information under § 70. 4 in the prior 365 days. Airlines shall make revisions as necessary as result of the review and submit them to the Director within 60 days.

Section 70.6 Travel Permits

This provision requires any person who knows that he or she is in the qualifying stage, as defined in § 70.1, of any quarantinable disease to obtain a travel permit from the Director if he/she intends to travel in interstate traffic or from one state or possession into any other state or possession.

Section 70.6 prohibits interstate carriers from knowingly transporting or accepting for transport any person in the qualifying stage of a quarantinable disease without a travel permit issued by the Director. If a person possesses a travel permit, the carrier is required to take all steps necessary to prevent spread of the disease during transport.

Persons who know that they are in the qualifying stage of a quarantinable disease are prohibited from traveling in interstate traffic or from one state or possession into another without a permit issued by the Director. The person issued a permit is required to maintain possession of the permit at all times during travel, and to comply with its conditions. Persons whose application for a travel permit has been denied may submit a written appeal within two business days in accordance with 70.31.

An order of the CDC Director is not necessary for travel permits to be required under this section, rather these are ongoing requirements. CDC expects that the need to issue a travel permit will arise infrequently. CDC envisions that the circumstances under which the use of travel permits would be necessary include (1) to prevent spread of quarantinable disease in interstate traffic or from one state or possession into any other state or possession; (2) upon request of a health authority; and (3) in the event of inadequate local control. The requirement of travel permits pertains to individuals who know they are in the qualifying stage of quarantinable disease and thus requires actual knowledge of one's condition. Similarly, section 70.6 provides that a carrier may not knowingly transport a traveler in the qualifying stage of a quarantinable disease without a permit.

The Director may additionally apply the provisions of this section to persons and carriers traveling entirely within the boundaries of a state or possession upon the request of a cognizant health authority or in the event of inadequate local control if the Director determines that such persons' travel or the operations of the carrier have an effect on interstate commerce. In such cases, the Director will issue an order advising persons of the application of this provision to intrastate traffic that affects interstate commerce. CDC believes that travel permits may be an important public health tool in the event of a public health emergency that necessitates the control of intrastate movement or the orderly evacuation of infected individuals to other locations within a state or possession.

Section 70.7 Responsibility With Respect to Minors, Wards, and Patients

This section clarifies that parents, guardians, physicians, nurses, and other persons may not procure transportation for children, wards, or patients whom they know to be in the qualifying stage of a quarantinable disease without obtaining a travel permit from the Director if such a permit is required under this part. Because minor children, wards, and hospitalized persons may not be able to procure transportation on their own, the responsibility for obtaining the travel permit falls to their guardians and/or other persons in whom their care is entrusted. This provision is a carryover from existing § 70.7, with the exception that the provision has been changed to specifically reference travel permits. Persons whose application for a travel permit has been denied may submit a written appeal within two business days in accordance with 70.31.

Section 70.8 Military Services

Under section 361 of the PHS Act (42 U.S.C. 264), the HHS Secretary has broad authority to enact regulations to prevent the introduction, transmission, and spread of communicable diseases. This is a statute of general applicability and thus applies to the military and its service members traveling on military carriers. Section 70.8, however, exempts the military services and their members traveling on military carriers from certain provisions of Part 70. Specifically, the military services and their members traveling on military carriers are exempt from the following provisions: § 70.6(a) (travel permits requirements relating to carriers), § 70.11 (sanitary measures), and § 70.12 (detention of carriers affecting interstate commerce). A limited exemption is also created with respect to § 70.6(c) (travel permit requirements relating to persons who know that they are in the qualifying stage of a quarantinable disease) and § 70.7 (Responsibility with respect to minors, wards, and patients), provided that the person authorizing the service member's travel on a military carrier takes measures consistent with those prescribed by the Director to prevent the possible transmission of infection to others during travel. This section is largely carried over from existing § 70.8. Furthermore, while not specifically exempt, carriers belonging to the military services are not subject to requirements relating to reporting of deaths or illness on board flights (§ 70.2 & § 70.3) and passenger information (§ 70.4 & § 70.5) because aircraft operated by the military services do not operate ''commercially.'' These exemptions exist because the U.S. military has established mechanisms to prevent disease spread on board its carriers and among its personnel. HHS also wishes to minimize any potential disruption of military activities.

Section 70.9 Vaccination Clinics

This provision replaces current § 70.9, recently promulgated as an interim final rule. The current section authorizes the Director to establish vaccination clinics and to charge persons not enrolled in Medicare Part B a user fee to cover costs associated with administration of vaccine. The proposed regulation contains similar authority, and additionally requires vaccination clinics to comply with recordkeeping and other instructions issued by the Director to ensure safe administration, handling, monitoring and storage of vaccines. These requirements include collection and maintenance of information on vaccine recipients including age, gender, date of vaccination, vaccine lot number, prior vaccination, concurrent vaccinations, Vaccine Adverse Events Reporting System Report/Adverse Event Report Number (if applicable), and verification that the vaccination conferred immunity. In addition, the reason for vaccination (*e.g.* post exposure, pre-exposure prophylaxis, military, administrative requirement [pre-employment, school entry], member of high risk group, pre-travel, general vaccination, or other reason) must be stated. The Director may waive or modify these requirements in the event of a public health emergency.

Section 70.10 Establishment of Institutions, Hospitals and Stations

This provision authorizes the Director to enter into voluntary agreements with public or private institutions for the purpose of establishing places for care and treatment. This provision is based upon legal authority provided in 42 U.S.C. 267. With the approval of the Secretary, the Director may select suitable sites for the establishment of quarantine stations and places for care and treatment. Additional legal authorities relevant to the control, management, and control of institutions, hospitals, and stations established by the Secretary are also contained in 42 U.S.C. 248.

Section 70.11 Sanitary Measures

Section 361(a) of the PHS Act (42 U.S.C. 264(a)) provides that in carrying out regulations, the Secretary

> may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary.

Section § 70.11 implements this statutory provision by authorizing the Director, in consultation with other Federal agencies as appropriate, to inspect and order the application of such sanitary measures (as that term is defined) to any carrier affecting interstate commerce or to things on board the carrier that the Director reasonably believes to be infected or contaminated by a communicable disease.

Paragraph (a) updates, consolidates and makes applicable to interstate situations the ''disinfection,'' ''disinfestations,'' ''disinsection,'' and other provisions contained in current 42 CFR Part 71. It explains that the Director, in consultation with other federal agencies as appropriate, may inspect and order the carrier, or other entity specified in the order, as the party responsible for applying such measures as the Director deems necessary to prevent the introduction, transmission, or spread of communicable diseases.

Paragraph (b) explains that CDC shall not bear the expense of applying the sanitary measure or, expenses related to things on board. While the preceding paragraph states that CDC shall not bear related expenses, paragraph (c) indicates that CDC does not intend to prevent an entity conducting sanitary measures required by the Director from seeking reimbursement ''through contractual arrangements or other available means from entities other than the CDC.''

A written order to the carrier operator or owner of the cargo would be one method that CDC could use for ordering the application of sanitary measures, but would not be the exclusive method. Depending on the circumstances of the disease, CDC, for example, could notify carrier operators through publication in the **Federal Register** when the occurrence of a communicable disease outbreak in a foreign country increases the likelihood of the importation of infected persons or goods into the United States, and thus may affect interstate travel. In time-sensitive situations that present an imminent threat to human health and require the immediate application of sanitary measures, a CDC quarantine officer could also verbally order that such measures be carried out. Typically, an order to carry out sanitary measures would explain the risk to human health posed by the infected or contaminated carrier or article and contain instructions on which measures should be employed to abate the human health risk. Which sanitary measures should be employed in a given circumstance would be determined based on scientific and public health principles applicable to the threat to human health.

Under paragraph (c), the Director may apply sanitary measures to persons who are not in the qualifying stage of a quarantinable disease. Provisions specifically dealing with respect to persons who may be in the qualifying stage of a quarantinable disease may be found in §§ 70.6, and 70.14 through 70.24. When applied to a person or group of persons, a sanitary measure involves the application or direct exposure to such chemical, physical, or other processes that are designed to destroy the presence of infectious agents that may be outside the body. Under paragraph (c), such procedures may be carried out only with the consent of the person. Sanitary measures applied to a person or group of persons are intended to kill agents (or vectors capable of conveying infectious agents) outside the body by direct exposure to a chemical, physical or other process designed to destroy such infectious agents or vectors. During an outbreak of avian influenza, for example, persons exiting a farm containing infected birds would have all visible organic matter removed from their shoes with disposable towels. Those persons would then transit through a foot bath containing an effective virucidal solution. As an additional example, persons infected with body lice during an outbreak of epidemic typhus would be treated with appropriate antibiotics and an effective topical pediculocidal agent, and would have their clothing washed in hot water and detergent. The sanitary measures applicable to carriers, animals or things include detention, destruction, seizure, disinfection, disinfestations, disinsection and any other measures deemed necessary to prevent the introduction, transmission or spread of communicable diseases. If the Director orders the destruction or export of animals, articles, or things in accordance with this section, the owner of such animals, articles, or things may appeal the measure, within two business days, in accordance with Section 70.31.

CDC invites comments on any and all aspects of the proposed process for issuing orders to conduct sanitary measures and the appeals process.

Section 70.12 Detention of Carriers Affecting Interstate Commerce

In addition to the provisions listed in Section 70.11, this provision further authorizes the Director, in consultation with such other federal agencies as appropriate, to detain a carrier until the necessary measures outlined in Section 70.11 have been completed. The expense of applying sanitary measures and detention shall not be borne by CDC. If the Director orders the detention of a carrier in accordance with this section, the carrier owner may appeal the detention, within two business days, in accordance with Section 70.31.

CDC invites comments on any and all aspects of the proposed process for issuing orders to conduct sanitary measures and the appeals process.

Section 70.13 Screenings to Detect Ill Persons

This section authorizes the Director at airports and other locations to conduct screenings to detect the presence of ill persons. The definition of ''ill persons'' appears in the definitions section. Methods of screening may include visual inspection, electronic temperature monitors, and other methods determined appropriate by the Director to detect the presence of ill persons.

Section 70.14 Provisional Quarantine

Quarantine officers routinely conduct short term examinations of ill passengers at airports and other ports of entry to assess the presence of disease. Such examinations generally occur on a voluntary basis with the consent of the ill passenger. In situations where a passenger withholds his or her consent though those situations are few in number, the Director may nevertheless need to detain that person to determine whether the person may be in the qualifying stage of a quarantinable disease. This section is primarily intended to deal with those situations.

Section 361(b) of the Public Health Service Act (42 U.S.C. 264(b)) authorizes the ''apprehension, detention, or conditional release'' of persons to prevent the introduction, transmission, and spread of specified communicable diseases from foreign countries into the United States and from one State or possession into another. Section 70.1 3(a) authorizes the Director to provisionally quarantine a person or group of persons believed to be in the qualifying stage of a quarantinable disease. Ordinarily, provisional quarantine will be ordered by the quarantine officer at the port of entry, but may also be ordered by other authorized agents of the Director. In accordance with sections 311 and 365 of the PHS Act (42 U.S.C. 243 and 268), the Director may seek the assistance of state and local authorities and of U.S. Customs and Coast Guard officials, respectively, in the enforcement of quarantine rules and regulations.

Under § 70.14, paragraph (b), provisional quarantine commences on the occurrence of any one of three events: (i) Service of a written provisional quarantine order on the person or group of persons; (ii) a verbal order from an authorized party (typically the quarantine officer at the port of entry) that the person or group of persons are being provisionally quarantined; or (iii) placement of actual movement restrictions on the person or group of persons. ''Actual movement restrictions'' occur when, as determined by the Director, a person under the same circumstances would understand that he or she is being detained and thus is not free to leave. In most circumstances, provisional quarantine is a brief detention lasting only as long as necessary for the quarantine officer (or other authorized agent) to ascertain whether the person or groups of persons are a possible carrier of disease. Under paragraph (c), however, provisional quarantine may continue for up to three business days, provided that persons subject to provisional quarantine may be released sooner if the Director determines that detention is no longer necessary. In the event it is necessary to quarantine an individual beyond three business days, the Director will serve the individual with a quarantine order.

A time frame of up to three business days for provisional quarantine is necessary to confirm whether certain disease-causing microorganisms are present in samples that may be obtained from ill or deceased persons.

Confirmation generally requires in vitro cultivation of the organism followed by identification, direct visualization of the organism in tissue samples, amplification of organism-specific nucleic acid sequences (e.g. PCR confirmation), or detection of organism-specific antibodies generated in response to the infection. Before these tests can be performed, samples must be collected and shipped to CDC, a process likely to take 24 hours. Once received, completion of culture and identification of bacteria requires a minimum of 24–48 hours. Direct visualization in tissue samples typically requires 12–24 hours. Quicker methods (amplification or antibody detection) may be available for some diseases. Even under optimal circumstances, however, the most modern testing methods require a minimum of 12 hours. In addition to the time required for sample collection, shipping and testing, the Director may need up to an additional 24 hours to assimilate test results with the findings of other investigations before arriving at a well-informed determination on the need for a quarantine order.

A time frame of up to three business days comports with the requirements of due process. While there are no federal cases establishing a bright line for quarantine-type detentions, there are several federal cases dealing with ''alimentary canal'' smugglers, *i.e.,* persons who smuggle drugs in their intestines by swallowing balloons. In *United States* v. *Montoya de Hernandez,* 473 U.S. 531 (1985), the U.S Supreme Court analogized holding a suspected alimentary canal smuggler to detaining someone for suspected tuberculosis, noting that ''both are detained until their bodily processes dispel the suspicion that they will introduce a harmful agent into this country.'' Federal courts have upheld detention periods ranging from 16 hours to 20 days based on ''reasonable suspicion'' for suspected alimentary canal smugglers. Accordingly, provisionally quarantining a person suspected of carrying a specified communicable disease and affording that individual an opportunity for an administrative hearing during that period is consistent with due process requirements. Under paragraph (d), in the event that the Director determines that it is necessary to continue to detain such persons beyond three business days, the Director may serve the person or group of persons with a quarantine order in accordance with §§ 70.16–70.18.

Under paragraph (e), persons subject to provisional quarantine may be offered medical treatment, prophylaxis, or vaccination as the Director deems necessary to prevent the transmission or spread of disease. Medical treatment, prophylaxis, or vaccination will typically occur in a hospital setting, but may occur in other settings as the Director deems necessary. Medical treatment, prophylaxis, or vaccination shall occur on a voluntary basis, provided that persons who refuse remain subject to provisional quarantine. Medical treatment, prophylaxis, or vaccination may be provided in accordance with the provisions set forth in § 70.21.

Paragraph (f) explains that nothing in § 70.14 shall be construed to limit the Director's ability to detain a person or group of persons on a voluntary basis or offer such persons medical treatment, prophylaxis, or vaccination on a voluntary basis.

Section 70.15 Provisional Quarantine Orders

This section explains the content of a provisional quarantine order issued in accordance with § 70.11 and the process for serving an order on a person or group of persons. Paragraph (a) explains that the provisional quarantine order shall be served by the Director at the time that provisional quarantine commences or as soon thereafter as the Director determines that the circumstances reasonably permit. Service will typically occur through personal service, for example, by the quarantine officer or another authorized representative serving the person or group of persons with a copy of the provisional quarantine order at the port of entry or hospital facility, but may also occur through other methods of personal service. Due process requires that the method of serving the order in any case be reasonably designed to accomplish actual service. Because personal service may be impracticable or undesirable in certain circumstances, for example, when it is necessary to provisionally quarantine a large group of persons on a very short time-frame, paragraph (b) authorizes service through posting or publishing the order in a conspicuous location when the Director deems it necessary. Under paragraph (c), in circumstances where the Director deems public posting or publishing necessary or desirable, the Director may omit the names and/or identities of the persons and take other measures respecting the privacy of persons, for example, using initials, instead of full names, or other pseudonyms.

Paragraph (d) describes the information contained in the provisional quarantine order and states that the order shall be in writing and signed by the Director. While due process is a flexible concept that varies depending upon the particular circumstances of the event, a key element of due process is a written order that provides sufficient notice to the person of the actions that the government proposes to take and describes how to contest the government's decision. In order to comply with this fundamental concept of due process, paragraph (d) requires that the order advise the person or group of persons of the following:

- The Director's reasonable belief that the person or group of persons is in the qualifying stage of a quarantinable disease based on information available to the Director at the time, such as travel history, clinical manifestations, or any other evidence of infection or exposure;
- The Director's reasonable belief that either: (i) the person or group of persons is moving or about to move from a State to another State; or (ii) is a probable source of infection to persons who will be moving from a State to another State;
- The suspected quarantinable disease;
- That the person or group of persons may be provisionally quarantined for three business days and that at the end of such period the person or group shall be released or, if determined by the Director, served with a quarantine order;
- That the person or group of persons may be released earlier if the Director determines that provisional quarantine is no longer warranted;

Section 70.16 Quarantine

The Director has historically recommended medical isolation and/or home quarantine of persons with suspected quarantinable diseases. Isolation and quarantine have generally been carried out with the consent of persons or their authorized representatives. This section is primarily intended to deal with the small number of situations where the person refuses to comply on a voluntary basis with the Director's instructions, or in situations where the Director otherwise believes that the mandatory quarantine is necessary. It describes the Director's authority to quarantine persons that the Director believes are in the qualifying stage of a quarantinable disease.

The quarantine of persons believed to be infected with communicable diseases is a prevention measure that has been used effectively to contain the spread of disease. Quarantine differs from provisional quarantine in its potentially longer duration, generally determined by the disease's periods of incubation and communicability. Under paragraph (a), the Director may issue a quarantine order whenever the Director reasonably believes that a person or group of persons are in the qualifying stage of a quarantinable disease. In general, the Director's belief that a person is in the qualifying stage of a quarantinable disease will be based on scientific principles such as clinical manifestations, diagnostic tests or other medical tests, epidemiologic information, laboratory tests, physical examination, or other available evidence of exposure or infection. For interstate quarantine only, the Director will make an additional determination that either (i) the person or group of persons are moving or about to move from a State to another State; or (ii) that the person or group of persons are a probable source of infection to persons who will be moving from a State to another State.

Under paragraphs (b), (c), and (d), as with provisional quarantine, the Director may offer medical treatment, prophylaxis, or vaccination to persons subject to quarantine as the Director deems necessary to prevent the transmission or spread of disease. Medical treatment, prophylaxis, or vaccination may occur in a hospital or other settings, including homes, as the Director deems necessary. Medical treatment, prophylaxis, or vaccination will occur on a voluntary basis, provided that persons who refuse remain subject to quarantine until the period of incubation and communicability have passed. In the event such persons are quarantined, they may request an administrative hearing.

Under paragraph (d), the Director may also order quarantine where examination, medical treatment, prophylaxis, or vaccination is medically contra-indicated or not reasonably available.

Under paragraph (e), the length of quarantine shall not exceed the period of incubation and communicability, as determined by the Director, for the quarantinable disease. While flexibility regarding the length of quarantine must be maintained by the Director in order to allow for the possibility of new variant or bioengineered strains of specified communicable diseases, in general the periods of incubation and communicability are as follows:

Disease	Incubation period following exposure	Period of communicability following onset of illness
Cholera	Few hours—5 days	7–14 days.
Diphtheria	2–5 days	30 days.
Infectious Tuberculosis	Primary: 4–6 weeks; Secondary: variable	14–60 days.
Influenza	1–4 days	5–14 days.
Plague	Pneumonic: 1–7 days (usually 2–4)	48 hours–14 days.
Yellow Fever	3–14 days	Viremia documented as long as 14 days into illness.
SARS	2–10 days	21 days.
Marburg	2–16 days	60–90 days.
Ebola	2–21 days	60 days.
Crimean-Congo	2–12 days	12 days.
Smallpox	7–17 days	10 days.

The periods of incubation and communicability are intended to provide an estimate of the time an individual might be placed in quarantine or isolation, respectively. These time frames are based on accepted medical facts related to these diseases and would be considered part of the basic knowledge possessed by physicians familiar with the diagnosis and treatment of these diseases. For many of the diseases, such as tuberculosis and viral hemorrhagic fever, the range of possible periods of incubation and communicability, based on published individual case reports, is significantly longer. To provide a more realistic sense of the time during which isolation or quarantine may be necessary, CDC listed ranges that, in the opinion of subject matter experts, encompass the vast majority of cases of these diseases. In all cases, the listed ranges are shorter than the upper limit of documented periods of incubation or communicability.

For this purpose, it is important to distinguish between the two terms: Quarantine and isolation. Quarantine refers to the restriction of movement of persons who have been exposed to a communicable disease, but have not yet become ill or able to transmit that disease to others. Isolation, on the other hand, is the restriction of movement of persons ill with a communicable disease in a stage where transmission is possible. In general, when a person is exposed to one of the diseases listed in this table, existing authority allows the Director to place that person under quarantine up to the length of time listed under the incubation period for each disease. If, during the time of quarantine, the person becomes ill, the authorities allow for them to be isolated for a period up to that listed under period of communicability.

For example, a person with a potential exposure to SARS could be under quarantine for up to 10 days. However, if that person became ill, he or she would no longer be in quarantine, but would be isolated for the duration of illness or period of communicability (up to 21 days). If the person under quarantine for the incubation period did not become ill within 10 days of the time the exposure was thought to have occurred, he or she would be released.

An opportunity to request an administrative hearing for purposes of reviewing the quarantine order is provided for under these regulations. The person or group may also seek judicial review of the quarantine order through a petition for writ of habeas corpus pursuant to 28 U.S.C. 2241. Habeas corpus is the traditional legal mechanism for contesting detention by the government. *See Hamdi,* 124 S.Ct. at 2644. There is one litigated case involving the exercise of federal quarantine authority to quarantine an exposed person, *United States* v. *Shinnick,* 219 F.Supp.789 (E.D.N.Y. 1963).

In *Shinnick,* the U.S. Public Health Service medically isolated an arriving passenger in a hospital for 14 days because she had been in Stockholm, Sweden, a city that the World Health Organization had declared to be a smallpox-infected local area. The patient, moreover, could not show proof of vaccination. The district court upheld the detention, finding that health authorities had acted in good faith because there had been an opportunity for exposure while the patient had been in Stockholm. The court further noted that there was no way of determining for 14 days whether the patient was actually infected with smallpox and that she was especially susceptible to infection because there was a history of unsuccessful vaccinations.

Paragraph (g) explains that nothing in § 70.16 shall be construed to limit the

Director's ability to quarantine a person or group of persons on a voluntary basis.

Section 70.17 Content of Quarantine Order

This section requires that quarantine orders issued by CDC be signed by the Director and describes the content of the order. A written order that provides sufficient notice to the person of the actions that the government proposes to take and describes how to contest the government's decision is a key element of due process. In order to comply with this fundamental concept of due process and the requirements of Section 361 of the Public Health Service Act (42 U.S.C. 264), this section requires that the quarantine order contain the following information:

- The identity of the person or group of persons to be quarantined, if known;
- The location where such person or group of persons is to be quarantined;
- The date and time at which quarantine commences and ends;
- The suspected quarantinable disease;
- A statement that the Director reasonably believes that (i) such person or group of persons is in the qualifying stage of a quarantinable disease; and that either (ii) such person or group of persons will move or is about to move from one State to another State; or (iii) is a probable source of infection to persons who will be moving from a State to another State;
- A statement regarding the basis for the Director's belief that such person or group of persons is in the qualifying stage of a quarantinable disease, *e.g.,* clinical manifestations, physical examination, laboratory tests, diagnostic tests or other medical tests, epidemiologic information, or other evidence of exposure or infection available to the Director at the time;
- A statement that persons shall comply with conditions of quarantine, including, but not limited to, examination, medical monitoring, medical treatment, prophylaxis, or vaccination, or other conditions of quarantine deemed by the Director to be necessary to prevent the transmission or spread of communicable disease;
- A statement that persons may refuse examination, medical monitoring, medical treatment, prophylaxis, or vaccination, but that if they choose to do so they remain subject to quarantine;
- A statement that persons under quarantine, any time while the quarantine order is in effect, may request that the Director hold a hearing to review the quarantine order.

Section 70.18 Service of Quarantine Order

This section explains the process for serving a quarantine order on a person or group of persons. Paragraph (a) explains that a copy of the quarantine order shall be served at the time that quarantine commences or as soon thereafter as the Director determines that the circumstances reasonably permit. Service will typically occur through personal service, for example, by an agent authorized to enforce quarantine serving the person or group of persons with a copy of the quarantine order at home or at a hospital or other quarantine facility, but may also occur through other methods of service. Because personal service may be impracticable in certain circumstances, for example, when it is necessary to quarantine a large group of persons, paragraph (b) also authorizes service through posting or publishing the order in a conspicuous location when the Director deems it necessary or desirable. In any case, due process requires that the method of serving the order be reasonably designed to accomplish actual service. Under paragraph (b), in circumstances where the Director deems public posting or publishing necessary or desirable, the Director may omit the names and/or identities of the persons and take other measures respecting the privacy of persons, for example, using initials, instead of full names, or pseudonyms.

Section 70.19 Medical Examination and Monitoring

This provision authorizes the Director to order medical examination or monitoring of persons believed to be in the qualifying stage of a quarantinable disease. Production of information concerning familial and social contacts, travel itinerary, medical history, place of work and vaccination status may also be ordered by the Director. This information will permit determinations to be made concerning the scope of potential exposure, the identity of those in recent contact with the person, and the potential vulnerability of the person to the disease. Persons may refuse medical examination and monitoring, but remain subject to provisional quarantine or quarantine. In the event that persons who refuse medical examination or monitoring are served with a quarantine order, they may request an administrative hearing.

Section 70.20 Hearings

This section describes the procedures for an administrative hearing relating to a quarantine order. An administrative review by the agency is in addition to and apart from any judicial review of the Director's determination that may be available, for example, through the filing of a petition for a writ of habeas corpus under 28 U.S.C. 2241. The opportunity to contest the government's actions in a meaningful time, place, and manner is a fundamental element of due process. An administrative hearing under this section is an informal proceeding conducted by the agency where the hearing officer reviews the determination to quarantine a person or group of persons. Under paragraph (a), a person or group of persons (or an authorized representative) must specifically request that the CDC Director hold an administrative hearing. The CDC Director will then schedule the administrative hearing to take place within one business day of the request for a hearing. As part of the quarantine order, the CDC Director will provide the person or group with information concerning how to request an administrative hearing, *e.g.*, contact information, telephone numbers as stated in paragraph (c). Typically, requests can be made by informing the quarantine officer, either verbally or in writing, or by calling a telephone number established by the CDC Director for that purpose. Notice of the administrative hearing will be provided to the person or group of persons under quarantine (or to an authorized representative) through any method the CDC Director determines to be reasonably designed to provide notice that the administrative hearing has been scheduled. The method may include, for example, e-mail, telephone, or written notice.

Under paragraph (d), the CDC Director may designate a hearing officer to review the available medical or other evidence of exposure or infection available and make findings as to whether the person or group of persons are in the qualifying stage of a quarantinable disease and recommendations as to whether the person or group of persons should be released or remain in quarantine. Under section 369 of the Public Health Service Act (42 U.S.C. 272), medical officers of the United States, when performing duties as quarantine officers at any port or place within the U.S., are authorized to take declarations and administer oaths in matters pertaining to the administration of quarantine laws and regulations.

The hearing officer may be someone within the agency, but will not be the same person who ordered the quarantine. While the hearing officer retains ultimate discretion regarding matters to be heard, the hearing will be limited to genuine and substantial issues of fact, *e.g.*, regarding whether the person or group of persons is in the qualifying stage of a quarantinable disease and whether the person or group should be released or remain in quarantine. Matters not subject to a hearing may include questions relating to the legality or constitutionality of statutes or regulations and matters that are neither genuine nor substantial, *e.g.*, quality of food, availability of entertainment.

The administrative hearing will ordinarily be closed to the public to protect the medical privacy of the person or group of persons under quarantine, unless the person or group of persons request that the hearing be open. The hearing officer, however, may record the hearing through transcription, audio or video tape, summary notes of the proceeding, or other means. At the discretion of the hearing officer, the administrative hearing may be based on written submission. A hearing involving live testimony should, to the extent practicable, provide opportunity for participation via telephone or other remote means. Under paragraph (e), a person or group of persons in quarantine may authorize a representative to appear at the hearing. Under paragraph (f), the CDC Director shall take such measures as the CDC Director determines to be reasonably necessary to allow a person or group of persons under quarantine to communicate with their authorized representatives. Measures may, for example, include establishment of video-conferencing facilities, e-mail terminals, telephone or cellular phone services, and other similar devices or technologies.

During the administrative hearing, the person or group of persons subject to quarantine will be given an opportunity to call witnesses and present testimony. Within the discretion of the hearing officer, administrative hearings may be consolidated when the number of persons or other factors renders individual participation impracticable or when factual issues affecting the group are typical of those affecting the individual. The hearing officer retains ultimate discretion to determine the conduct of hearings, but will generally follow these procedures:

- The hearing officer will ask the parties if they wish to make a short statement outlining their concerns and desired outcomes. This is not part of the testimony, but a summary preview of the testimony and evidence for the hearing officer;
- The hearing officer will ask the parties to present evidence to support their positions and desired outcomes of the hearing. Witnesses may be called and the parties may ask questions. The hearing officer will swear in any witnesses offering testimony;
- The hearing officer will ask each party for comments regarding the evidence or testimony presented by the other party and for a short summary of reasons for the desired outcome;
- The hearing officer will inform the parties that a report and recommendation outlining the hearing officer's findings regarding the evidence of exposure or infection will be presented to the CDC Director for final agency determination.

Under paragraph (g), the hearing officer may order a medical examination of the person or group of persons under quarantine when a medical examination would assist in reasonably determining whether the person or group is in the qualifying stage of a quarantinable disease. Persons requested to undergo a medical examination by the hearing officer may refuse, but remain subject to quarantine.

Under paragraph (h), at the conclusion of the administrative hearing, the hearing officer will, based upon his or her review of the evidence of exposure or infection made available to the hearing officer, make findings and a written recommendation to the CDC Director whether the person or group of persons should be released or remain in quarantine. The hearing officer will provide the CDC Director with the hearing report and recommendation as soon as possible after the conclusion of the hearing. Under paragraph (h), the CDC Director, based upon the hearing officer's findings and written recommendation and the administrative record, shall within one business day after the conclusion of the hearing, order the release or continued quarantine of the person or group of persons. The CDC Director's order will be carried out without delay. Furthermore, because it is difficult to foresee all of the circumstances under which persons may request to be heard, paragraph (h)(2) permits the CDC Director to issue additional instructions and guidelines considered necessary to govern the conduct of hearings.

Paragraph (k) states that the quarantine order will be deemed final administrative action either when the Director has accepted or rejected the hearing officer's written recommendation or three business days after the request for a hearing, whichever comes first.

Section 70.21 Care and Treatment of Persons

Under section 322(a) of the PHS Act (42 U.S.C. 249) persons detained in accordance with quarantine laws may be treated and cared for by HHS. Such persons may receive care and treatment at the expense of HHS at a public or private medical or hospital facility, when authorized by the officer in charge of the quarantine station at which the application is made. CDC, in its sole discretion and subject to available appropriations, is authorized to pay, as a payer of last resort, expenses of care and treatment for persons detained in accordance with quarantine laws. For quarantinable diseases, eligible expenses are limited to those for costs and items reasonable and necessary for the care and treatment of the person from the time the person is referred to a hospital or other medical facility for treatment until the time that quarantine expires. For other diseases, eligible expenses are limited to those associated with services and items relating to care and treatment prior to diagnosis; expenses associated with care and treatment following diagnosis will not be paid by CDC.

Section 70.22 Foreign Nationals

This section sets forth procedures for notifying consular offices of the provisional quarantine or quarantine of their foreign nationals. These procedures are consistent with requirements found in the Vienna Convention on Consular Relations regarding consular notification. In general, U.S. government requirements regarding the detention of foreign nationals may be accessed at: *http://travel.state.gov/law/consular/consular_636.html.*

Section 70.23 Administrative Record

Another key element of due process is the existence of a record describing the agency's actions for a court to review. This section describes the content of a person's administrative record. An administrative record will consist of the following, where applicable:

- Provisional quarantine and/or quarantine order;
- Any medical, laboratory, epidemiologic, or other information in support thereof;
- Evidence submitted by the person under provisional quarantine and/or quarantine;
- Written findings and recommendation of the hearing officer; and
- Hearing transcript, if any, or summary notes of the hearing.

Section 70.24 Requests by State (including political subdivisions thereof), Possession, or Tribal Health Authorities

This provision authorizes the Director to take whatever steps necessary to prevent the introduction, transmission or spread of communicable diseases upon the request of a health authority. Expressly referred to in the provision are requests for issuance of a provisional quarantine order or a quarantine order. Under section 311 of the PHS Act (42 U.S.C. 243), the Secretary is authorized to cooperate with and aid states and local authorities in the enforcement of their quarantine and other health regulations. Paragraph (c) clarifies that nothing in this section is intended to impose a condition or limit the ability of the Director to exercise any of the public health measures provided for in part 70, or in the case of possessions, part 71.

Section 70.25 Measures in the Event of Inadequate Local Control

This section is a carryover from existing § 70.2 which authorizes the CDC Director to take measures to prevent the spread of communicable diseases between States or between States and possessions whenever the Director determines that the measures taken by any State or possession (including political subdivisions) are insufficient. Under Section 361(a) of the PHS Act, the measures that the Director may take include inspection, fumigation, disinfection, sanitation, pest extermination, and destruction of animals or articles believed to be sources of infection, and other measures. The proposed regulatory language is consistent with that appearing in Section 361(a) of the PHS Act. The proposed section also makes clear that the Director may make a determination of inadequate local control with respect to public health measures taken by Indian Tribes in Indian country. While a determination of inadequate local control under this section does not require the concurrence of the IHS Director, to the extent practicable, when taking actions in Indian Country the Director will consult with the IHS Director prior to such action and once a determination has been made, the Director will send notification to both the Director, IHS and to the Tribe or tribes affected.

Section 70.26 Federal Facilities

This section clarifies that, in addition to the public health measures outlined in part 70, the Director may take whatever further public health measures or combination of measures the Director deems necessary with respect to facilities owned or operated by the federal government. The federal government has a variety of different jurisdictional and proprietary arrangements with State and local governments, as well as with private entities, concerning federal facilities. In some cases, the federal government maintains exclusively federal campuses, while in other cases, jurisdiction with respect to activities occurring on federal facilities is shared with State and local governments. This section simply clarifies that the Director may take public health measures with respect to federal facilities. Pursuant to 42 U.S.C. 243, the Director may request the assistance of State and local authorities in enforcing federal quarantine rules and regulations. Paragraph (b) clarifies that this section does not preclude the Director from requesting such assistance with respect to facilities owned or operated by the federal government.

Section 70.27 Indian Country

This section is intended to implement provisions appearing in 25 U.S.C. 198 and 231; 25 U.S.C. 1661; and 42 U.S.C. 2001.

Pursuant to 25 U.S.C. 198, the Secretary of the Interior may quarantine any Indian found to be afflicted with ‘‘tuberculosis, trachoma, or other contagious or infectious disease.’’ The Secretary of the Interior, through 25 U.S.C. 231, may also permit State agents and employees to enter upon Tribal lands for the purposes of making inspections of health and educational conditions and enforcing sanitation and quarantine regulations.

42 U.S.C. 2001 transferred all functions, responsibilities, authorities, and duties relating to the conservation of the health of Indians, including 25 U.S.C. 198 and 231, from the Secretary of the Interior to the Secretary of HHS, which were redelegated to the Director of the Indian Health Service (IHS) by 25 U.S.C. 1661. Any action the Director of CDC takes under these sections must be in concurrence with the Director of IHS after consultation with the affected Tribe or Tribes.

The grant of authority in 25 U.S.C. 198 and 231 is in addition to the Director's authority under 42 U.S.C. 264, and this section of the proposed rule supplements the Director's authority to impose public health measures to prevent interstate disease transmission. In other words, with respect to carriers in Indian country, the Director may apply any of the public health measures appearing in this part if such carriers have an effect on interstate commerce. Similarly, with respect to a person or group of persons in Indian country, the Director may exercise public health measures appearing in this part provided that such person or group of persons is in the qualifying stage of a quarantinable disease and either (i) moving or about to move from a State to another State; or (ii) a probable source of infection to persons who will be moving from a State to a State.

Under this section, the Director, with the concurrence of the IHS Director and after consulting with the affected Tribes or Tribes may enter onto Indian country for the purpose of enforcing federal quarantine rules and regulations. This section provides that, in addition to the public health measures outlined in Part 70, the Director may impose public health measures with regard to provisional quarantine under § 70.14 and § 70.15, quarantine under § 70.16–§ 70.18, § 70.20, and medical examination and monitoring under § 70.19, in Indian country without making a finding that such person or group of persons is moving or about to move from a State to another State or is a probable source of infection to persons who will be moving from a State to another State. In such circumstances, a finding that such persons are in the ‘‘qualifying stage of a quarantinable disease’’ would be required.

Paragraph (b) provides that any quarantine authorized by paragraph (a) must take place in a hospital or other place for treatment and that any person who is subject to provisional quarantine or quarantine may refuse medical examination, monitoring, treatment, prophylaxis, or vaccination, but remain subject to provisional quarantine or quarantine. Paragraph (c) further explains that any person who is the subject of a provisional quarantine order or quarantine order authorized by paragraph (a) has the same rights as provided for elsewhere in this part.

Furthermore, under paragraph (d), the Director, with the concurrence of the IHS Director and after consulting with the affected Tribes or Tribes, may authorize agents and employees of any State to enter Indian country for the sole purpose of enforcing federal quarantine rules and regulations. This authority is subject to any rules or regulations the IHS Director may choose to promulgate under 25 U.S.C. 231.

Section 70.28 Special Powers in Time of War

This section implements statutory authority contained in section 363 of the PHS Act (42 U.S.C. 266). Under this authority, the Director, in consultation with the Secretary of the Department of Defense or his/her designee and without making a finding of interstate movement, may, in time of war, apprehend, detain, or conditionally release persons: (1) In the qualifying stage of a quarantinable disease; and (2) to be a probable source of infection to members of the military services or to individuals engaged in the production or transportation of arms, munitions, ships, food, clothing, or other supplies for the military services. Any person who is the subject of a provisional quarantine order or quarantine order authorized under this section has the same rights as provided for provisional quarantine or quarantine elsewhere in this part.

Section 70.29 Penalties

This section describes the penalties for violating federal quarantine rules and regulations. Under 42 U.S.C. 271, criminal penalties exist for violating regulations enacted under the authority of Section 361 of the PHS Act (42 U.S.C 264). Under the sentencing classification provisions of 18 U.S.C. 3559 and 3571, violations of the quarantine regulations, classified as Class A misdemeanors, are subject to greater penalties. Violation by an individual is punishable by a fine of up to $250,000 or one year in jail, or both. Organizations may be fined up to $500,000 per violation.

Section 70.30 Implementation Through Order

This section explains that the Director may implement any of the provisions of this part through an order issued and signed by the Director. In the recent past, the Director has issued a variety of orders to deal with urgent public health threats, including: Notice of embargo of civets (January 13, 2004); Notice of embargo of birds (Class: Aves) from specified Southeast Asian countries (February 4, 2004); Order lifting the ban of bird and bird products from specified Southeast Asian countries (March 10, 2004), and Joint Order (issued with the FDA) prohibiting transportation or distribution of certain rodents associated with the monkeypox outbreak (June 11, 2003) followed by promulgation of an Interim Final Rule (November 4, 2003). This section codifies the preexisting practice of the agency with respect to implementation through an order.

Section 70.31 Appeals of Actions Required Pursuant to 70.6, 70.7, 70.11 or 70.12

A new 70.31 would allow a written appeal to the Director within two business days in the event that the Director denies an application for a travel permit pursuant to 70.6 or 70.7, orders the destruction of animals, articles, or things, pursuant to 70.11, or the detention of a carrier pursuant to 70.12. The Director may nevertheless immediately implement the actions allowed in 70.6, 70.7, 70.11 and 70.12.

Following is a summary of changes to the current regulations:

Sections Cancelled:
70.3 All communicable diseases
70.6 Apprehension and detention of persons with specific diseases

Sections Moved:
70.2 Measures in the event of inadequate local control moved to 70.22

Sections Added:
70.4 Passenger information
70.5 Written plan for passenger information and designation of an airline agent
70.6 Travel permits
70.9 Vaccination clinics
70.10 Establishment of institutions, hospitals and stations
70.11 Sanitary measures
70.12 Detention of carriers affecting interstate commerce
70.13 Screenings to detect ill persons
70.14 Provisional quarantine
70.15 Provisional quarantine orders
70.16 Quarantine
70.17 Content of quarantine order
70.18 Service of quarantine order
70.19 Medical examination and monitoring
70.20 Hearings
70.21 Care and treatment of persons
70.22 Foreign nationals
70.23 Administrative record
70.24 Requests by State (including political subdivisions thereof), possession, or tribal health authorities
70.25 Measures in the event of inadequate local control
70.26 Federal facilities
70.27 Indian country
70.28 Special powers in time of war
70.29 Penalties
70.30 Implementation through order
70.31 Appeals of actions required pursuant to 70.6, 70.7, 70.11 or 70.12

TABLE IV–1.—SECTIONS UPDATED AND/OR RECODIFIED IN 42 CFR PART 70

Current regulation — Section	Proposed regulation — Section
70.1 General definitions	70.1 Scope and definitions.
70.2 Measures in the event of inadequate local control	70.2 Report of death or illness on board flights.
	70.3(new) Written plan for reporting of deaths or illness on board flights and designations of an airline agent.
70.3 All communicable diseases	70.4(new) Passenger information.
	70.5(new) Written plan for passenger information and designation of an airline agent.
70.4 Report of disease	70.6(new) Travel permits.
70.5 Certain communicable diseases; special requirements	70.7 Responsibility with respect to minors, wards, and patients.
70.6 Apprehension and detention of persons with specific diseases	70.8 Military services.
70.7 Responsiblity with respect to minors, wards, and patients.	70.9(new) Vaccination clinics.
70.8 Members of military and naval forces	70.10(new) Establishment of institutions, hospitals and stations.
	70.11(new) Sanitary measures.
	70.12(new) Detention of carriers affecting interstate commerce.
	70.13(new) Screenings to detect ill persons.
	70.14(new) Provisional quarantine.
	70.15(new) Provisional quarantine orders.
	70.16(new) Quarantine.
	70.17(new) Content of quarantine order.
	70.18(new) Service of quarantine order.
	70.19(new) Medical examination and monitoring.
	70.20(new) Hearings.

TABLE IV–1.—SECTIONS UPDATED AND/OR RECODIFIED IN 42 CFR PART 70—Continued

Current regulation	Proposed regulation
Section	Section
	70.21(new) Care and treatment of persons. 70.22(new) Foreign nationals. 70.23(new) Administrative record. 70.24(new) Requests by State (including political subdivisions thereof), possession or tribal health authorities. 70.25 Measures in the event of inadequate local control. 70.26 Federal facilities. 70.27 Indian country. 70.28 Special powers in time of war. 70.29 Penalties. 70.30(new) Implementation through order. 70.31 Appeals of actions required pursuant to 70.6, 70.7, 70.11 or 70.12.

V. Summary of Proposed Changes to 42 CFR Part 71

The foreign quarantine regulations are used to control and prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States. Sections of this regulation are used in the day-to-day activities of quarantine officers. The proposed rule reduces the number of subparts from six to two. Many of the new sections further clarify current activities. Proposed subpart B, Importations, contains the restrictions on importation of nonhuman primates, certain kinds of animals, etiological agents, hosts, and vectors, and dead bodies. CDC proposes to change only § 71.55 in subpart B.

The following is a section-by-section analysis:

Subpart A—Definitions and General Provisions

Section 71.1 Scope and Definitions

This section explains that 42 CFR Part 71 contains regulations to prevent the introduction, transmission, and spread of communicable diseases from foreign countries into the United States. This part also contains the regulations to prevent the spread of disease among possessions of the United States and from a possession into a State. The definitions contained in this part are comparable to those appearing in Part 70. The following definitions have been added or modified to be consistent with modern quarantine concepts and current medical principles and practice: ''airline,'' ''airline agent,'' ''business day,'' ''bill of health,'' ''commander,'' ''deratting certificate,'' ''deratting exemption certificate,'' ''detention,'' ''Director,'' ''emergency contact information'', ''flight information,'' ''hearing officer,'' ''ill person,'' ''infectious agent,'' ''International Health Regulations,'' ''medical monitoring,'' ''military services,'' ''possession,'' ''provisional quarantine,'' ''quarantine,'' ''quarantinable disease,'' ''sanitary measures,'' ''State,'' ''ship,'' ''shipline,'' ''shipline's agent,'' and ''United States.''

The definition of an ill person as it applies to this part was modified to be consistent to that which applies to Part 70.

In contrast with the requirement in Section 361(d)(1) (42 U.S.C. 264(d)(1)) of the PHS Act that the Director make findings under Part 70 that a person is (1) in a qualifying stage of a quarantinable disease and (2) is moving or about to move from a State to another State or who is a probable source of infection to persons so moving or about to move, there are no such requirements when a person is entering the United States from a foreign country or a possession of the United States.

Section 71.2 Designation of Yellow Fever Vaccination Centers; Yellow Fever or Other Validation Stamps

This section contains provisions comparable to those contained in current § 71.3.

According to Annex 7 of the WHO International Health Regulations, member states must designate yellow fever vaccination centers authorized to administer yellow fever vaccine. Licensed medical providers become certified as centers through issuance of a Uniform Stamp Number by a designated health authority. CDC, pursuant to current § 71.3, delegated this authority to state and territorial health departments (SHDs). SHDs file duplicate listings of all certified vaccination centers with CDC. The authorization requirements and certification processes are determined by each SHD, and are not the same in every State.

Upon certification, the SHD sends a notice of the new certification to the vaccine manufacturer and to CDC. Upon receipt, CDC sends a letter to the new center, confirming contact information and offering inclusion on CDC's secure Web-based registry of certified vaccination centers. The Web site is maintained by CDC and SHDs, and is updated upon notice of certification termination or changes in contact information. Several SHDs now file duplicated listings via the website.

Section 71.3 Vaccination Clinics

This section contains provisions comparable to those contained in § 70.9.

Section 71.4 Bills of Health

Section 366 of the PHS Act (42 U.S.C. 269) provides that, except as otherwise prescribed in regulations, any vessel at any foreign port or place clearing or departing for any port or place in a State or possession shall be required to obtain from the consular officer of the United States, Public Health Service officer, or other medical officer of the U.S., a bill of health setting forth the sanitary history of the vessel. Under existing § 71.11, carriers at any foreign port clearing or departing for any U.S. port are not required to obtain or deliver a bill of health. Under proposed § 71.4, the Director, to the extent permitted by law and in consultation with such other federal agencies as the Director may deem necessary, may require a carrier at any foreign port clearing or departing for any U.S. port to obtain a bill of health. While the Director does not intend to require a bill of health for carriers engaged in routine traffic, concern over bioterrorism and rapidly emerging infectious diseases makes inclusion of this important public health tool imperative.

Section 71.5 Suspension of Entries and Imports from Designated Places

This section implements statutory authority contained in section 362 of the PHS Act (42 U.S.C. 265). Under this authority, the Director, to the extent permitted by law and in consultation with such other federal agencies as the Director may deem necessary, may prohibit, in whole or in part, the introduction of persons and property from foreign countries or places whenever the Director determines that the risk of introduction of a disease into the United States is increased by the introduction of persons or property from such foreign countries or places. In carrying out this section, the Director, through order, would designate the persons and property from the foreign countries or places subject to the prohibition on introduction, as well as the period of time that such prohibition would remain in effect.

Section 71.6 Report of Death or Illness on Board Flights

This section contains provisions applicable to airlines operating flights on an international voyage, destined for a U.S. port, comparable to those established for airlines engaged in interstate traffic under § 70.2.

Section 71.7 Written Plan for Reporting of Deaths or Illness on Board Flights and Designation of an Airline Agent

This section contains provisions applicable to airlines operating flights on an international voyage, destined for a U.S. port, comparable to those established for airlines engaged in interstate traffic under § 70.3

Section 71.8 Report of Death or Illness on Board Ships

Paragraph (a) of this section establishes requirements applicable to a shipline operating ships on an international voyage comparable to the requirements applicable to airlines in section 71.6. Ships operating between Canadian ports and ports on the Puget Sound or on the Great Lakes and connected waterways are not covered by this section.

Paragraphs (b)–(e) of this section require any shipline operating ships on an international voyage destined for a U.S. port to report to the quarantine station nearest the port of arrival any death or ill person as soon as made known to the ship's commander and, where possible, at least 24 hours before arrival. The shipline shall also report any deaths or ill persons onboard ships during the 15-day period prior to expected arrival, or since departure from a U.S. port (whichever period of time is shorter). Cases or suspected cases of communicable disease during an international voyage from one U.S. port to another are required to be reported to the quarantine station, and the ship must take measures to prevent spread of the disease as directed by the Director. Any death or ill person during a stay in port must be reported. The number of cases (including zero) of diarrhea, febrile respiratory disease, febrile rash illness, or febrile neurologic illness during an international voyage must be reported through a method designated in the shipline's written plan under § 71.9.

Paragraph (f) enables the Director to order shiplines with ships on an international voyage destined for a U.S. port to disseminate to passengers and crew public health notices and other information deemed necessary to prevent the introduction, transmission, or spread of communicable diseases. This provision is comparable to that described for airlines on in international voyage in § 71.6.

Section 71.9 Written Plan for Reporting of Deaths or Illness on Board Ships and Designation of a Shipline's Agent

This provision creates a requirement for shiplines with ships on an international voyage destined for a U.S. port comparable to that created for airlines on an international voyage in § 71.7. Ships operating between Canadian ports and ports on the Puget Sound or on the Great Lakes and connected waterways are not covered by this section. CDC believes that a 90-day time frame for development of a written plan and an additional 90 days for implementation after the final publication of this rule to be appropriate because ships should already have such procedures in place. CDC is soliciting comment on whether this timeframe is appropriate. During the phase-in period established by new § 71.7, ships are still expected to comply with the reporting requirements contained in current 71.21(a) and (c) (Radio report of death or illness) and 71.35 (Report of death or illness on carrier during stay in port).

Section 71.10 Passenger Information

This section contains provisions comparable to those contained in § 70.4, except that this section is also applicable to ships on an international voyage. Ships operating between Canadian ports and ports on the Puget Sound or on the Great Lakes and connected waterways are not covered by this section.

Section 71.11 Written Plan for Passenger Information and Designation of an Airline or Shipline Agent

This section contains provisions comparable to those contained in § 70.5, except that this section is also applicable to shiplines operating ships on an international voyage destined for a U.S. port. Ships operating between Canadian ports and ports on the Puget Sound or on the Great Lakes and connected waterways are not covered by this section.

Section 71.12 Inspections

This section consolidates provisions contained in current 42 CFR Part 71.

Section 71.13 Sanitary Measures

This section contains provisions comparable to those contained in § 70.11.

Section 71.14 Detention of Carriers

This section contains provisions comparable to those contained in § 70.12 and current § 71.31(b).

Section 71.15 Carriers of U.S. Military Services

This section carries over provisions contained in current § 71.34.

Section 71.16 Screenings to Detect Ill Persons

This section contains procedures comparable to those contained in § 70.13 at U.S. ports.

Section 71.17 Provisional Quarantine of Arriving Persons

This section contains procedures comparable to those contained in § 70.14.

Section 71.18 Provisional Quarantine Orders

This section contains procedures comparable to those in § 70.15.

Section 71.19 Quarantine

This section contains procedures comparable to those in § 70.16.

Section 71.20 Content of Quarantine Order

This section contains procedures comparable to those in § 70.17.

Section 71.21 Service of Quarantine Order

This section contains procedures comparable to those in § 70.18.

§ 71.22 Medical Examination and Monitoring

This section contains provisions comparable to those contained in § 70.19.

Section 71.23 Hearings

This section contains procedures comparable to those in § 70.20.

Section 71.24 Care and Treatment of Arriving Persons

This section contains provisions comparable to those contained in § 70.21.

Section 71.25 Arriving Foreign Nationals

This section contains provisions comparable to those contained in § 70.22. In general, U.S. government requirements regarding the detention of foreign nationals may be accessed at: *http://travel.state.gov/law/consular/consular_636.html.*

Section 71.26 Administrative Record

This section contains procedures comparable to those in § 70.23.

Section 71.27 Food, Potable Water, and Waste: U.S. Seaports and Airports

This section carries over provisions contained in current § 71.45.

Section 71.28 Health Documents in International Traffic

This section carries over provisions contained in current § 71.46.

Section 71.29 Special Provisions Relating to Airports: Office, Examination, and Quarantine Facilities

Under 8 CFR 234.4, in order to be designated an ''international airport,'' an airport must fulfill requirements established by the Secretaries of Commerce, Transportation, Health and Human Services, and Homeland Security. The list of airports designated as ''international airports'' may be found at 19 CFR 122.13. The proposed section carries over existing authority requiring each U.S. airport which receives international traffic to provide, without cost to the Government, suitable office, isolation, and other exclusive space for carrying out the federal responsibilities under this part. The proposed section also adds a new provision requiring U.S. airports receiving international traffic to provide suitable quarantine space. The specifications for space requirements to carry out quarantine activities are incorporated into the Federal Inspection Service manual. In carrying out this provision, CDC intends to collaborate closely with the U.S. Department of Homeland Security.

Section 71.30 Establishment of Institutions, Hospitals and Stations

This section contains provisions comparable to those in § 70.10.

Section 71.31 Penalties

The penalties listed in this section are the same as those listed in § 70.29.

Section 71.32 Implementation Through Order

This section contains measures comparable to those in § 70.30.

Section 71.33 Appeals of Actions Required Pursuant to 71.13 or 71.14

A new 71.33 would allow a written appeal to the Director within 2 business days in the event that the Director orders the export or destruction of animals, articles, or things, pursuant to 71.13 or the detention of a carrier pursuant to 71.14. The Director may nevertheless immediately implement the actions provided in 71.13 and 71.14.

Subpart B—Importations

Section 71.51 Dogs and Cats

This section remains unchanged. The text has been set out for the convenience of the reader, however, CDC does not invite comments on this section.

Section 71.52 Turtles, Tortoises, and Terrapins

This section remains unchanged. The text has been set out for the convenience of the reader, however, CDC does not invite comments on this section.

Section 71.53 Nonhuman Primates

This section remains unchanged. The text has been set out for the convenience of the reader, however, CDC does not invite comments on this section.

Section 71.54 Etiological Agents, Hosts, and Vectors

This section remains unchanged. The text has been set out for the convenience of the reader, however, CDC does not invite comments on this section.

Section 71.55 Dead Bodies

Embalming is no longer an option for avoiding a permit when importing dead bodies. Additionally, the Director can impose additional conditions.

Section 71.56 African Rodents and Other Animals that May Carry the Monkeypox Virus

This section remains unchanged. The text has been set out for the convenience of the reader, however, CDC does not invite comments on this section.

Following is a summary of changes to the current regulations:

Sections cancelled:
71.3 Designation of yellow fever vaccination centers: Validation stamps
71.21 Radio report of death or illness
71.27 Issuance of Deratting Certificates and Deratting Exemption Certificates
71.33 Persons: isolation and surveillance
71.35 Report of death or illness on carrier during stay in port
71.41 General provisions
71.42 Disinsection of imports
71.43 Exemption for mails
71.44 Disinsection of aircraft
71.48 Carriers in intercoastal and interstate traffic

Sections modified:
71.1 Scope and definitions
71.4 Bills of health
71.29 Special provisions relating to airports: Office, examination, and quarantine facilities
71.31 Penalties
71.55 Dead bodies

Sections redesignated:
71.14 Carriers of U.S. military services
71.26 Food, potable water, and waste: U.S. seaports and airports

Sections added:
71.2 Designation of yellow fever vaccination centers; Yellow fever or other validation stamps
71.3 Vaccination clinics
71.5 Suspension of entries and imports from designated places
71.6 Report of death or illness on board flights
71.7 Written plan for reporting of deaths or illness on board flights and designation of an airline agent
71.8 Report of death or illness on board ships
71.9 Written plan for reporting of deaths or illness on board ships and designation of a shipline agent
71.10 Passenger information
71.11 Written plan for passenger information and designation of an airline or shipline agent
71.12 Inspections
71.13 Sanitary measures
71.14 Detention of carriers
71.16 Screenings to detect ill persons
71.17 Provisional quarantine of arriving persons
71.18 Provisional quarantine orders
71.19 Quarantine
71.20 Content of quarantine order
71.21 Service of quarantine order
71.22 Medical examination and monitoring
71.23 Hearings
71.24 Care and treatment of arriving persons
71.25 Arriving foreign nationals
71.26 Administrative record
71.28 Health documents in international traffic
71.30 Establishment of institutions, hospitals and stations
71.32 Implementation through order
71.33 Appeals of actions required pursuant to 71.13 or 71.14

TABLE V–1.—SECTIONS UPDATED AND/OR RECODIFIED IN 42 CFR PART 71

Current regulation	Proposed regulation
Subpart A—Definitions and General Provisions Proposed Regulation	A. Subpart A—General Provisions
71.1 Scope and definitions	71.1 Scope and definitions.
71.2 Penalties	71.2 (modified) Designation of yellow fever vaccination centers; yellow fever or other validation stamps.
71.3 Designation of yellow fever vaccination centers; Validation stamps.	71.3 (new) Vaccination clinics.
	71.4 Bills of health.
	71.5 (new) Suspension of entries and imports from designated places.
	71.6 (new) Report of death or illness on board flights.
	71.7 (new) Written plan for reporting of deaths or illness on board flights and designation of an airline agent.
Subpart B—Measures at Foreign Ports	
71.11 Bills of Health	71.8 (new) Report of death or illness on board ships.
	71.9 (new) Written plan for reporting of deaths or illness on board ships and designation of a shipline's agent.
Subpart C—Notice of Communicable Disease Prior to Arrival	
71.21 Radio report of death or illness	71.10 (new) Passenger information.
	71.11 (new) Written plan for passenger information and designation of an airline or shipline agent.
Subpart D—Health Measures at U.S. Ports: Communicable Diseases	
	71.12 (new) Inspections.
71.31 General provisions	71.13 (new) Sanitary measures.
71.32 Persons, carriers, and things	71.14 (new) Detention of carriers.
71.33 Persons: isolation and surveillance	71.15 (modified) Carriers of U.S. military services.
71.34 Carriers of U.S. military services	71.16 (new) Screenings to detect ill persons.
71.35 Report of death or illness on carrier during stay in port	71.17 (new) Provisional quarantine of arriving persons.
	71.18 (new) Provisional quarantine orders.
Subpart E—Requirements Upon Arrival at U.S. Ports: Sanitary Inspections	
	71.19 (new) Quarantine.
	71.20 (new) Content of quarantine order.
	71.21 (new) Service of quarantine order.
	71.22 (new) Medical examination and monitoring.
	71.23 (new) Hearings.
71.41 General provisions	71.24 (new) Care and treatment of arriving persons.
	71.25 (new) Arriving foreign nationals.
71.42 Disinsection of imports	71.26 (new) Administrative record.
71.43 Exemption for mails	71.27 Food, potable water, and waste: U.S. seaports and airports.
71.44 Disinsection of aircraft	71.28 (new) Health documents in international traffic.
71.45 Food, potable water, and waste: U.S. seaports and airports	71.29 (modified) Special provisions relating to airports: Office, examination, and quarantine facilities.
	71.30 (new) Establishment of institutions, hospitals and stations.
71.46 Issuance of deratting certificates and deratting exemption certificates.	71.31 (new) Penalties.
71.47 Special provisions relating to airports: Office and isolation facilities.	71.32 (new) Implementation through order.
71.48 Carriers in intercoastal and interstate traffic	71.33 (new) Appeals of actions required pursuant to 71.13 or 71.14.
Subpart F—Importations	Subpart B—Importations
71.51 Dogs and cats	71.51 Dogs and cats.
71.52 Turtles, tortoises, and terrapins	71.52 Turtles, tortoises, and terrapins.
71.53 Nonhuman primates	71.53 Nonhuman primates.
71.54 Etiological agents, hosts, and vectors	71.54 Etiological agents, hosts, and vectors.
71.55 Dead bodies	71.55 (modified) Dead bodies.
71.56 African rodents and other animals that may carry monkey pox virus.	71.56 African rodents and other animals that may carry monkey pox virus.

VI. Required Regulatory Analyses Under Executive Order 12866, the Unfunded Mandates Reform Act, and the Regulatory Flexibility Act

We have examined the impacts of the proposed regulation under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages, distributive impacts, and equity). Unless we certify that the rule is not expected to have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act, as amended by the Small Business Regulatory Flexibility Act (SBREFA), requires agencies to analyze regulatory options that would minimize any significant economic impact of a rule on small entities. Section 202 of UMRA requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments in the aggregate, or by the private sector, of $100 million in any one year (adjusted annually for inflation). We have conducted analyses of the proposed rule, and have determined that the rule is consistent with the principles set forth in the Executive Order and in these statutes.

We believe that the proposed regulation is a significant regulatory action under the Executive Order. We also believe that it is a major rule under the Congressional Review Act. At this time we are not certifying that the proposed rule would not have a significant impact on a substantial number of small entities under the Regulatory Flexibility Act and have prepared an Initial Regulatory Flexibility Analysis, as required.

A ''significant regulatory action'' is defined in the Executive Order in the relevant part as:

> Any regulatory action that is likely to result in a rule that may have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.

The Regulatory Flexibility Act and the Congressional Review Act (Subtitle E of SBREFA) similarly define ''significant impact'' and ''major rule,'' respectively.

Finally, our Unfunded Mandates Reform Act analysis concludes that the proposed rule will not have any significant economic impact on State, local, or Tribal governments. However, the proposed rule would have a significant impact on the private sector, particularly air carriers. This impact is more than offset by the benefits of the proposed rule, which is designed to enhance our ability to effectively counter the threat of introduction, transmission, and spread of infectious disease via travel. The benefits accruing to public health and safety will also extend to the airline industry and the economy generally.

The analyses undertaken to meet the above requirements are presented in detail in the report titled Regulatory Impact Analysis of Proposed 42 CFR part 70 and 42 CFR part 71, which can be found in the Rulemaking Record (CDC, 2005) (hereinafter referred to as the RIA).

A. Objectives and Basis for the Proposed Regulation

The rule is necessary to minimize the risk of introduction, transmission, and spread of infectious disease via travel. In a recent study, the Institute of Medicine, National Academy of Sciences, found:

> Whether naturally occurring or intentionally inflicted, infections can cause illness, disability, and death in persons while disrupting whole populations, economies, and governments. And because national borders offer trivial impediment to such threats, especially in the highly interconnected and readily traversed ''global village'' of our time, one nation's problem soon becomes every nation's problem (Institute of Medicine, 2003).

Stopping an outbreak—whether it is naturally occurring or caused intentionally—requires the use of the most rapid and effective public health tools available. One of those tools is quarantine—restricting the movement of persons exposed to infection to prevent them from infecting others, including family members, friends, and neighbors. Quarantine of exposed persons may be the best initial way to prevent the uncontrolled spread of highly dangerous biologic agents such as smallpox, plague, and Ebola fever—especially when combined with other health strategies such as vaccination, prophylactic drug treatment, patient isolation, and other appropriate infection control measures.

B. The Nature of the Impacts

We commissioned the Volpe National Transportation Systems Center (2005) to undertake a study concerning the need for access to data enabling us to rapidly identify and locate at-risk persons to control the spread of infectious diseases. In the course of the study, airlines expressed concern over business and cost considerations associated with future data sharing. We would pursue collection of this vital data with a commitment to minimize the effect on airline operations. Full advantage would be taken of the trend toward online booking and passenger information input. Every effort would be made to merge our data collection efforts with those already undertaken by the airlines for national security and other purposes. During the course of rule development, we will seek comment from the airlines and their passengers concerning the most efficient means of data collection.

Failure to efficiently address the health-related effects of infectious disease spread through travel poses substantial adverse economic consequences. Reliable estimates are that the SARS' economic impacts in Asia in 2003 might have totaled as much as U.S. $28.4 billion, as discussed in Fan (2003). In Toronto, after SARS was detected, hotel occupancy rates were cut in half, and conventions were cancelled. CBS News Online (2003) reported that the Canadian Government spent $40M (CAN) to counteract both the medical impacts (surgical backlogs) of SARS quarantines and the public concern about safe travel into Ontario. To the extent that economic activity shifts from on region to another, estimates of regional impacts overstate national or international impacts. Nevertheless, the SARS experience proves that fear of contagion and the reaction to that fear can have severe economic impacts on nations where such contagions are detected.

Airlines were severely affected by SARS, with the St. Louis Business Journal (2003) stating ''the outbreak of SARS has had a greater impact on the global airline industry than the war in Iraq, according to a study by OAG, a firm that provides flight schedule information.''

Since the mere threat of an outbreak can affect the public health system and damage the economies of affected nations and the travel industry, it must be contained promptly to mitigate public reaction. Automated tools to acquire passenger information would enable CDC to more effectively employ its staff in tracing and identifying travelers.

The major impacts of this rule will fall on the airlines and the global distribution systems (GDSs), travel agencies, and other reservation booking operations to gather the data from passengers and submit the proposed required crew manifest and passenger data, as needed. It will also fall on the passengers themselves, who must take time to supply the information (see Sections F and G below for more detail). Our current belief is that any data collection-related costs borne by these entities will be substantially outweighed by avoidance of public health and economic costs associated with infectious disease outbreaks spread via travel.

The other requirements of the proposed rule are primarily clarifications or cover tasks that are currently being performed by agencies at the state and local levels. In particular, for sanitary measures, the proposed regulation duplicates CDC regulatory language from 42 CFR part 71, related to international commerce in part 70, which relates to interstate commerce. Although this may appear to be an expansion of authority, we argue that there is no economic impact from this change in language for two reasons. First, the regulation will not change historical practice during an outbreak. In lieu of CDC action, State and local public health authorities have the power to order sanitary measures or destruction of cargo to prevent the spread of illness. For example, during the 2003 monkeypox event, the state of Wisconsin banned the sale, importation, and display of prairie dogs to stop the spread of the disease. Thus, the additional language will change the authority under which sanitary measures are taken from State to Federal jurisdictions, but the measures would be taken in any event, so there is no economic effect.

Second, the economic impact of a sanitation order may differ significantly depending on the circumstances. Experience shows that, in some cases, public health officials' sanitation orders do not generate costs over and above the costs that the outbreak itself creates. Affected markets often respond immediately to health risk information. For example, demand for pet prairie dogs collapsed virtually overnight when they were identified as potential carriers of monkeypox. Thus, the value of the pet prairie dog inventory was destroyed by the loss of a market even before health authorities sequestered them. In other cases, such as a sanitation order affecting a standard commodity such as chicken or beef, whose price would likely not collapse in the presence of an outbreak, the order itself may be the vehicle that destroys at least part of the value of the shipment. Because a sanitation order restricts the supply of a product, in yet other cases it may even cause prices to rise. Regardless, government intervention ensures that those with less information are not made vulnerable to the disease and can reestablish safe conditions and public trust in the product.

We invite comment concerning the economic impact of this proposed regulation.

C. Need for the Rule

As discussed in more detail above, we believe that the rule is necessary to minimize the risk of introduction, transmission, and spread of infectious disease via travel. The need for the regulation is driven by a demonstrated market failure. An externality exists when one person's or party's actions impose uncompensated costs to other parties. By exposing fellow travelers to potential illness and possible death, an ill traveler imposes uncompensated costs on the fellow travelers, travel providers, and the individuals that they, in turn, might expose. Due to the national and international nature of travel and the transmission of communicable diseases, regulation at the Federal level is the most appropriate mechanism for protecting public health.

D. Baseline

A first step in economic analysis of a regulatory action is the identification of a baseline, a depiction of the world in the absence of any action, from which to calculate the effects of the regulation. In the absence of the changes proposed in this regulation, we would continue to use the approaches taken during the SARS outbreak. We would meet flights containing suspected contagious passengers and attempt to obtain location and contact data from both passengers and crew members before disembarkation. Ill passengers on planes from affected areas would be evaluated and referred for medical care when appropriate.

As with SARS, data concerning cases identified after disembarkation would have to be manually gathered, compiled, and processed from flight manifests, customs declarations, and any other available sources relevant to the case. This manual process has the following shortcomings:

- Manifests contain only the passenger name and seat number.
- Custom declarations are completed by the passenger by hand and are often illegible.
- Names on the customs declarations do not necessarily match those on the manifests. Phone numbers are not included on customs forms, and only one customs form is filled out per family.

Hard copy data gathered from manifests and customs declarations frequently takes several days to obtain. Data must then be keyed into a database. Entering the data and verifying addresses may take several more days. The time to do manual tracking of passengers could frequently be expected to take longer than the incubation period of many infectious diseases.

E. Alternatives

Economic analysis of a regulation is based on the concept of incremental change: What would happen without a rule versus what would happen with it. The current regulatory environment provides a base case against which the changes in behavior precipitated by the new rule are compared.

Overall, the proposed rule seeks to:

- Clarify administrative procedures to ensure due process rights to quarantined individuals.
- Mandate that carriers maintain and provide to CDC passenger information in electronic formats.
- Clarify requirements for reporting sick passengers.
- Clarify sanitary measures taken with respect to interstate commerce.
- Clarify coordination with state and tribal authorities.

CDC performed a section-by-section comparison of the current and proposed rule. Many provisions of the proposed rule codify practices that have evolved over the years. As these practices are part of current practice at CDC and in the industry, their codification does not impose new costs upon society.

The major cost component of the proposed regulation is creation and maintenance of a passenger information database including home address, emergency contact, and itinerary information. Under current regulations, the airlines do not typically collect this information in an easily accessible format, nor do they maintain it for the proposed 60-day period. Airlines, Global Distribution Systems (GDSs), and travel agencies may already collect some of it, however. If the information can be shared, then this data collection may be relatively invisible to the traveler and primarily a programming problem for the airlines, although passengers will incur some opportunity costs of their time to provide information and travel agencies and similar entities will incur some costs to collect the data. This scenario is CDC's ''Point of Sale'' (POS) scenario. However, CDC also examined the situation where a wholly separate information collection must be undertaken at departure; this process could add to check-in times and entail gathering information that is already gathered by many travel agencies, generating additional real and opportunity costs for carriers and passengers. This is the ''Point of Departure'' (POD) scenario.

The proposed rule defines a basic set of information to be collected from all passengers. The information includes permanent address, e-mail address, passport information, traveling companions or group, emergency contact information (including at least name of an alternate person or business and a phone number), phone number(s) for the passenger, itinerary, and other flight information. This set of data is greater than the set of information currently collected by the airlines, GDSs, or travel agencies. The incremental costs of collecting, storing, and producing this information on demand in contrast with the no-action base case represent the compliance costs of the proposed rule.

CDC looked at three options for the proposed rule. The first option (Option 1—International Only) would cover international flight arrivals and trips on vessels arriving from non-U.S. locations only. The second option would cover these international flights and vessel trips and would add domestic flights landing in or taking off from large and medium size U.S. airports specified by CDC (Option 2—International plus Large and Medium Hubs) (see Appendix A for this list). The third option would also cover international flights and vessel trips and would add all domestic flights (Option 3—International plus All Domestic). CDC proposes Option 2 for this rulemaking.

CDC compared the estimated costs and monetized benefits associated with the proposed rule (Section I). CDC also examined whether any costs should be considered regarding sanitary measures taken with interstate commerce (Section B).

F. Cost Analysis of Proposed Option and Alternatives

F.1 Profile of Airline and Cruise Ship Industries

Under the proposed rule, costs to industry will be incurred primarily by the airline and cruise ship industries. Additional sectors would also incur some costs to collect additional passenger information. (See the RIA [CDC, 2005] for profile information on these other sectors, which include travel agencies and GDSs.) Compliance costs can be broadly categorized into one-time costs, such as computer reprogramming for each airline or cruise line, and recurring costs that will be incurred for each passenger traveling with that carrier. Foreign carriers incur costs under all three options and are included for projecting the total cost of the proposed rule. However, the financial impact to carriers is projected only for U.S.-owned companies.

Airline Industry

Commercial air carriers are classified according to the size of the aircraft and type of service provided. Airlines operating aircraft with more than 60 seats are classified as large certificated carriers, and further distinguished as major, national, and regional according to annual revenues. Carriers operating aircraft with 60 seats or fewer may be classified as small certificated carriers and commuter airlines. Some commercial air carriers operate under code-sharing partnerships with other, typically major, airlines. Generally, reservations are made with, and flight manifests are generated by, the parent airline, not the codeshare airline (Franz, 2005). We estimate that 23 codeshare airlines fly exclusively under other airlines' codes (RAA, 2005).

Table VI.F–1 presents flight operation and passenger information for air carriers likely to be affected by the proposed rule (BTS 2005a, 2005b, 2005c) under Option 3; that is, passenger-carrying arrivals from foreign countries, as well as interstate and intrastate flights within the U.S. This option covers 217 airlines, carrying 696 million passengers on 10.4 million flights. Option 1 (International Only) covers 184 airlines, 10 percent of Option 3 passengers, and 6 percent of the Option 3 flights, while Option 2 (International Only plus Large and Medium Hubs) covers 217 airlines, 90 percent of the Option 3 passengers, and 77 percent of the Option 3 flights.

TABLE VI.F–1.—FLIGHTS AND PASSENGERS CARRIED BY AIRLINES ON ROUTES AFFECTED BY RULE, REVENUE AND NET INCOME JULY 1, 2003—JUNE 30, 2004

[All potentially affected international and domestic flights]

Airline type	Number	Passengers (millions)		Flights (thousands)		Revenue ($ millions)	Net income ($ millions)
		Total	Average	Total	Average		
Major	13	522.8	40.21	5,898	454	$6,857	$(357)
National	24	113.9	4.75	2,535	106	$512	$19
Large regional	12	5.1	0.43	60	5	$87	$(0.4)
Medium regional	8	2.5	0.31	71	9	$30	$(0.4)
Small/commuter	47	18.9	0.40	1,579	34	$53	NA
Foreign flag	113	32.9	0.29	239	2	NA	NA
Total	217	696.1	NA	10,382	NA	NA	NA

Source: BTS 2005a, 2005b, 2005c. Revenue for 31 small certificated carriers and commuters taken from Dun & Bradstreet or estimated from similar airlines based on average revenue per passenger. Carriers and commuters taken from Dun & Bradstreet or estimated from similar airlines based on average revenue per passenger.

Cruise Ship Industry

The cruise ship industry provides international water transportation to passengers. The well-known portion of this industry comprises large-to-very large firms, best typified by the ''big three'' of the global industry: Carnival, Royal Caribbean, and Star Cruises. A second tier includes smaller cruise lines that serve similar markets and niche markets. A third, much smaller segment comprises small operations that provide shorter-distance international water transportation to passengers traveling from outside the U.S. in regions such as the Great Lakes and the Pacific Northwest, or from Canada and the Caribbean. Finally, there are also lines that own and operate ferries that carry passengers between, for example, Seattle, WA, and Vancouver, B.C., Canada, or between Ohio and Ontario, Canada.

In theory, any vessel could be affected by the rule because ships are inherently mobile. Nevertheless, the general itineraries of the lines as currently posted on Web sites were considered the likeliest indicator of whether they would be affected by the proposed regulation in the near future. Affected cruise lines were identified on the basis that: (1) They serve U.S. ports, and (2) they have itineraries with at least one international destination.

Most of the largest cruise lines are members of the International Council of Cruise Lines (ICCL); of the 16 cruise lines in this category, two are U.S.-owned. The second tier consists of 16 cruise or ferry lines that are not members of ICCL, but are considered large operations under the terms of the small business analysis. One cruise line in this group is U.S.-owned. Small cruise lines and international ferry lines number 25; all of these appear to be U.S.-owned. Table VI.F–2 summarizes relevant data for the cruise line industry and presents limited financial data for U.S.-owned cruise and ferry lines.

TABLE VI.F–2.—AVAILABLE DATA FOR U.S. CRUISE LINES

Number of cruise lines	Foreign or domestic	Total			Average		
		Ships	Passengers	Revenues ($ millions)	Ships per line	Berths per ship	Revenues per line ($ millions)
Large Cruise Lines, ICCL Members							
14	Foreign	112	65,997,060	NA	8	1,733	NA
2	USA	8	2,520,760	$869	4	927	$434.5
Large Cruise Lines, Non-ICCL Members							
15	Foreign	42	3,630,700	NA	2.8	257	NA
1	USA	3	465,120	$49	3	456	$49
Small Cruise and Ferry Lines*							
0	Foreign	0	0	NA	0	0	NA
25	USA	48	1,852,090	$138	3.6	76	$19.7

*Complete data were unavailable for small cruise lines; therefore, revenue data and averages shown are based on 7 of the 25 small lines.

F.2 Incremental Costs to Industry of Data Collection

Data Collection Costs

Under the POS scenario, CDC assumed that legal and logistical barriers to carriers accessing DHS and GDS databases were removed, and therefore they could access information that passengers input directly into a database when they make their reservations. These databases might belong to DHS, the airline or a GDS. Travel agents, however, would need to collect additional information to complete the purchase of tickets. Thus, the only data collection costs to industry under this scenario would be borne by travel agencies. There are, however, opportunity costs to passengers, since passengers must devote time to providing additional information when they make reservations (discussed later in this section).

Under the POD scenario, CDC assumed that airlines would incur the data gathering costs and that the amount of incremental data to be gathered is greater than the amount of incremental data to be gathered under the POS scenario. Unless a passenger is a frequent flier customer, much of the information that travel agencies routinely gather, such as home or business address and telephone number and/or e-mail address, is not collected by the airlines routinely.

CDC based its assumptions for incremental data collection time on industry estimates for and comments on DHS' proposed implementation of Section 231 of the Enhanced Border Security and Visa Reform Act of 2002, and direct industry discussions (FR, 2003; IATA, 2003; Qantas, 2003; Volpe, 2004). Providing an address, for example, is expected to add 45 seconds to information collection time, according to industry estimates. To estimate the cost of data collection by travel agents under the POS scenario, CDC assumed that approximately 30 percent of passengers will book through travel agents, and travel agents need an additional 45 seconds to gather information from passengers to cover the new data needs. Travel agencies already collect much of the information required, but a few pieces of information might not be universally collected. These might include e-mail address, passport information, and emergency contact information. This information was considered equivalent to the amount of information that would need to be gathered for an address. Thus 45 seconds was considered a reasonable estimate under the POS scenario.

Under the POD scenario, CDC assumed that somewhat longer times, such as 1.5 minutes per non-frequent flier passenger, are needed to compile the additional information and to obtain or verify emergency contact information. Additionally, airlines are forecast to hire additional personnel to facilitate information gathering at the time of airport check-in. Such workers would be provided with portable workstations so that information could be gathered while passengers are waiting in line or at the departure gates. These additional workers would be needed to avoid excessive queuing time for passengers.

The incremental costs for gathering information by travel agencies are estimated to be $5.2 million to $53.7 million yearly, depending on option under the POS scenario. Under the POD scenario, these costs will fall on the airlines and cruise lines and will total $65.1 to $316.3 million annually, depending on the option.

Reprogramming Costs

Each of the regulatory options also involves potentially substantial reprogramming by carriers so that a variety of information from several different databases can be linked to information compiled prior to or at departure and saved electronically with the manifest data currently collected by the airlines. Discussions with industry indicate that this reprogramming might cost from $5 million to $15 million per major airline. These reprogramming costs are primarily a function of the need to add data fields and integrate data systems, but are relatively invariant with respect to the number of fields added. Smaller airlines appear to have IT systems that are less complex and more flexible than those of major airlines, so reprogramming costs should be substantially lower (Airline Web Sites, 2005; Delta, 2005; FR, 2003; Pace, 2005; Sun Country, 2005).

CDC assumed major and foreign airlines will each incur reprogramming costs of $10 million. These costs are assumed to decrease with airline size; small certificated/commuter airlines are projected to incur costs of $10,000 each.

Although CDC spoke to airlines about what their anticipated reprogramming costs might be, CDC is requesting additional information and comment from airlines or others who might have information that would assist CDC in further estimating reprogramming costs, particularly costs for smaller airlines and cruise lines. Codeshare airlines will incur zero reprogramming costs because they do not have their own reservation systems. Large cruise lines are assigned a cost of $125,000, based on DHS' proposed implementation of the Enhanced Border Security and Visa Reform Act (FR, 2003). Costs of $10,000 are assigned to small cruise lines and ferries.

In addition to air carriers and cruise lines, under the POS scenario (but not the POD scenario), GDS operators and travel agents will also incur reprogramming costs. Companies that own and operate GDSs will need to modify databases to accept additional fields from Web-based systems and travel agencies. CDC estimated that four major GDS systems dominate the U.S. market, and these companies will incur reprogramming costs on the order of $5 million each. Travel agencies and other tour-booking companies are assumed to incur reprogramming costs of $1,000 per establishment to update their Web links with the GDS. CDC estimates that about 18,000 establishments will incur these costs.

Reprogramming costs are annualized at 7 percent over 10 years. CDC estimates that reprogramming will cost the airlines $105.9 million to $107.5 million on an annualized basis under either scenario. For cruise lines, the estimated costs of reprogramming total $0.6 million (annualized) over all options and scenarios. For travel agencies, GDSs, and similar entities, CDC estimates that reprogramming will cost $5.4 million on an annualized basis over all options, which is added to the totals for reprogramming for airlines and cruise lines under the POS scenario. Total costs for reprogramming under the POS scenario range from $111.9 million to $113.5 million per year, depending on option. Under the POD scenario, because the burden of data collection shifts to airlines, these costs are slightly less—$106.5 million to $108.1 million per year.

Archiving and Other Administrative Costs

Major airlines tend to keep flight manifests in electronic format for only a few days because their intensive flight operations would otherwise result in massive storage requirements (United, 2005; Volpe, 2004). Incremental costs will be incurred for archiving manifest and passenger information in electronic format up to 60 days, as well as administrative costs for submitting data each time CDC requests data and for documenting how they will collect data and submit it to CDC. This includes time to provide passenger lists and data for the 10–12 times per month CDC expects to routinely request this information. It is assumed that, with the software modifications in place, such routine requests will require only a small amount of time to process and submit data. CDC assumed major, national, and foreign airlines would require 5 percent of a full-time-equivalent airline database manager to handle these tasks, declining to 1 percent for small certificated/commuter airlines. For cruise lines, ICCL members are assigned 5 percent, other large lines are assigned 3 percent, and small lines and ferries are assigned 1 percent. The average wage for this occupation is taken to be $44.00 per hour fully loaded (BLS, 2005). CDC assumed archiving will occur on 50-gigabyte tapes, and airlines will need a maximum of 12 tapes over a 3-month period. Because these tapes can be recycled and reused for a number of years, annualized costs of tapes are assumed minimal. Storage space requirements are also considered negligible. CDC estimated annual archiving and administrative tasks (under either scenario) would cost $676,000 to $710,000 for airlines, depending on option, and $140,000 for cruise lines across all options, for a total of $816,000 to $855,000 depending on option. GDSs and travel agencies would not have an equivalent responsibility to provide data to CDC, so no archiving or administrative costs are assumed for these entities.

Opportunity Costs to Passengers

Passengers incur an opportunity cost for the time they use in providing additional information to the carriers or others. Under the POS scenario, passenger time providing information at a minimum equals the time travel agencies require to collect that information (45 seconds). An additional amount of time (15 seconds) is assumed, on average, to allow time for those passengers using the Internet to input additional information into Web pages or for any passengers who must locate certain information, such as emergency contact telephone number or passport number. Thus, on average, all passengers are assumed to need one minute to provide additional information. (This figure has not been discounted to account for families and groups that may be able to provide the data more efficiently.) Under the POD scenario, CDC assumed it takes an average of 1.5 minutes for passengers to provide the required additional information to airlines/cruise lines.

The opportunity cost of passenger time is set at the value of passenger time on air carriers recommended by FAA (FAA–APO, 2003) of $28.60 per hour. This same value is used for cruise line passengers. CDC estimates that the opportunity costs to passengers of providing additional data total $67.6 to $367.3 million annually under the POS scenario and $90.5 million to $439.9 million annually under the POD scenario, depending on option. The opportunity cost to passengers is a non-industry social cost of the rule.

F.3 Projected National Costs of the Proposed Rule

CDC discounted future costs to their present value using the 7 percent discount rate recommended by OMB over 10 years. Costs are annualized so that options with costs occurring in different years can be compared. Tables VI.F–3a and VI.F–3b show the annualized national costs of the three options under the POS and POD scenarios, respectively. The biggest difference in costs among the three options within each scenario is the opportunity cost to passengers. Costs to industry rise only about 42 percent from Option 1 to Option 3 and only 38 percent from Option 1 to Option 2 under the POS scenario. Under the POD scenario, costs to industry more than double from Option 1 to Option 2, and increase slightly more for Option 3. Additionally, costs to the industries directly affected by the rulemaking (the rule does not directly affect GDSs or travel agencies) rise negligibly from one option to the next, with Option 1 costing about $107 million and the other two costing about $109 million annually under the POS scenario. Under the POD scenario, airlines and cruise ship industries incur all compliance costs as they are collecting and compiling all required passenger information.

Under the alternative scenario (Point of Departure Scenario) Option 3 would be associated with costs totaling $425.3 million to industry. Adding the $439.9 million opportunity costs to passengers to the industry costs yields a total for this scenario of $865.2 million per year.

TABLE VI.F–3A.—ESTIMATED ANNUALIZED NATIONAL COSTS FOR THE POINT OF SALE SCENARIO

[$ millions, 2004]

Affected entity	Option 1: International only	Option 2: International plus large and medium hubs	Option 3: International plus all domestic
Airlines	$106.6	$108.2	$108.2
Cruise lines	0.8	0.8	0.8
Travel agencies	7.6	50.5	56.1
GDSs	3.0	3.0	3.0
Total Industry Cost	$117.9	$162.4	$168.0
Opportunity cost to passengers	67.6	332.6	367.3
Total with Opportunity Cost	$185.5	$495.0	$535.3

TABLE VI.F–3B.—ESTIMATED ANNUALIZED NATIONAL COSTS FOR THE POINT OF DEPARTURE SCENARIO

[$ millions, 2004]

Affected entity	Option 1: International only	Option 2: International plus large and medium hubs	Option 3: International plus all domestic
Airlines	$133.4	$356.4	$386.3
Cruise lines	39.0	39.0	39.0
Travel agencies	0	0	0
GDSs	0	0	0
Total Industry Cost	$172.4	$395.4	$425.3
Opportunity cost to passengers	90.5	398.4	439.9
Total with Opportunity Cost	$262.9	$793.8	$865.2

G. Impacts on Industry

Impacts on industry, including airlines, cruise lines, travel agencies, and GDSs, were measured using a comparison of annualized costs per firm to each firm's revenues, if available. Impacts were identified where the annualized costs exceeded 1 percent of revenues and/or where the annualized costs exceeded the net income of a firm (airlines only). For airlines, we used a second test, comparing annualized costs to net income (similar baseline net income figures are not available for the other entities). Impacts were identified where annualized compliance costs exceeded net income, where net income was currently positive.

Under the Point of Sale scenario, CDC determined that no airlines, cruise lines, GDSs, or travel agencies, would experience annualized costs in excess of 1 percent of revenues under any of the options analyzed. For those airlines for which net income is available and positive, CDC estimates one airline would incur compliance costs exceeding net income.

Under the Point of Departure scenario, CDC estimates that one airline would incur annualized compliance costs greater than 1 percent of revenues under Option 1, and two airlines would exceed the 1 percent level under Option 2. Four airlines are expected to incur costs exceeding 1 percent of revenues under Option 3. Furthermore, one airline would incur annualized compliance costs exceeding its baseline net income under all three options. There is no change to the impact results among the other affected entities.

H. Benefits

As discussed above, the benefits of the proposed regulation are associated with the faster suppression of infectious disease outbreaks spread via travel. More efficient traceback of infectious individuals can lead to more complete and effective prophylaxis and quarantine. The reduction of the frequency and scale of outbreaks should result in a commensurate reduction in the opportunity costs of outbreak-related public health efforts to Federal, State, and local governments.

In addition to the avoided illnesses and deaths from the proposed rule, more effective control of an outbreak will reduce the economic impact of infectious disease outbreaks. The SARS outbreak is estimated to have reduced incomes in East and Southeast Asia by $12.3 billion to 28.4 billion (Fan, 2003). Such regional impact measurements overstate the global impact of disease outbreaks because they generally do not take into account the redirection of investment, travel, and purchasing from affected areas to unaffected areas. The global impact would be the net loss of consumer and producer surpluses (*e.g.*, how much travelers might have preferred to travel to China instead of other destinations) due to the outbreak-caused adjustments in economic activity. Nevertheless, the affected nation does experience a loss. For example, if an outbreak of disease in the U.S. similar to the SARS outbreak in Toronto occurred, it could have a large negative effect on the U.S. economy through impacts such as those on the travel and tourism industries, even though the net impact, measured globally, might not be significant. Because forecasting such impacts for the U.S. economy is so speculative and unique to specific outbreaks, these types of benefits from net reductions in economic impacts are not estimated.

Other potentially sizeable benefits that could not be quantified include reductions in stress on health care systems due to disease outbreaks, reductions in cases of common illnesses, such as measles, through an ability to rapidly contact passengers who might have been exposed, and reductions in anxiety among those who do not become ill that are associated with fears of contracting an illness during an outbreak.

The most direct effect of the CDC rule changes is improved contact tracing leading to better health outcomes when an outbreak threatens. In epidemiological models, the speed of response is often more important than the specific action taken (Barrett *et al.*, 2005; Lipsitch, 2003). Whether the chosen action is vaccination, quarantine, and/or isolation, early implementation lowers the illness and death toll. Thus one way to quantify benefits is to compare a base case in which intervention proceeds using existing tools with alternatives in which intervention can proceed more rapidly. (The more rapid intervention is made possible because passenger information that includes contact information is readily available.) The benefits of the alternative are measured in terms of the number of prevented deaths and illnesses.

To estimate the effect of faster contact tracing, CDC applied a Susceptible-Exposed-Infectious-Recovered (SEIR) epidemiological model that includes the effects of vaccination, quarantine, isolation, and asymptomatic carriers. The model forecasts the number of deaths, illness days, isolation days, and quarantine days given parameters that characterize the illness and the public health intervention. Each outcome measure is monetized by the public's willingness to pay (WTP) to avoid death and illness.

The risks of illness and death from an infectious disease are similar to risks from some environmental hazards in that they are involuntary, pervasive, and random. Thus, we updated values from the Environmental Protection Agency's evaluation of the benefits of the Clean Air Act (Kochi, *et al.*, 2003) to 2004 dollars as a measure of WTP for changes in the risk of death or value of a statistical life (VSL). We applied this $6.9 million to the number of deaths the SEIR model forecast would be avoided by faster government action. Johnson *et al.* (1997) found a WTP to avoid a day of severe cough was $56 (updated to 2004 with CPI). In addition, the WTP for workdays lost to illness and recovery is measured as wages lost. CDC valued these losses using the median usual weekly earnings of full-time wage and salary workers, $128 per day (BLS, 2005). Lost earnings are an element of WTP that was not captured by Johnson *et al.* (1997) so it is appropriate to add the two components together.

The parameters of the model were selected to simulate the first 200 days of a SARS-like disease spreading in a large city. In the base case intended to represent current practice, intervention began in the sixth week after introduction, isolated 40 percent of infectious patients, and quarantined 30 percent of contacts. To model the three options, ERG assumes interventions begin in the fifth week, 70 percent of infectious patients are isolated, and 60 percent of contacts are quarantined. Table VI.H–1 shows the improvement in outcomes with earlier public health intervention.

TABLE VI.H–1.—OUTCOMES IN BASE CASE AND EARLY INTERVENTION

Outcome	Base case	Earlier intervention	Difference
Deaths	900	37	863
Illness days	18,075	670	17,405
Isolation days	23,753	1,000	22,753
Recovery days	14,460	536	13,924
Quarantine days	127,967	5,013	122,954

Table VI.H–2 shows the WTP values for the deaths and days of incapacity avoided in a single outbreak by implementing each option. However, the rule will presumably be in place for many years and be effective in many situations. In order to show the long run benefits of the rule, it is necessary to forecast the frequency and scale of epidemic events. CDC assumed that epidemics on the scale of the modeled outbreak would occur once every 5 years over the 10-year planning horizon. Table VI.H–2 shows the WTP in current dollars as well as the 10-year annualized discounted values at three and seven percent.

TABLE VI.H–2.—ESTIMATED WILLINGNESS TO PAY FOR CHANGE IN OUTCOMES

[Million, 2004 dollars]

Outcome	Option 1: International only	Option 2: International plus medium and large hubs	Option 3: International plus all domestic
Deaths Avoided	$4,999.7	$5,901.9	$5,956.1
Other Outcomes Avoided:			
Illness days	2.7	3.2	3.2
Isolation days	3.5	4.2	4.2
Recovery days	1.4	1.7	1.7
Quarantine days	13.2	15.6	15.7
Total	$5,020.6	$5,926.5	$5,980.9
Annualized Benefits			
7 percent discount rate	$1,069.5	$1,262.5	$1,274.1
3 percent discount rate	$1,033.3	$1,219.8	$1,231.0

The effect of the earlier intervention reducing the number of deaths from 900 to 37 is remarkable but not inconceivable; compare the 43 SARS deaths in Canada where preparations were made and there were effective public health measures with the 299 SARS deaths in Hong Kong. A Monte Carlo simulation demonstrated that the set of parameters used in the analysis yielded a benefit estimate at the 42nd percentile of a range of possible parameter choices. While some alternative assumptions could result in considerably smaller benefits estimates, many other alternative assumptions could result in much larger estimates. Although we cannot know the appropriate assumptions to model the epidemics that will be encountered in the future, it is not difficult to imagine outbreaks whose control would exceed this level of benefits. We invite comments on the benefits model, which is described in detail in the RIA (CDC, 2005).

I. Comparison of Costs and Benefits

The primary cost impact of the proposed rule is the collection and maintenance of crew and passenger data. The economic analysis focused primarily on air and water carriers, and secondarily, under the POS scenario, on GDSs and travel agencies, all of which are likely to modify computer systems and collect passenger information in order to come into compliance or meet airline/cruise line requirements. Some data sought by CDC is already or soon may be collected by other government agencies (*e.g.,* the Transportation Security Administration's Advanced Passenger Information System or APIS). For the purposes of the analysis, it is assumed CDC will not gain access to this data and will have to collect the data itself, either directly at departure (POD scenario) or indirectly, through cooperation with travel agencies and GDSs (POS scenario). For more discussion of the potential for data collection overlap, see the RIA (CDC, 2005). Potential costs savings may result should CDC gain access to APIS data. However, it is not possible to estimate those savings at this time due to multiple uncertainties. These uncertainties include the extent to which CDC would have access to such data and the list of data elements that is consistently collected under APIS.

Tables VI.I–1a and VI.I–1b summarize the estimated annualized costs and benefits associated with the proposed rule under the POS and POD scenarios, respectively. Table VI.I–1c presents these same results assuming the actual costs are at the midpoint between the two bounding scenarios. The benefits of the rule are measured in terms of the number of deaths and illnesses prevented by rapid intervention. The costs and benefits of the rule are considered over a 10-year period. As the table shows, under all options, the benefits substantially outweigh the costs under either scenario and assuming actual costs are the midpoint of costs under the two scenarios.

TABLE VI.I–1A.—ANNUALIZED DISCOUNTED VALUE OF COSTS AND BENEFITS OF THE POS SCENARIO OVER A 10-YEAR PLANNING PERIOD

Parameter	Option 1: International only		Option 2: International plus medium and large hubs		Option 3: International plus all domestic	
	Total cost and benefit	Incremental net benefit	Total cost and benefit	Incremental net benefit	Total cost and benefit	Incremental net benefit
At 7 percent discount rate:						
Costs	$185.5		$495.0		$535.3	
Benefits	1,070		1,263		1,274	
Net Benefit	884.5		768.0	($116.5)	738.7	($29.3)
At 3 percent discount rate:						
Costs	$165.7		$475.0		$515.3	
Benefits	1,033		1,220		1,231	
Net Benefit	867.3		745.0	($122.3)	715.7	($29.3)

TABLE VI.I–1B.—ANNUALIZED DISCOUNTED VALUE OF COSTS AND BENEFITS OF THE POD SCENARIO OVER A 10-YEAR PLANNING PERIOD

Parameter	Option 1: International only		Option 2: International plus medium and large hubs		Option 3: International plus all domestic	
	Total cost and benefit	Incremental net benefit	Total cost and benefit	Incremental net benefit	Total cost and benefit	Incremental net benefit
At 7 percent discount rate:						
Costs	$262.9		$793.8		$865.2	
Benefits	1,070		1,263		1,274	
Net Benefit	807.1		469.2	($337.9)	408.8	($60.4)
At 3 percent discount rate:						
Costs	$244.1		$774.7		846.1	
Benefits	1,033		1,220		1,231	
Net Benefit	788.9		445.3	($343.6)	384.9	($60.4)

TABLE VI.I–1C.—ANNUALIZED DISCOUNTED VALUE OF COSTS AND BENEFITS OF THE MIDPOINT BETWEEN THE POS AND POD SCENARIO OVER A 10-YEAR PLANNING PERIOD

Parameter	Option 1: International only		Option 2: International plus medium and large hubs		Option 3: International plus all domestic	
	Total cost and benefit	Incremental net benefit	Total cost and benefit	Incremental net benefit	Total cost and benefit	Incremental net benefit
At 7 percent discount rate:						
Costs	$224.2		$644.4		$700.3	
Benefits	1,070		1,263		1,274	
Net Benefit	845.8		618.6	($227.2)	573.7	($44.9)
At 3 percent discount rate:						
Costs	204.9		$624.9		$680.7	
Benefits	1,033		1,220		1,231	
Net Benefit	828.1		595.1	($233.0)	550.3	($44.8)

As a second analysis, the cost effectiveness of the options was considered. In order to include both mortality and morbidity effects in a single metric for cost effectiveness analysis, these measures were converted to Quality Adjusted Life-Years (QALYs). (See the RIA for more information on how QALYs are calculated.)

The QALY losses avoided by implementation of the proposed rule annualized at 7 percent are presented in Tables VI.I–2a (POS scenario),VI.I–2b (POD scenario), and VI.I–2c (midpoint). As with the dollar denominated benefit estimates, the number of deaths avoided is the largest component of benefits. Costs per QALY for Options 1 and 2 are less than $300,000 under the higher-cost POD scenario.

In the cost-effectiveness analysis, the options are ranked in order of ascending numbers of QALYs. The average cost effectiveness of the options is calculated as the cost of each option divided by the number of QALYs associated with each option ($/QALY). To calculate the incremental cost-effectiveness of each option, each option's costs and QALYs are first calculated as the incremental cost and incremental number of QALYs going from that option to the next higher option. The incremental cost is then divided by the incremental number of QALYs. This method is also used for Option 1, which is incremental to the no-action alternative (not explicitly shown). The no-action alternative has zero cost and zero QALYs.

As Tables VI.I–2a and VI.I–2b show, after Option 1 (international flights and cruise lines only) under either scenario, costs rise quickly. Option 2 (international plus large and medium hubs) is associated with a slightly lower average cost effectiveness value compared to Option 3 (international plus all domestic), but a significantly lower incremental cost effectiveness value compared to Option 3 under either scenario.

TABLE VI.I–2A.—AVERAGE AND INCREMENTAL COST EFFECTIVENESS OF THE OPTIONS UNDER THE POS SCENARIO

[Ranked by number of QALYs]
[7 percent discount rate]

Option	Annualized cost ($ millions)	QALYs	Incremental cost ($ millions)	Incremental QALYs	Average cost effectiveness ($/QALY)	Incremental cost effectiveness ($/QALY)
Option 1	$185.5	2,257	$185.5	2,257	$82,189	$82,189
Option 2	495.0	2,665	309.5	408	185,752	758,652
Option 3	535.3	2,689	40.3	24	199,074	1,678,333

TABLE VI.I–2B.—AVERAGE AND INCREMENTAL COST EFFECTIVENESS OF THE OPTIONS UNDER THE POD SCENARIO

[Ranked by number of QALYs]
[7 percent discount rate]

Option	Annualized cost ($ millions)	QALYs	Incremental cost ($ millions)	Incremental QALYs	Average cost effectiveness ($/QALY)	Incremental cost effectiveness ($/QALY)
Option 1	$262.9	2,257	$262.9	2,257	$116,478	$116,478
Option 2	793.8	2,665	530.9	408	297,865	1,301,275
Option 3	865.2	2,689	71.4	24	321,752	2,974,167

TABLE VI.I–2B.—AVERAGE AND INCREMENTAL COST EFFECTIVENESS OF THE OPTIONS AT THE MIDPOINT OF COSTS BETWEEN THE POS AND POD SCENARIO

[Ranked by number of QALYs]
[7 percent discount rate]

Option	Annualized cost ($ millions)	QALYs	Incremental cost ($ millions)	Incremental QALYs	Average cost effectiveness ($/QALY)	Incremental cost effectiveness ($/QALY)
Option 1	$224.2	2,257	$224.2	2,257	$99,333	$99,333
Option 2	644.4	2,665	420.2	408	241,809	1,029,963
Option 3	700.3	2,689	55.8	24	260,413	2,326,250

In a third analysis of costs and benefits, a breakeven analysis was performed. In a breakeven analysis, the number of years between outbreaks that would need to occur for benefits to equal costs is calculated. The benefits of one outbreak were discounted as if the outbreak would occur five years in the future and annualized to be comparable to annualized costs. Dividing annualized costs by annualized benefits indicates the number of outbreaks that would need to occur during the planning period for benefits to equal costs. Dividing the planning period, 10 years, by this number shows the expected period of time between outbreaks. If this period is longer than the expected recurrence of serious outbreaks, then the expected benefits outweigh the expected costs.

Table VI.I–3 shows these results for the three options considered under the POS and POD scenarios, as well as under a midpoint cost assumption. Whether or not one believes that there will be two outbreaks of this magnitude in the next 10 years, it may be reasonable to expect that there may be one such outbreak in 9 to 27 years, as represented for the midpoint cost assumption.

TABLE VI.I–3.—COSTS IN TERMS OF THE NUMBER AND FREQUENCY OF OUTBREAKS

	Annualized costs ($ millions, 2004)	Number of outbreaks in 10 years for benefits to equal costs	Frequency of outbreaks to equal costs (years)
POS Scenario:			
Option 1	$185.5	0.31	32.7
Option 2	495.0	0.82	12.3
Option 3	535.3	0.88	11.3
Mid-Point:			
Option 1	224.2	0.37	27.1
Option 2	644.4	1.06	9.4
Option 3	700.3	1.15	8.7
POD Scenario:			
Option 1	262.9	0.43	23.1
Option 2	793.8	1.35	7.7
Option 3	865.2	1.43	7.1

J. Regulatory Flexibility Analysis

CDC considered the proposed regulation's effects on small entities, as required by the Regulatory Flexibility Act (RFA; 5 U.S.C. *et seq.*; Pub. L. 96–354) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA; Pub. L. 104–121). The RFA establishes, as a principle of regulation, that agencies should tailor regulatory and informational requirements to the size of entities, consistent with the objectives of a particular regulation and applicable statutes. The agency has prepared an Initial Regulatory Flexibility Analysis (IRFA). This analysis suggests that this rule will not have a significant effect on a substantial number of small businesses, small organizations, or small governmental jurisdictions. However, CDC is asking for comment on the costs and impacts of the rule on small entities. As required by the RFA, in the final rule, CDC will provide the public comments it received in response to the proposal, prepare a Final Regulatory Flexibility Analysis (FRFA) and make a determination whether a certification of no significant impact on a substantial number of small entities is appropriate.

The Small Business Administration defines small airlines as those with fewer than 1,500 employees and small water carriers as those with fewer than 500 employees. Department of Transportation (DOT) data indicates that there are 43 airlines (NAICS 481111) with fewer than 1,500 employees (BTS, 2005a and 2005b). Employment is not reported for an additional 32 airlines and another 19 airlines have no financial data whatsoever. We assume that all 32 with no employment data are small, there are 75 small airlines that might be affected by the proposed rule. International ownership links complicate estimation of the number of small cruise lines (NAICS 438112). When ferry and charter boat companies operating in the Great Lakes, Gulf of Mexico, Pacific Northwest, or Florida with foreign port itineraries are considered, we estimate that there are approximately 20 small firms in the cruise industry subject to the regulation.

GDSs and travel agencies might also be affected by the proposed regulation under the POS scenario. Census Bureau data indicate there are 21,679 small travel agency (NAICS 561510) establishments in the U.S. (Census, 2004). Larger travel companies own 4,559 of these establishments, so we estimate that the remaining 17,120 are small firms. Using similar reasoning, we estimate there are 703 small other reservation booking firms (not listed as travel agencies) in the U.S. All GDSs are considered large.

CDC, as discussed earlier, considered three options under two scenarios. The first option requires information to be collected from passengers only for those arriving on international flights and cruise lines with international to domestic itineraries. Option 2 adds domestic flights from medium and large airports to Option 1, and Option 3 adds all domestic flights to Option 1. The two scenarios are the Point of Sale scenario, under which CDC assumes that the airlines will be able to gain access to data collected by travel agencies and GDSs and will not have to collect data from passengers at the point of departure. In the second scenario, CDC assumes that the logistical and legal barriers to this information sharing are such that all information would need to be collected by the airlines at the point of departure (the Point of Departure scenario).

CDC did consider Option 1, which represents an option for minimizing the number of affected small firms and their associated costs (since it covers fewer flights and passengers). Small firms are less likely to provide international flights than large firms. CDC did not select this option because CDC believes that Option 2 provides better protection of human health with only slightly greater potential impacts (and only under the POD scenario). Although CDC could have considered an option in which some or all airlines and cruise lines considered small by Small Business Administration Standards were exempted from providing data, CDC did not believe that this approach would adequately protect human health. Although the airlines defined as small carry only 5–10 percent of passengers (depending on option), this represents as many as 35 million passengers annually and as many as 22 percent of flights. Furthermore, the nature of the airline industry is such that some of the smaller airlines, which comprise a major portion of the codeshare airlines, would avoid some of the major costs of the proposed rule. The codeshare airlines do not have their own reservation systems. These are managed by their larger airline partners. A significant cost of the proposed rule entails the reprogramming of the reservation system software. CDC does not believe any codeshare airline will share in any of these costs, since the larger airlines are very dependent on the codeshare airlines to fill the gaps in their itinerary offerings.

CDC applied a revenue test to assess the impact of added costs on small businesses. Under the POS scenario, costs are less than 1 percent of revenues for all affected airlines and cruise lines under Option 2. Even among the small travel agencies, costs are less than one-half of one percent of small travel agencies' average revenues. These small businesses are estimated to incur costs of less than $700 per year per firm under Option 3.

Under the Point of Departure scenario, Option 2, CDC estimates that two small airlines out of 91 small airlines and cruise lines analyzed might incur annualized compliance costs in excess of one percent of revenues, should the carriers themselves need to collect all of the passenger information required prior to passenger boarding.

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VII. Other Administrative Requirements

A. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13045 requires HHS to determine whether the proposed rule is economically significant. The Executive Order further requires HHS to determine whether the proposed rule would create an environmental health or safety risk disproportionately affecting children. HHS has determined that this proposed rule of general applicability is consistent with the principles set forth in the Executive Order.

B. Paperwork Reduction Act of 1995

The Centers for Disease Control and Prevention has determined that this notice of proposed rulemaking contains 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 provisions is given below with an estimate of the annual reporting 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 (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of the publication of this notice. Please send written comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS D–74, Atlanta, GA 30333.

Proposed Project: Control of Communicable Diseases; Interstate and Foreign Quarantine—Revision—Division of Global Migration and Quarantine (DGMQ), National Center for Infectious Diseases (NCID), Centers for Disease Control and Prevention.

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 or from one State or possession into another. Legislation and existing regulations governing interstate and foreign 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 rodent inspections and the cruise ship sanitation program, inspections are performed only on those vessels and aircraft which report illness prior to arrival or when illness is discovered upon arrival. Other inspection agencies assist quarantine officers in public health screening of persons, pets, and other importations of public health importance and make referrals to PHS when indicated. 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, CDC maintains clearance to collect certain information and impose recordkeeping requirements related to quarantine responsibilities under two separate OMB control numbers: 0920–0488 for 42 CFR Part 70 Interstate quarantine and 0920–0134 Foreign Quarantine. CDC proposes to revise reporting and recordkeeping requirements under the current OMB control numbers for sections in the rule that have been modified or retained. Additionally, CDC proposes to add new sections containing reporting and recordkeeping requirements for interstate and foreign quarantine to the existing 0920–0488 and 0920–0134, respectively.

Interstate Quarantine

Under OMB control number 0920–0488, the following section will be modified: 70.6 Travel permits. CDC proposes to add the following sections: 70.2 Report of death or illness on board flights; 70.3 Written plan for reporting of deaths or illness on board flights and designation of an airline agent; 70.4 Passenger information; 70.5 Written plan for passenger information and designation of an airline agent; and, 70.19 Medical examination and monitoring.

Control of disease transmission within the United States is largely considered to be the province of state and local health authorities, with federal assistance being sought by those authorities on a cooperative basis, without application of federal regulations. Interstate quarantine regulations administered by CDC were developed to facilitate federal action in the event of large outbreaks requiring a coordinated effort involving several states, or in the event of inadequate local control. While it is not known whether, or to what extent, situations may arise in which these regulations would be invoked, contingency planning for domestic emergency preparedness is not uncommon. Should a domestic emergency occur, the reporting and record keeping requirements contained in the regulations will be used by CDC to carry out quarantine responsibilities as required by law, specifically, to prevent the spread of communicable diseases from one state or possession into any other state or possession. The information would only be collected when it is required, and is the minimum necessary to meet statutory obligations. CDC uses one form to collect essential information in the following sections:

42 CFR 70.3: All communicable diseases.

42 CFR 70.4: Report of disease.

42 CFR 70.5: Certain communicable diseases; special requirements.

CDC's proposed rule cancels § 70.3 and modifies 70.4 and 70.5 into a new section 70.6. The current permit form will be modified to reflect that the application is now made only to the Director as set forth in 70.6(c)(2).

In addition to 70.6, CDC proposes adding reporting requirements at the following sections:

70.2 Report of death or illness on board flights. This requirement, currently only in the foreign quarantine regulations, now extends to airlines operating flights in interstate traffic in this proposed rule.

70.3 Written plan for reporting of deaths or illness on board flights and designation of an airline agent. The first year in which the plan is required after the final rule takes effect imposes the largest burden. However, the time to assemble the initial plan is expected to be minimal as airlines are already required to have these procedures in place under the current regulation. In subsequent years, airlines are required to annually review the plan and make revisions as necessary. Airlines are also required to conduct drills or exercises to annually test and evaluate the effectiveness of the plan. Any revisions as a result of the annual review or the drills or exercises must be submitted to the Director.

70.4 Passenger information. This is a new requirement for any airline operating flights in interstate traffic to collect certain information, including name and best contact information, from passengers arriving in or departing from any of the airports listed in Appendix A. This information will be used to notify passengers in case of exposure to a communicable disease. CDC recognizes that other federal agencies—in particular the Department of Homeland Security—currently collects some of the information that CDC is requesting in the proposed rule. To that end, CDC and DHS are exploring options to reduce the potential burden of dual reporting.

70.5 Written plan for passenger information and designation of an airline agent. The burden for this section is greatest in the first year. In subsequent years, airlines are required to annually review the plan and make revisions as necessary. Airlines are also required to conduct drills or exercises to annually test and evaluate the effectiveness of the plan. Any revisions as a result of the annual review or the drills or exercises must be submitted to the Director.

70.19(b) Medical examination and monitoring. Persons believed to be in the qualifying stage of a quarantinable disease may be asked to provide the Director with information related to familial and social contacts, travel itinerary, medical history, place of work, and vaccination status.

Foreign Quarantine

Under OMB control number 0920–0134, the following sections will be modified: 71.6 and 71.8. These reporting requirements currently fall under 71.21.

New reporting and recordkeeping requirements proposed to be added to 0920–0134 include: 71.7 Written plan for reporting of deaths or illness on board ships and designation of an airline agent; 71.9 Written plan for reporting of deaths or illness on board ships and designation of a shipline agent; 71.10 Passenger information; 71.11 Written plan for passenger information and designation of an airline or shipline agent; and, 71.22 Medical examination and monitoring.

Currently, 42 CFR Part 71 comprises the following citations that require reporting or recordkeeping:

42 CFR 71.21 Radio 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(b)(3) and (d) Requirements for admission of dogs and cats.

42 CFR 71.52(d) Application for permits to import turtles.

42 CFR 71.53(d) and (e) Requirements for registered importers of nonhuman primates.

The proposed rule modifies these recordkeeping and reporting requirements as follows:

71.6 Reports of death or illness on board flights and 71.8 Report of death or illness on board ships. These requirements clarify the current section 71.21 Radio report of death and illness.

71.7 Written plan for reporting of deaths or illness on board flights and designation of an airline agent and 71.9 Written plan for reporting of deaths or illness on board ships and designation of a shipline's agent. These requirements are comparable to requirements in Sections 70.3.

71.10 Passenger information. This requirement applies to any airline operating flights or shipline operating ships on an international voyage destined for a U.S. port and contains reporting requirements comparable to 70.4.

71.11 Written plan for passenger information and designation of an airline or shipline agent. This requirement is comparable to requirements found in 70.5.

71.22 Medical examination and monitoring. This section contains reporting requirements comparable to 70.19.

The reporting and recordkeeping requirements in § 71.51, 71.52, and 71.53 do not change in this proposed rule.

Description of Respondents: Respondents may include airplane pilots, ships' captains, travelers, state health departments, territorial health departments, and airline industry personnel. The nature of the quarantine response would dictate which forms are completed by whom.

TABLE VII. B.1.—ESTIMATED ANNUAL REPORTING BURDEN

CFR Section	Number of respondents	Annual frequency per response	Total number of responses	Hours per response (in minutes)	Total hours
42 CFR 70.2	1,549	1	1,549	2/60	52
42 CFR 70.3 and 42 CFR 71.7 (first year)	217	1	217	60/60	217
42 CFR 70.3 and 42 CFR 71.7 (subsequent years)	217	1	217	10/60	36
42 CFR 70.4	278,400,000	1	278,400,000	1/60	5,568,000
42 CFR 70.5 and 42 CFR 71.11	274	1	274	600/60	2,740
42 CFR 70.6	2,000	1	2,000	15/60	500
42 CFR 70.19	18	1	18	30/60	9
42 CFR 71.6	1,549	1	1,549	2/60	52
42 CFR 71.8	57	54	3,135	5/60	261
42 CFR 71.9	57	1	57	180/60	171
42 CFR 71.10	142,213,640	1	142,213,640	1/60	2,844,273
42 CFR 71.22	18	1	18	30/60	9
Total					8,416,320

Our estimates are based on experience to date with current recordkeeping and reporting requirements of 42 CFR Parts 70 and 71. In addition, the estimate for proposed new reporting requirements at 70.4 Passenger Information is based on statistics from the Bureau of Transportation Statistics showing passengers carried by airlines affected by the rule for the period July 1, 2003–June 30, 2004. The number of passengers on domestic flights for this period was estimated to be 556.8 million; this number was reduced by 50% based on quarterly calculations from mid 2003 to mid 2004, which consistently showed that about 54% of domestic flights contained trip segments of 1.85 on average (i.e., an adjustment was made for the fact that about half of all domestic travel includes one or more connecting flights). Estimates for reporting requirements at 71.10 Passenger information were also obtained from the Bureau of Transportation Statistics (for international airline passengers) and from available data for U.S. cruise lines. An estimated 142,213,640 passengers on airlines and shiplines will report information under 71.10.

A detailed analysis of the costs to the airline and shipline industries for the reporting and recordkeeping requirements of this propose rule, including the opportunity costs to passengers providing this information, can be found under Part VI of this NPRM.

C. Environmental Assessment

The Director has determined that provisions amending 42 CFR Parts 70 and 71 will not have a significant impact on the human environment.

D. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (published at 65 FR 67249 on November 9, 2000), requires agencies to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' The phrase ''policies that have tribal implications'' is defined in the Executive Order to include regulations and other policy statements or actions that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.''

This proposed rule will have a substantial direct effect as defined by the Executive Order requiring consultation with Tribal representatives and an analysis of Tribal impacts.

Current federal law (42 U.S.C. 243, 264) gives the Secretary of Health and Human Services (HHS) the authority to implement disease control measures in situations that could impact interstate commerce, including quarantine of persons suspected of carrying certain communicable diseases who are (1) traveling from one state to another or (2) likely to infect others traveling from one state to another. The Secretary has delegated this statutory authority to the Director. Under current law (25 U.S.C. 198, 231, 2001), the Secretary, acting through the IHS Director, also has the authority to implement disease control measures, such as quarantine, in Indian country, if necessary. There are currently no federal regulations that implement the IHS Director's statutory authority to quarantine persons with communicable diseases.

The federal regulations that implement CDC's statutory authorities for communicable disease control are in the Code of Federal Regulations, 42 CFR Parts 70 and 71. These regulations implement CDC's existing statutory authority to detain and/or quarantine persons suspected of carrying certain communicable diseases that pose a threat to the public's health. CDC's authority to quarantine persons extends only to the communicable diseases listed in an Executive Order of the President, including cholera, diphtheria, tuberculosis, plague, smallpox, yellow fever, viral hemorrhagic fevers, SARS, and influenza caused by novel or reemergent influenza viruses that are causing, or have the potential to cause, a pandemic.

Under proposed section 70.24, Tribal health authorities will be able to ask the Director for assistance to prevent the spread of communicable diseases from State to State. Under proposed section 70.25, the Director may determine that the measures taken by a Tribe are inadequate to prevent the spread of communicable diseases. Under the proposed section 70.27, the Director, with the concurrence of the of the IHS Director and after consulting with the affected Tribe, may impose provisional quarantine under 70.14–70.15, quarantine under 70.16–70.18, 70.20 and medical examination and monitoring under 70.19 in Indian country. The Director may act under this section without making a finding that the person or group of persons is moving or about to move from a State to another State or is a probable source of infection to persons who will be moving from a State to another State.

Furthermore, under Section 70.27, subsection (d), the Director, with the concurrence of the Director of the Indian Health Service and after consulting with the affected Tribe or Tribes may authorize agents and employees of any State government to enter Indian country for the sole purpose of enforcing federal quarantine rules and regulations. This authority is subject to any rules or regulations the Director of the Indian Health Service may choose to promulgate under 25 U.S.C. 231. This section is intended to implement provisions appearing in 25 U.S.C. 198 and 231, 25 U.S.C. 1661, and 42 U.S.C. 2001.

Pursuant to 25 U.S.C. 198, the Secretary of the Interior may quarantine Native Americans on Tribal lands for ''tuberculosis, trachoma, or other contagious or infectious disease.'' Under 25 U.S.C. 231, the Secretary of the Interior may also permit State agents and employees to enter upon Tribal lands for purposes of making inspection of health and educational conditions and enforcing sanitation and quarantine regulations. All Indian health programs and functions were transferred from the Secretary of the Interior to the Secretary of HHS by 42 U.S.C. 2001, and delegated to the Director of IHS by 25 U.S.C. 1661. The authority found in 25 U.S.C. 198 and 231 supplements the Director's authority under section 361 of the PHS Act (42 U.S.C. 264). Any action the Director takes under these sections must be in concurrence with the Director of the Indian Health Service after consultation with the affected Tribe or Tribes. CDC's Division of Global Migration and Quarantine has technical expertise in quarantine. Such cooperation between the Indian Health Service and the CDC would potentially streamline operations and clarify procedures regarding quarantine on Tribal lands.

Furthermore Indian Tribes, like States, are sovereign entities with police power authority to enact their own quarantine rules and regulations. Thus, Tribal governments are able to enforce any Tribal quarantine law to the extent that such laws exist. The proposed rule would not preempt the enactment of Tribal quarantine rules and regulations, to the extent that such Tribal laws do not conflict with the exercise of federal quarantine law under the proposed rule.

Tribal participation in and support of planned revisions of regulations governing the control of communicable diseases is critical. HHS Tribal Consultation Policy calls for a tribal impact statement and appropriate consultation with tribal representatives prior to promulgation of a regulation. This consultation process began during the FY 2005 HHS Regional Tribal Consultation Sessions and the HHS National Tribal Budget Consultations, prior to the publication of this NPRM. In order to ensure that all Tribes are provided every opportunity to participate in and comment on planned revisions of current quarantine regulations, CDC is also soliciting written comments in the form of a Dear Tribal Leader letter being sent to all Tribal leaders. The preamble for the final regulation resulting from this rulemaking process will contain the tribal summary impact statement required by the Executive Order.

E. Executive Order 12630: Governmental Actions and Interference With Constitutionally Protected Property Rights

Under Executive Order 12630, if the contemplated rule would require a Federal taking of private property, then a takings analysis is required. The agency must address the merits of the rule and the implications for constitutionally protected property rights.

The Fifth Amendment to the United States Constitution prohibits the taking of private property for public use without just compensation. Though courts may find that a per se taking has occurred due to government action requiring a property owner to sacrifice ''all economically beneficial use'' of the property *see Lucas* v. *South Carolina Coastal Council,* 505 U.S. 1003 (1992), the takings analysis generally used by courts is set forth in *Penn Central Transportation Co.* v. *New York City,* 438 U.S. 104 (1978). The *Penn Central* analysis focuses on the character of the government action and the economic impact on the property owner, particularly regarding the extent to which the regulatory action at issue interferes with the owner's distinct investment-backed expectations. Also, though the *Lucas* per se approach is not generally used by courts in analyzing takings cases, it is important to note that the decision in that case also stands for the proposition that a taking will be held not to have occurred if the affected property constitutes a nuisance.

Goldblatt v. *Hempstead,* 369 U.S. 590 (1962) was cited by the *Penn Central* court as illustrative of the burdens that may be imposed upon a property owner in the face of regulatory action designed to serve a substantial public purpose. That case involved a city safety ordinance enacted to prohibit excavation below the water table. That prohibition effectively barred the property owner from further operation of a sand and gravel business that had been in existence for over 30 years. Because the restriction served a substantial public purpose, the court held that no taking had occurred. *See also, North American Cold Storage Co.* v. *City of Chicago,* 211 U.S. 306 (1908) holding that a statute authorizing seizure and destruction of food unfit for human consumption was constitutional despite the lack of notice and opportunity to be heard).

Section 361(a) of the PHS Act (42 U.S.C. 264(a)) provides that in carrying out regulations the Secretary ''may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary.'' This authority was carried out in the preexisting rule in § 71.32(b), which authorized the Director to require the application of a variety of measures (detention, disinfection, disinfestations, fumigation, and other related measures) whenever the Director had reason to believe that an arriving carrier or any article or thing on board the carrier may be infected or contaminated with a communicable disease. Furthermore, under preexisting § 71.31(b), the Director could require the detention of the carrier until the completion of such measures. This authority is carried forward in the proposed rule in § 71.13 (Sanitary measures) and 71.14 (detention of carriers). The proposed rule also makes these requirements applicable to carriers affecting interstate commerce or things on board such carriers in § 70.11 (Sanitary measures). These sections clarify that the expense of applying sanitary measures are borne by the affected carrier or, in the case of things on board the carrier, expenses are borne by the owners.

Thus, the character of regulatory actions that would be taken under the proposed regulation is most accurately characterized as protection of the public health in the form of avoidance of the introduction, transmission or spread of infectious disease. Owners of property posing a threat of introduction, transmission or spread of infectious disease cannot have a reasonable investment-backed expectation that their property should move freely while posing such a threat. *See B&F Trawlers, Inc.* v. *the United States,* 27 Fed. Cl. 299, 306 (Ct. Fed. Cl. 1992) (holding that U.S. Coast Guard's lawful destruction of a burning vessel as a danger to navigation was not a compensable taking). Alternatively, the presence of carriers and things on board carriers in interstate and foreign traffic reasonably believed by the Director to be sources of communicable disease qualify as nuisances because they directly threaten human health and safety. Accordingly, the proposed regulations do not constitute a taking, and compensation is not required under the Fifth Amendment.

The Director's use of these regulations must, of course, be reasonable and based on the judgment that such steps are necessary to prevent the introduction, transmission or spread of communicable diseases. On the facts of a particular case, a court could ultimately find that the Director's belief was unreasonable, the steps taken were unnecessary, a nuisance did not exist, and a taking therefore occurred. Proper use, however, of the ''reasonable belief'' and ''necessity'' provisions contained in the proposed regulation would result in a finding of ''no taking'' under the requisite analysis.

F. Executive Order 13132: Federalism

Under Executive Order 13132, if the contemplated rule would limit or preempt State authorities, then a Federalism analysis is required. The agency must consult with State and local officials to determine whether the rule would have a substantial direct effect on State or local governments, as well as whether it would either preempt State law or impose a substantial direct cost of compliance on them.

Section 361(e) of the PHS Act (42 U.S.C. 264(e)) provides that ''[n]othing in this section or Section 266 of this title [relating to special quarantine powers in time of war], or the regulations promulgated under such sections, may be construed as superseding any provision under State law (including regulations and including provisions established by political subdivisions of States), except to the extent that such a provision conflicts with an exercise of Federal authority under this section or Section 266 of this title.'' The proposed rule is consistent with this statutory provision.

Through numerous forums such as conferences, tabletop exercises, response efforts, and meetings, CDC has consulted with state and local public health officials and health-care providers about the appropriate role of the federal government in exercising public health powers such as those described in the proposed rule. CDC seeks to continue this consultation through solicitation of comments from state and local public health officials on all aspects of the rule.

G. Executive Order 13211: Energy Effects

HHS is required by Executive Order 13211 to produce a statement of energy effects if the proposed rule is significant or economically significant and likely to have a significant adverse effect on the supply, distribution, or use of energy. HHS has determined that the proposed rule does not have that effect and that a statement of energy is therefore not required.

H. National Technology Transfer and Advancement Act

This Act, 15 U.S.C. 272, requires adoption of technical standards developed or adopted by voluntary consensus standard bodies in rules promulgated by HHS. No voluntary consensus standards are applicable and feasible with regard to the proposed rule.

I. Family Policy Analysis

Title 5 U.S.C. 601 requires agencies to determine whether a proposed rule would affect family well-being. Section 70.7 of the proposed regulation makes parents or guardians responsible for obtaining travel permits prior to procuring transportation for children or wards known by the parents or guardians to be in the qualifying stage of a communicable disease. While the proposed provision undoubtedly places responsibility on parents and guardians, it would be unreasonable to conclude that this responsibility adversely affects family well-being, particularly in view of the beneficial effects on families and the population as a whole associated with preventing the spread of infectious disease.

J. Executive Order 12988: Civil Justice Reform

HHS has completed the required reviews and has determined that the proposed rule meets the standards in Executive Order 12988. The preemptive effect of the rule is explained in section VII.F., Federalism, above. The rule has no retroactive effect. With respect to administrative hearings, the rule allows persons or groups of persons made subject to a quarantine order to request a hearing to dispute the genuine and substantial issues of fact. The rule clearly states that the quarantine order is not final until the Director approves or rejects the hearing officer's recommendation, or 3 business days after the request for hearing is made.

K. Plain Language

Executive Order 12866 requires each agency to write all rules in plain language. We try to write clearly. If you can suggest how to improve the clarity of these regulations, call or write Jennifer Brooks at the address listed above.

VIII. Solicitation of Comments

CDC solicits comments on various issues specifically identified in the preamble as well as any other issues that are relevant to the proposed regulation. Specifically, CDC solicits information, data, and comment on the following topics:

• Whether the time frames to develop and submit the plans described in following sections are sufficient. and, if it is not, what are the difficulties in meeting each of these schedules:

—§ 70.3 Reporting of death or illness, plan and implementation.
—§ 70.5 Passenger and crew information, plan and implementation.
—§ 71.7 Reporting of death or illness on board flights, plan and implementation.
—§ 71.9 Reporting of death or illness on board ship, plan and implementation.
—§ 71.11 Passenger and crew information, plan and implementation.

• In addition to soliciting comment on relative merits of the fully analyzed alternative options presented in Section VI, CDC also solicits comment on regulatory options that may fall outside the scope of the options analyzed in the regulatory impact analysis, including but not limited to the scope of the passenger information collected and the extent of the coverage of interstate travel.

• The most efficient means of collecting accurate passenger contact information, particularly from airlines and passengers:

○ § 70.4 Passenger information
○ § 71.10 Passenger information

• The economic analysis in this proposal, including the estimated costs.

• The paperwork reduction analysis, including the accuracy of the burden estimates and the practical utility of the data.

• The estimated costs based on the assumption that data collection efforts could be coordinated with contemporary rulemaking efforts by other Federal agencies.

• Whether the rule, particularly those sections pertaining to quarantine, hearings, and appeals (§§ 70.14–70.20; 70.31; 71.17–71.23; 71.33), provide adequate due process to individuals and entities that may be affected by them.

List of Subjects

42 CFR Part 70

Communicable diseases, Public health, Quarantine, Reporting and recordkeeping requirements, Travel restrictions.

42 CFR Part 71

Airports, Animals, Communicable diseases, Harbors, Imports, Pesticides and pests, Public health, Quarantine, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, we propose to amend 42 CFR Parts 70 and 71 to read as follows:

CHAPTER I—PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

1. Part 70 is revised to read as follows:

PART 70—INTERSTATE QUARANTINE

Sec.

Authority: 25 U.S.C. 198, 231, and 1661; 42 U.S.C. 243, 248, 249, 264–272, and 2001.

§ 70.1 Scope and definitions.

(a) The purpose of this part is to prevent the introduction, transmission, and spread of communicable diseases from one State into any other State. Regulations to prevent the spread of disease from foreign countries into the States are contained in 42 CFR Part 71. Except where otherwise indicated, regulations to prevent the spread of disease among possessions of the United States or from a possession into a State are contained in 42 CFR Part 71.

(b) As used in this part, the terms listed below in alphabetical order shall have the following meanings:

Aircraft commander means any person serving on an aircraft with responsibility for its operation and navigation.

Airline means any air carrier, foreign or domestic, operating commercial passenger flights under regular schedules within the United States.

Airline agent means any person who is authorized to act for or in place of the owner or operator of an airline for the purposes of carrying out the airline's responsibilities described in this part.

Business day means any full business day during which the Centers for Disease Control and Prevention is open for regular business (excluding Saturdays, Sundays, and legal holidays) from 9 a.m. in the morning to 5 p.m. in the evening, Eastern Standard Time.

Carrier means, except where otherwise specified, a ship, shipline, vessel, airline, aircraft, train, road vehicle, or other means of transport, including military carriers.

Communicable disease means an illness due to an infectious agent or its toxic products which arises through transmission of that agent or its products from an infected person or animal or a reservoir to a susceptible host, either directly or indirectly through an intermediate animal host, vector, or the inanimate environment.

Detention, when applied to carriers, animals, articles, or things means the temporary holding on a voluntary or involuntary basis of such carriers, animals, articles, or things, until the completion of such sanitary measures as may be required under this part.

Director means 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.

Disinfection means the killing of infectious agents or inactivation of their toxic products outside the body of a person or on the surface of a thing by direct exposure to chemical or physical agents.

Disinfestation means any chemical or physical process serving to destroy or remove undesired small animal forms, particularly arthropods or rodents.

Disinsection means the operation in which measures are taken to kill the insect vectors of human disease.

Emergency contact information means the following information pertaining to a person (other than the passenger or crewmember) or an entity (such as a business) that has the ability to contact the passenger or crewmember on an emergency basis:

(i) The full name (first, last, middle initial, suffix) of the person or business name of the entity;

(ii) The permanent address; and

(iii) A phone number (either home, work, or mobile).

Flight information means for each airline operating a flight in interstate traffic (including any intermediate stops between the flight's origin and final destination) the airline name, flight number, city of arrival, date of arrival, date of departure, seat number for any passenger or crewmember, arrival gate, and arrival terminal.

Hearing officer means a person designated by the Director or the Secretary to conduct administrative hearings under this part or another authorized representative as approved by the Director or the Secretary.

Ill person means a person who:

(i) Has a temperature of 100.4° F (or 38° C) or greater accompanied by one or more of the following: Rash, swelling of the lymph nodes or glands, headache with neck stiffness, or changes in level of consciousness or cognitive function; or

(ii) Has a temperature of 100.4° F (or 38° C) or greater that has persisted for more than 48 hours; or

(iii) Has diarrhea, defined as the occurrence in a 24-hour period of three or more loose stools or of stools in an amount greater than normal (for the person); or

(iv) Has one or more of the following: Severe bleeding, jaundice, or severe, persistent cough accompanied by bloody sputum, respiratory distress, or a temperature of 100.4° F (or 38° C) or greater; or

(v) Displays other symptoms or factors that are suggestive of communicable disease, which the Director may describe in an order as the Director determines necessary.

Indian country means:

(i) All land within the limits of any Indian reservation under the jurisdiction of the United States Government, notwithstanding the issuance of any patent, and, including rights-of-way running through the reservation;

(ii) All dependent Indian communities within the borders of the United States whether within the original or subsequently acquired territory thereof, and whether within or without the limits of a state; and

(iii) All Indian allotments, the Indian titles to which have not been extinguished, including rights-of-way running through the same.

Indian tribe means any Indian tribe, band, nation or other organized group or community, including any Alaska Native village or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians.

Infectious agent means an organism (*e.g.,* bacteria, fungus, helminth, prion, protozoan, rickettsia, virus, or bioengineered variant thereof) that is capable of producing infection or infectious disease.

Interstate traffic, except as otherwise provided in paragraph (ii) of this definition, means:

(i) The movement of any carrier or the transportation of persons or property, including any portion of such movement or transportation that is entirely within a State—

(A) From a point of origin in any State to a point of destination in any other State; or

(B) Between a point of origin and a point of destination in the same State but through any contiguous State or foreign country.

(ii) Interstate traffic does not include the following:

(A) The movement of any carrier or the transportation of persons or property on an international voyage as defined in 42 CFR Part 71; or

(B) The movement of any carrier which is solely for the purpose of its repair, reconstruction, rehabilitation, or storage.

Medical monitoring means close medical or other supervision of a person or group of persons on a voluntary or involuntary basis to permit prompt recognition of infection or illness.

Military service means the U.S. Air Force, U.S. Army, the U.S. Coast Guard, the U.S. Marine Corps, the U.S. Navy, and any National Defense Reserve Fleet vessels engaged in military operations at the direction of the U.S. Department of Defense.

Possession means, in addition to Puerto Rico, any other possession of the United States.

Provisional quarantine means the detention on an involuntary basis of a person or group of persons reasonably believed to be in the qualifying stage of a quarantinable disease until a quarantine order has been issued or until the Director determines that provisional quarantine is no longer warranted.

Public health emergency, as used in this part, means:

(i) Any disease event as determined by the Director with either documented or significant potential for regional, national, or international disease spread or with actual or potential interference with the free movement of people or goods between States and possessions within the United States or other countries or sovereignties; or

(ii) Any disease event designated as a public health emergency by the Secretary pursuant to section 319(a) of the Public Health Service Act (42 U.S.C. 247d(a)).

Qualifying stage means:

(i) A communicable stage of the disease; or

(ii) A precommunicable stage, if the disease would be likely to cause a public health emergency if transmitted to other persons.

Quarantine means the holding on a voluntary or involuntary basis, including the isolation, of a person or group of persons in such place and for such period of time as the Director deems necessary or desirable to prevent the spread of infection or illness.

Quarantinable disease means any of the communicable diseases listed in an Executive Order, as provided under section 361 of the Public Health Service Act. Executive Order 13295, of April 4, 2003, as amended by Executive Order 13375 of April 1, 2005, contains the current revised list of quarantinable diseases, and may be obtained at *http://www.cdc.gov* and *http://www.archives.gov/federal_register.* If this Order is amended, HHS will enforce that amended order immediately and update that Web site.

Sanitary measures means:

(i) When applied to carriers, animals, articles, or things: Detention; destruction of animals, articles, or things that the Director deems to be sources of dangerous infection to human beings; disinfection; disinfestations; disinsection; fumigation; pest extermination; seizure; or any other measure or combination of measures, whether voluntary or involuntary, that the Director deems necessary or desirable to prevent the introduction, transmission, or spread of communicable diseases; or

(ii) When applied to a person or group of persons, the killing of infectious agents (or vectors capable of conveying infectious agents) outside the body by direct exposure to any chemical, physical, or other process designed to destroy such infectious agents.

Secretary means the Secretary of the Department of Health and Human Services.

State means in addition to the several States, only the District of Columbia.

United States means the States and possessions of the United States.

Vector means an animal (including insects) or thing which conveys or is capable of conveying infectious agents from a person or animal to another person or animal.

§ 70.2 Report of death or illness on board flights.

(a) Any airline operating flights in interstate traffic shall, pursuant to the written plan required under § 70.3, report any deaths or ill persons that occur on board to the Director as soon as such occurrences are made known to the aircraft commander and, where possible, at least one hour before arrival.

(b) The Director, whenever necessary for purposes of preventing the introduction, transmission or spread of communicable diseases, may order airlines operating a flight in interstate traffic to disseminate to passengers and crew public health notices, recommended public health measures, and other public health information. Such information shall be disseminated at the time and in a manner specified in the Director's order.

§ 70.3 Written plan for reporting of deaths or illness on board flights and designation of an airline agent.

(a) Within 90 days of the final publication of this rule, any airline operating flights in interstate traffic shall develop a written plan sufficient to ensure reporting of deaths or illness on board flights as required by § 70.2.

(b) The written plan shall include the full name (i.e., first, last, middle initial, suffix), official title, business telephone number, and e-mail address (if available), of an airline agent who shall serve as a point of contact between the Director and the airline concerning reports of deaths or ill persons.

(c) The written plan shall include policies and procedures necessary to facilitate communication between the Director and the airline agent on a 24-hour basis, 7 days a week.

(d) Within 90 days of the final publication of this rule, a copy of the written plan shall be submitted to the Director.

(e) Airlines shall implement the written plan within 180 days of the final publication of this rule.

(f) Airlines shall review the written plan one year after implementation and annually thereafter. The review shall include drills or exercises to test and evaluate the effectiveness of the written plan unless the airline has reported ill passengers or deaths on board a flight under § 70.2 in the prior 365 days. Airlines shall revise the plan as necessary after any review. Any revisions of the written plan shall be submitted to the Director within 60 days.

(g) Airlines that intend to commence operation of flights in interstate traffic after the effective date in paragraph (a) of this section shall submit a written plan meeting the requirements of this section to the Director before commencing operations. The airline shall implement the written plan by the later of the two following dates: Either 180 days after the final publication of this rule, or upon commencement of operations.

§ 70.4 Passenger information.

(a) Any airline operating flights in interstate traffic shall, pursuant to the written plan required under § 70.5, solicit from each passenger (or head of household if the passenger is a minor) and crewmember traveling on those flights in interstate traffic arriving in or departing from any of the airports listed in Appendix A the information contained in the data fields specified in paragraph (e) of this section.

(b) Any information obtained by the airline pursuant to paragraph (a) in this section shall be maintained by the airline in an electronic database for 60 days from the end of the flight.

(c) For each passenger (or head of household if the passenger is a minor) and crewmember traveling on an interstate flight, the airline may solicit the information in paragraph (e) of this section from such person's authorized agent.

(d) Within 12 hours of a request by the Director to the airline's agent, the airline, pursuant to the written plan under § 70.5, shall transmit to the Director in an electronic format the data fields specified in paragraph (e) of this section.

(e) The data fields as applicable to the individual passenger (or head of household if the passenger is a minor) or crewmember, shall include the following:

(1) Full name (first, last, middle initial, suffix);

(2) Emergency contact information;

(3) E-mail address;

(4) Current home address (street, apartment #, city, state/province, postal code);

(5) Passport number or travel document number, including the issuing country or organization (in the case of foreign nationals only);

(6) Names of traveling companions or group;

(7) Flight information;

(8) Returning flight (date, airline number, and flight number);

(9) At least one of the following current phone numbers (in order of preference): mobile, home, pager, or work.

(f) In addition to data fields specified in paragraph (e) of this section, when necessary to prevent the introduction, transmission, or spread of communicable diseases, the Director through order may also require that airlines transmit additional information in the airline's possession.

(g) Information collected solely in order to comply with this regulation may only be used for the purposes for which it is collected.

(h) Airlines shall ensure that passengers are informed of the purposes of this information collection at the time passengers arrange their travel.

§ 70.5 Written plan for passenger information and designation of an airline agent.

(a) Within six months of the final publication of this rule, any airline operating flights in interstate traffic shall develop a written plan sufficient to ensure transmission of passenger and crew information for those flights in interstate traffic arriving in or departing from any of the airports listed in appendix A to part 70 as required by § 70.4.

(b) The written plan shall include:

(1) Policies and procedures for the transmission of data in an electronic format available to both the airline and the Director using industry standards for data encoding, transmission, and security;

(2) Policies and procedures for the transmission of the data within 12 hours of a request by the Director to the airline's agent;

(3) The full name (*i.e.*, first, last, middle initial, suffix), official title, business telephone number, and e-mail address (if available), of an airline agent who shall serve as a point of contact between the Director and the airline concerning requests for and transmission of passenger and crew information data;

(4) Policies and procedures necessary to facilitate communication between the Director and the airline's agent on a 24-hour basis, 7 days a week;

(5) Policies and procedures for soliciting the information contained in the data fields required by § 70.4(e) from the passenger (or head of household if the passenger is a minor), crewmember, or such persons' authorized agent; and

(6) Policies and procedures for maintaining responsive information obtained by the airline in an electronic database for 60 days from the end of the flight as required by § 70.4(b).

(c) Within six months of the final publication of this rule, a copy of the written plan shall be submitted to the Director.

(d) Airlines shall implement the written plan within 2 years of the final publication date of this rule. Within 60 days of implementation, airlines shall conduct drills or exercises to test and evaluate the effectiveness of the written plan and revise the plan as necessary after any drill or exercise. Any revisions of the written plan shall be submitted to the Director within 60 days.

(e) Airlines shall review the written plan one year after implementation and annually thereafter. The review shall include drills or exercises to test and evaluate the effectiveness of the written plan unless the airline has transmitted passenger and crewmember information under § 70.4 in the prior 365 days. Airlines shall revise the plan as necessary after any review. Any revisions of the written plan shall be submitted to the Director within 60 days.

(f) Airlines that intend to commence operation of flights in interstate traffic arriving in or departing from any of the airports listed in appendix A to part 70 after the effective date in paragraph (a) of this section shall submit a written plan meeting the requirements of this section to the Director before commencing operations. The airline shall implement the written plan by the later of the two following dates: either 2 years after the final publication of this rule, or upon commencement of operations.

(g) Pending the development or implementation of the written plan as required by this section, the Director, through order, may require that airlines transmit to the Director, in a format available to both the airline and the Director, any of the information required by § 70.4 that may be in the airline's possession.

§ 70.6 Travel permits.

(a) The operator of any carrier operating in interstate traffic or moving from one state or possession into another shall not:

(1) Accept for transportation any person whom the operator knows to be in the qualifying stage of a quarantinable disease, unless such person presents a permit issued by the Director authorizing such travel; or

(2) Transport any person whom the operator knows to be in the qualifying stage of a quarantinable disease in violation of any of the terms or conditions prescribed in the travel permit issued by the Director.

(b) Whenever a carrier operating in interstate traffic or moving from one state or possession into another transports a person who is in the qualifying stage of a quarantinable disease bearing a travel permit issued by the Director, the operator of the carrier shall take such measures to prevent the spread of the disease, including submission of the carrier to inspection, sanitary measures and the like, as the Director deems necessary.

(c) Requirements relating to travelers who know that they are in the qualifying stage of a quarantinable disease:

(1) No such person shall travel in interstate traffic or from one state or possession to another without a written permit of the Director.

(2) Application for a permit authorizing travel may be made directly to the Director.

(3) Upon receipt of an application, the Director, taking into consideration the risk of introduction, transmission, or spread of the disease in interstate traffic or from one state or possession into another, shall reject it or issue a permit that may be conditioned upon compliance with such precautionary measures as the Director shall prescribe.

(4) A person 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 carriers, as required by its terms.

(5) A person who has had his/her request for a permit denied may submit a written appeal in accordance with § 70.31.

(d) The Director may additionally apply the provisions in paragraphs (a) through (c) of this section to persons and carriers traveling entirely within a state or possession whenever the Director determines that such person's travel or the carrier's operations will have an effect on interstate commerce upon the request of a health authority in accordance with § 70.24 or whenever the Director, with the concurrence of the Secretary, makes a determination of inadequate local control in accordance with § 70.25.

§ 70.7 Responsibility with respect to minors, wards, and patients.

(a) A parent, guardian, physician, nurse, or other such person shall not transport, nor procure or furnish transportation for any minor child or ward, patient or other such person whom they know to be in the qualifying stage of a quarantinable disease, without a travel permit issued by the Director if such a permit is required under this part.

(b) A parent, guardian, physician, nurse, or other such person who has had his/her request for a permit denied may submit a written appeal in accordance with § 70.31.

§ 70.8 Military services.

(a) The Director may exempt carriers belonging to the military services from § 70.6(a) and §§ 70.11 and 70.12, provided that such carriers take adequate sanitary measures to prevent the introduction, transmission, and spread of communicable diseases.

(b) The requirements of §§ 70.6(c) and 70.7 shall not apply to members of the military service or Public Health Service, or to the medical care or hospital beneficiaries of the military service, Department of Veterans Affairs, or Public Health Service, provided that:

(1) Such persons are traveling on military carriers under competent orders; and

(2) The person authorizing the travel on a military carrier has taken public health measures consistent with those prescribed by the Director to prevent the introduction, transmission, or spread of quarantinable diseases during the travel period.

§ 70.9 Vaccination clinics.

(a) The Director may establish vaccination clinics, through contract or otherwise, authorized to issue certificates of vaccination and administer vaccines and/or other prophylaxis. When authorized by the Director, certificates of vaccination may be issued and authenticated by electronic means.

(b) A vaccination clinic established by the Director shall collect and maintain, for such time as determined by the Director, the following information from vaccine recipients:

(1) Gender;

(2) Age;

(3) Vaccination date;

(4) Vaccine lot number;

(5) Prior vaccinations;

(6) Reason for vaccination (*e.g.*, post-exposure, pre-exposure, member of high risk group, general vaccination);

(7) Concurrent vaccinations;

(8) Vaccine Adverse Events Reporting System Report/Adverse Event Report Number; and

(9) Verification that the vaccine conferred immunity (if applicable).

(c) In addition to the requirements in paragraph (b) of this section, a vaccination clinic established by the Director shall comply with such additional recordkeeping requirements and other instructions that the Director may issue for the safe administration, handling, monitoring, and storage of vaccines.

(d) In the event of a public health emergency, the Director may waive or modify any of the requirements in paragraph (b) of this section.

(e) A vaccination fee may be charged for individuals not enrolled in Medicare Part B to cover costs associated with administration of the vaccine and/or other prophylaxis. Such fee is to be collected at the time that the vaccine is administered. The vaccination fee, if imposed, is shown in the following table:

Vaccine	Effective dates	Amount
Fluarix	[1] 1/25/05	[2] $25.00

[1] Continuing for one year.
[2] $7.00 for the vaccine and $18.00 for administration.

§ 70.10 Establishment of institutions, hospitals and stations.

(a) The Director, with the approval of the Secretary, may, from time to time, select sites suitable for, and establish such institutions, hospitals, and stations in the States and possessions of the United States as the Director, with the approval of the Secretary, deems necessary or desirable for carrying out the functions in this part.

(b) The Director may enter into voluntary agreements with public or private institutions as the Director deems necessary or desirable for carrying out the functions in this part.

§ 70.11 Sanitary measures.

(a) Whenever the Director reasonably believes that any carrier affecting interstate commerce, or animal, article, or thing on board such carrier is or may be infected or contaminated with a communicable disease, the Director, may, in consultation with other federal agencies as appropriate:

(1) Inspect the carrier, animal, article, or thing on board the carrier, and/or

(2) Order the carrier, or other entity specified in the order, to apply such sanitary measures as the Director deems necessary to prevent the introduction, transmission, or spread of communicable diseases.

(b) CDC shall not bear the expense of any sanitary measures required or ordered by the Director. The carrier or other entity specified in the order issued pursuant to 70.11(a) shall bear the responsibility for the application of such measures.

(c) Sections 70.11(a) and 70.11(b) shall not preclude any entity ordered to conduct sanitary measures pursuant to § 70.11(a) from arranging to have such measures conducted by other entities through contractual or other arrangements, or from seeking reimbursement for any costs associated with sanitary measures through contractual or other arrangements.

(d) The Director may apply such sanitary measures to persons who are not in the qualifying stage of a quarantinable disease, with their consent, as may be required to destroy the presence of infectious agents or vectors.

§ 70.12 Detention of carriers affecting interstate commerce.

(a) The Director whenever necessary to prevent the introduction, transmission, or spread of communicable diseases and in consultation with such other federal agencies as the Director deems necessary may require the detention of any carrier affecting interstate commerce and all animals, articles, or things onboard the carrier until the completion of the measures outlined in this part.

(b) CDC shall not bear any expenses relating to the detention of the carrier; or any associated expenses related to animals, articles, or things on board the carrier.

(c) Section 70.12(b) shall not preclude any entity from seeking reimbursement for any costs associated with detention of a carrier pursuant to section 70.12(a) through contractual arrangements or other available means from entities other than the CDC.

§ 70.13 Screenings to detect ill persons.

The Director may, at airports or other locations, conduct screenings of persons or groups of persons to detect the presence of ill persons. Such screenings may be conducted through visual inspection, electronic temperature monitors, or other means determined appropriate by the Director to detect the presence of ill persons.

§ 70.14 Provisional quarantine.

(a) The Director may provisionally quarantine a person or group of persons who the Director reasonably believes to be in the qualifying stage of a quarantinable disease and:

(1) Moving or about to move from one State to another State; or

(2) A probable source of infection to persons who will be moving from a State to another State.

(b) Provisional quarantine shall commence upon:

(1) The service of a written provisional quarantine order;

(2) A verbal provisional quarantine order; or

(3) Actual movement restrictions placed on the person or group of persons.

(c) Provisional quarantine shall end three business days after provisional quarantine commences, except that the person or group of persons shall be released earlier if the Director determines that provisional quarantine is no longer warranted.

(d) In the event that the Director determines that it is necessary to provisionally quarantine a person or group of persons beyond three business days, then the Director shall serve the person or group of persons with a written quarantine order in accordance with this part.

(e) A person or group of persons subject to provisional quarantine may be offered medical treatment, prophylaxis, or vaccination, as the Director deems necessary to prevent the introduction, transmission or spread of the disease; such persons may refuse such medical treatment, prophylaxis, or vaccination, but remain subject to provisional quarantine.

(f) Nothing in this section shall be construed to limit the Director's ability to detain a person or group of persons on a voluntary basis or to offer such persons medical treatment, prophylaxis, or vaccination on a voluntary basis.

§ 70.15 Provisional quarantine orders.

(a) Provisional quarantine orders shall be served by the Director:

(1) At the time that provisional quarantine commences; or

(2) As soon thereafter as the Director determines that the circumstances reasonably permit.

(b) Provisional quarantine orders shall be served either through personal service or, in circumstances where the Director deems it necessary by posting or publishing the order in a conspicuous location.

(c) In circumstances where the Director deems public posting or publishing necessary, the Director may omit the names and/or identities of persons and take other measures respecting the privacy of persons.

(d) The provisional quarantine order shall be in writing, signed by the Director, and include the following information:

(1) A statement regarding the basis for the Director's reasonable belief that the person or group of persons is in the qualifying stage of a quarantinable disease based on information available to the Director at the time, such as travel history, clinical manifestations, or any other evidence of infection or exposure;

(2) A statement setting forth the Director's reasonable belief that either:

(i) The person or group of persons is moving or about to move from a State to another State; or

(ii) A probable source of infection to persons who will be moving from a State to another State;

(3) The suspected quarantinable disease;

(4) A statement advising the person or group or persons that they may be under provisional quarantine for three business days and that at the end of such period they shall be released or, if determined by the Director, served with a quarantine order;

(5) A statement advising the person or group of persons that they may be released earlier if the Director determines that provisional quarantine is no longer warranted;

(6) The location of provisional quarantine;

(e) When authorized by the Director, provisional quarantine orders may be issued and signed by electronic means.

§ 70.16 Quarantine.

(a) The Director may issue a quarantine order whenever the Director reasonably believes that:

(1) A person or group of persons are in the qualifying stage of a quarantinable disease based on, but not limited to, any of the following: clinical manifestations, diagnostic tests or other medical tests, epidemiologic information, laboratory tests, physical examination, or other evidence of exposure or infection available to the Director at the time; and either

(2) Moving or about to move from a State to another State; or

(3) A probable source of infection to persons who will be moving from a State to another State.

(b) In accordance with the Director's quarantine order, the Director may offer medical treatment, prophylaxis, or vaccination, as the Director deems necessary to prevent the introduction, transmission, or spread of the disease.

(c) Persons offered medical treatment, prophylaxis, or vaccination may refuse, but remain subject to quarantine.

(d) The Director's quarantine order may include the quarantine of a person or group of persons who refuse examination, medical treatment, prophylaxis, or vaccination, or for whom the Director determines that such examination, medical treatment, prophylaxis, or vaccination is medically contra-indicated or not reasonably available.

(e) The length of quarantine shall not exceed the period of incubation and communicability, as determined by the Director, for the quarantinable disease.

(f) Nothing in this section shall be construed to limit the Director's ability to quarantine a person or group of persons on a voluntary basis.

§ 70.17 Content of quarantine order.

(a) Quarantine orders shall be in writing, signed by the Director, and contain the following:

(1) The identity of the person or group of persons to be quarantined, if known;

(2) The location where such person or group of persons will be quarantined;

(3) The date and time at which quarantine commences and ends;

(4) The suspected quarantinable disease;

(5) A statement that the Director reasonably believes that:

(i) The person or group of persons are in the qualifying stage of a quarantinable disease; and that either

(ii) The person or group of persons will move or are about to move from one State to another State; or

(iii) The person or group of persons are a probable source of infection to persons who will be moving from a State to another State;

(6) A statement regarding the basis for the Director's reasonable belief that such person or group of persons are in the qualifying stage of a quarantinable disease, *e.g.*, clinical manifestations, physical examination, laboratory tests, diagnostic tests or other medical tests, epidemiologic information, or other evidence of exposure or infection available to the Director at the time;

(7) A statement that such persons shall comply with conditions of quarantine, including, but not limited to, examination, medical monitoring, medical treatment, prophylaxis, or vaccination, or other conditions of quarantine deemed by the Director to be necessary to prevent the introduction, transmission or spread of communicable disease;

(8) A statement that such persons may refuse examination, medical monitoring, medical treatment, prophylaxis, or vaccination, but remain subject to quarantine; and

(9) A statement that persons under quarantine, any time while the quarantine order is in effect, may request that the Director hold a hearing to review the quarantine order.

(b) When authorized by the Director, quarantine orders may be issued and signed by electronic means.

§ 70.18 Service of quarantine order.

(a) A copy of the quarantine order shall be personally served on the person or group of persons at the time that quarantine commences or as soon thereafter as the Director determines that the circumstances reasonably permit.

(b) In circumstances where the Director deems it necessary, the quarantine order may be posted or published in a conspicuous location, except that the Director may omit the names and/or identities of persons and take other measures respecting the privacy of persons.

§ 70.19 Medical examination and monitoring.

(a) The Director may order medical examination or monitoring of a person or group of persons that the Director reasonably believes to be in the qualifying stage of a quarantinable disease and:

(1) Moving or about to move from one State to another State; or

(2) A probable source of infection to persons who will be moving from a State to another State.

(b) Persons subject to medical examination or monitoring shall provide the Director with such information as the Director may order, including, but not limited to, familial and social contacts, travel itinerary, medical history, place of work, and vaccination status.

(c) Persons subject to medical monitoring shall report for such further medical examinations and comply with other conditions of monitoring as the Director orders.

(d) Persons may refuse medical examination or monitoring, but remain subject to provisional quarantine or quarantine, provided that if quarantined such persons may request a hearing in accordance with § 70.20.

(e) Nothing in this section shall be construed to limit the Director's ability to conduct medical examinations or place persons under medical monitoring on a voluntary basis or from engaging in other methods of voluntary disease surveillance.

§ 70.20 Hearings.

(a) Upon the request of a person or group of persons under quarantine, at any time while the quarantine order is in effect, the Director shall hold a hearing to review the quarantine order within one business day of the request.

(b) Requests for a hearing by a person or group of persons under quarantine shall be limited to genuine and substantial issues of fact in dispute.

(c) The Director shall provide notice of the hearing to the person or group of persons under quarantine through any method that the Director determines to be reasonably designed to notify the person or group of persons that such a hearing has been scheduled.

(d) The Director shall designate a hearing officer to review the medical or other evidence of exposure or infection available to the Director and make findings as to which person or group of persons are in the qualifying stage of a quarantinable disease and recommendations concerning which person or group of persons should be released or remain in quarantine.

(e) A person or group of persons in quarantine may authorize a representative to submit evidence concerning whether the person or group is in the qualifying stage of a quarantinable disease;

(f) The Director shall take such measures that the Director determines to be reasonably necessary to allow a person or group of persons in quarantine to communicate with their authorized representatives. Such measures, for example, may include the establishment of video-conferencing facilities, e-mail terminals, telephone or cellular phone services, and other similar devices or technologies.

(g) The hearing officer may order a medical examination of the person or group of persons in quarantine when, in the hearing officer's judgment, such a medical examination would aid in the determination of whether the person or group of persons are in the qualifying stage of a quarantinable disease, provided that such persons may refuse such examination.

(h) The hearing officer shall, based upon his or her review of the evidence of exposure or infection made available to the hearing officer, make findings and a written recommendation to the Director as to which, if any, person or group of persons should be released or remain in quarantine.

(i) The Director, based upon the hearing officer's findings and written recommendation and the administrative record shall within one business day after the conclusion of the hearing order the release or continued quarantine of the person or group of persons in quarantine.

(j) The Director may issue additional instructions and guidelines as the Director deems necessary governing the conduct of hearings.

(k) The quarantine order shall be deemed final either when the Director has accepted or rejected the hearing officer's written recommendation or three business days after the request for a hearing, whichever comes first.

§ 70.21 Care and treatment of persons.

(a) Persons subject to medical examination and monitoring, provisional quarantine, or quarantine in accordance with this part may receive care and treatment at the expense of the Director subject to paragraphs (b) through (f) of this section.

(b) Payment for such expenses shall be in Director's sole discretion and subject to the availability of appropriations.

(c) Any payment of expenses 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 only be paid by the Director after all third-party payers have made payment in satisfaction of their obligations.

(d) Payment shall be limited to those amounts the hospital or medical facility would customarily bill the Medicare system using the International Classification of Diseases, Clinical Modification (ICD–CM), and relevant federal regulations promulgated by the Centers for Medicare and Medicaid Services in existence at the time of billing.

(e) For quarantinable diseases, payment shall be limited to costs for services and items reasonable and necessary for the care and treatment of the person for the time period that begins when the Director refers the person to the hospital or medical facility for treatment and ends when, as determined by the Director, the period of provisional quarantine or quarantine expires.

(f) For diseases other than those described in paragraph (e) of this section, such payment shall be limited to costs for services and items reasonable and necessary for care and treatment of the person for the time period that begins when the Director refers the person to the hospital or medical facility and ends when the person's condition is diagnosed, as determined by the Director, with a non-quarantinable disease.

§ 70.22 Foreign nationals.

(a) The Director, in consultation with the U.S. Department of State as may be necessary, shall advise a foreign national under provisional quarantine or quarantine of such person's right to have the Director notify the consular post of the foreign state of such person's provisional quarantine or quarantine and to have any communications forwarded to the consular post without delay. In circumstances where required by international legal obligation, the Director shall, in consultation with the U.S. Department of State as may be necessary, directly notify the consular post of the foreign state of its foreign national's provisional quarantine or quarantine.

(b) When requested by the consular officer of the foreign state and in a manner that the Director determines to be practicable, the Director, in consultation with the U.S. Department of State as may be necessary, shall allow the consular officer to have access to the foreign national under provisional quarantine or quarantine for purposes of conversing and corresponding with the foreign national and arranging for the foreign national's legal representation.

(c) Any foreign national subject to provisional quarantine or quarantine shall have the same rights as provided for other persons subject to provisional quarantine or quarantine elsewhere in this part.

§ 70.23 Administrative record.

A person's administrative record shall, where applicable, consist of the provisional quarantine and/or quarantine order, and any medical, laboratory, epidemiologic, or other information in support thereof, evidence submitted by the person under provisional quarantine and/or quarantine, written findings and recommendation of the hearing officer, and the hearing transcript, if any, or summary notes of the hearing.

§ 70.24 Requests by State (including political subdivisions thereof), possession, or Tribal health authorities.

(a) The health authority of a State (including political subdivisions thereof) or Indian tribe may request that the Director take public health measures in accordance with this part and whatever further public health measures that the Director, in consultation with the health authority, deems necessary to prevent the introduction, transmission, or spread of communicable diseases.

(b) The health authority of a State (including political subdivisions thereof) or Indian tribe may request that the Director issue a provisional quarantine order or a quarantine order. Such requests shall set forth the health authority's reasonable belief that the person or group of persons to be quarantined or placed under provisional quarantine are in the qualifying stage of a quarantinable disease, and either:

(1) Moving or about to move from a State to another State; or

(2) A probable source of infection to persons who will be moving from a State to another State.

(c) Nothing in this part shall be construed to limit the ability of the Director to cooperate with or aid States and their political subdivisions or Indian Tribes in the enforcement of their quarantine rules and regulations or other health rules and regulations.

(d) The health authorities of a possession may request that the Director take whatever public health measures are applicable under this part or 42 CFR part 71 (including provisional quarantine or quarantine) and whatever further public health measures that the Director, in consultation with the health authority, deems necessary to prevent the introduction, transmission, or spread of communicable diseases.

(e) A request by a health authority under this section shall not be deemed a condition for implementation by the Director of any of the public health measures in this part, or in the case of possessions, 42 CFR part 71.

(f) The decision to undertake any of the activities requested in accordance with this section is within the sole discretion of the Director.

§ 70.25 Measures in the event of inadequate local control.

In addition to the public health measures in this part, whenever the Director, with the concurrence of the Secretary, determines that the measures taken by the health authorities of any State (including political subdivisions thereof), possession, or Indian Tribe are insufficient to prevent the spread of any communicable diseases from one State or possession into another, the Director may take such measures to prevent such spread of disease as the Director deems necessary including inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures.

§ 70.26 Federal facilities.

(a) In addition to the public health measures in this part, the Director, in consultation with the affected federal agencies, may take whatever further public health measures or combination of measures the Director deems necessary with respect to facilities owned or operated by the federal government in the United States.

(b) This section does not preclude the Director from requesting the assistance of State or local authorities in implementing the regulations appearing in this part or in implementing other public health measures or combination of measures.

§ 70.27 Indian country.

(a) In addition to the public health measures specified elsewhere in this part, with the concurrence of the Director of the Indian Health Service and after consulting with the affected Tribe or Tribes, the Director may impose the following public health measures with respect to persons in Indian country without making a finding that such person or group of persons are moving or about to move from a State to another State or are a probable source of infection to persons who will be moving from a State to another State:

(1) Provisional quarantine pursuant to §§ 70.14 and 70.15;

(2) Quarantine pursuant to §§ 70.16 through 70.18, 70.20; and

(3) Medical examination and monitoring pursuant to § 70.19.

(b) Any provisional quarantine, quarantine, or medical examination and monitoring authorized by paragraph (a) of this section must take place in a hospital or other place for treatment, but any person who is subject to such provisional quarantine or quarantine may refuse examination, medical monitoring, medical treatment, prophylaxis, or vaccination, but remains subject to provisional quarantine and quarantine.

(c) Any person who is the subject of a provisional quarantine order or quarantine order authorized by paragraph (a) of this section has the same rights as provided for provisional quarantine or quarantine elsewhere in this part.

(d) After consulting with the affected Tribe or Tribes, the Director may authorize the agents and employees of any State to enter Indian country for the sole purpose of enforcing federal quarantine rules and regulations if the Director of the Indian Health Service concurs (such concurrence being subject to any rules and regulations that the Director of the Indian Health Service may prescribe).

§ 70.28 Special powers in time of war.

(a) In addition to the public health measures in this part, the Director, in consultation with the Secretary of the U.S. Department of Defense or his or her designee, may, in time of war and to protect the military and naval forces and war workers of the United States, impose the following public health measures with respect to persons under paragraph (b) of this section without making a finding that such person or group of persons are in the qualifying stage of a quarantinable disease; and moving or about to move from a State to another State or are a probable source of infection to persons who will be moving from a State to another State:

(1) Provisional quarantine pursuant to §§ 70.14 and 70.15;

(2) Quarantine pursuant to § 70.16 through 70.18, 70.20; and

(3) Medical examination and monitoring pursuant to § 70.19.

(b) The persons subject to paragraph (a) of this section include any person that the Director reasonably believes to be:

(1) Infected with or exposed to a quarantinable disease; and

(2) A probable source of infection to members of the military services or to individuals engaged in the production or transportation of arms, munitions, ships, food, clothing, or other supplies for the military services.

(c) Any person who is the subject of a provisional quarantine order or quarantine order authorized by subsection (a) has the same rights as provided for provisional quarantine or quarantine elsewhere in this part.

§ 70.29 Penalties.

Persons in violation of this part are subject to a fine of no more than $250,000 or one year in jail, or both, or as otherwise provided by law. Violations by organizations are subject to a fine of no more than $500,000 per event or as otherwise provided by law.

§ 70.30 Implementation through order.

The Director may implement any of the provisions in this part through order issued and signed by the Director.

§ 70.31 Appeals of actions required pursuant to §§ 70.6, 70.7, 70.11 or 70.12

(a) The following persons may submit a written appeal in accordance with paragraph (b) of this section:

(1) A person whose application for a travel permit has been denied pursuant to § 70.6;

(2) A parent, guardian, physician, nurse, or other such person whose application for a travel permit has been denied pursuant to § 70.7;

(2) The owner of animals, articles, or things to be destroyed, if the Director determines that destruction is a necessary sanitary measure pursuant to § 70.11;

(3) The owner of a carrier to be detained pursuant to § 70.12.

(b) The appeal must be in writing and be submitted to the Director within 2 business days. The appeal must state the reasons for the appeal and show that there is a genuine and substantial issue of fact in dispute. The Director will issue a written response to the appeal, which shall constitute final agency action. This opportunity for an appeal shall not preclude the Director from acting immediately to exercise actions authorized under §§ 70.6, 70.7, 70.11 or 70.12.

Appendix A to Part 70—Calendar Year 2004 Enplanement Data as Published by the Federal Aviation Agency (FAA) for Large and Medium U.S. Airports [1]

Large Hubs

Hartsfield—Jackson Atlanta Intl Atlanta (ATL)
Chicago O'Hare Intl Chicago (ORD)
Los Angeles Intl Los Angeles (LAX)
Dallas/Fort Worth Intl Fort Worth (DFW)
Denver Intl Denver (DEN)
McCarran Intl Las Vegas (LAS)
Phoenix Sky Harbor Intl Phoenix (PHX)
John F Kennedy Intl New York (JFK)
Minneapolis—St Paul Intl Wold—Chamberlain Minneapolis (MSP)
George Bush Intercontinental Houston (IAH)
Detroit Metropolitan Wayne County Detroit (DTW)
Newark Liberty Intl Newark (EWR)
San Francisco Intl San Francisco (SFO)
Orlando Intl Orlando (MCO)
Miami Intl Miami (MIA)
Seattle–Tacoma Intl Seattle (SEA)
Philadelphia Intl Philadelphia (PHL)
General Edward Lawrence Logan Intl Boston (BOS)
Charlotte/Douglas Intl Charlotte (CLT)
La Guardia New York (LGA)
Washington Dulles Intl Chantilly (IAD)
Cincinnati/Northern Kentucky Intl Covington (CVG)
Baltimore–Washington Intl Glen Burnie (BWI)
Fort Lauderdale/Hollywood Intl Fort Lauderdale (FLL)
Honolulu Intl Honolulu (HNL)
Chicago Midway Intl Chicago (MDW)
Salt Lake City Intl Salt Lake City (SLC)
Tampa Intl Tampa (TPA)
San Diego Intl San Diego (SAN)
Ronald Reagan Washington National Arlington (DCA)

Medium Hubs

Metropolitan Oakland Intl Oakland (OAK)
Pittsburgh Intl Pittsburgh (PIT)
Portland Intl Portland (PDX)
Lambert–St Louis Intl St Louis (STL)
Cleveland–Hopkins Intl Cleveland (CLE)
Norman Y Mineta San Jose Intl San Jose (SJC)
Memphis Intl Memphis (MEM)
Luis Munoz Marin Intl San Juan (SJU)
Kansas City Intl Kansas City (MCI)
Louis Armstrong New Orleans Intl Metairie (MSY)
Sacramento Intl Sacramento (SMF)
John Wayne Airport—Orange County Santa Ana (SNA)
Raleigh–Durham Intl Raleigh (RDU)
Nashville Intl Nashville (BNA)
Indianapolis Intl Indianapolis (IND)
William P Hobby Houston (HOU)
Austin–Bergstrom Intl Austin (AUS)
San Antonio Intl San Antonio (SAT)
Bradley Intl Windsor Locks (BDL)
Ontario Intl Ontario (ONT)
Palm Beach Intl West Palm Beach (PBI)
General Mitchell Intl Milwaukee (MKE)
Southwest Florida Intl Fort Myers (RSW)
Albuquerque Intl Sunport Albuquerque (ABQ)
Port Columbus Intl Columbus (CMH)
Dallas Love Field Dallas (DAL)
Theodore Francis Green State Warwick (PVD)
Kahului Kahului (OGG)
Jacksonville Intl Jacksonville (JAX)
Reno/Tahoe Intl Reno (RNO)
Bob Hope Burbank (BUR)
Ted Stevens Anchorage Intl Anchorage (ANC)
Buffalo Niagara Intl Buffalo (BUF)
Manchester Manchester (MHT)
Eppley Airfield Omaha (OMA)
Norfolk Intl Norfolk (ORF)
Tucson Intl Tucson (TUS)

[1] (See § 70.4).

2. Part 71 is revised to read as follows:

PART 71—FOREIGN AND POSSESSIONS QUARANTINE

Subpart A—General Provisions

Sec.

Authority: 42 U.S.C. 243, 248, 249, and 264–272.

Subpart A—General Provisions

§ 71.1 Scope and definitions.

(a) The purpose of this part is to prevent the introduction, transmission, and spread of communicable disease from foreign countries into the United States. This part also contains the regulations to prevent the spread of communicable disease among possessions of the United States or from a possession into a State. Regulations to prevent the interstate spread of communicable diseases are contained in 42 CFR part 70.

(b) As used in this part, the terms listed below in alphabetical order shall have the following meanings:

Airline means any air carrier, foreign or domestic, operating commercial passenger flights under regular schedules arriving in or departing from the United States.

Airline agent means any person who is authorized to act for or in place of the owner or operator of an airline for purposes of carrying out the airline's responsibilities described in this part.

Business day means any full business day during which the Centers for Disease Control and Prevention is open for regular business (excluding Saturdays, Sundays, and legal holidays) from 9 a.m. in the morning to 5 p.m. in the evening, Eastern Standard Time.

Bill of Health means a document, in a form prescribed by the Director, setting forth the sanitary history and condition of a carrier or the port from which the carrier departs and stating that the carrier has in all respects complied with the regulations prescribed in this part.

Carrier means a ship, shipline, vessel, aircraft, airline, train, road vehicle, or other means of transport, including military carriers.

Commander means any person serving on an aircraft or ship with responsibility for its operation and navigation.

Communicable disease means an illness due to a specific infectious agent or its toxic products which arises through transmission of that agent or its products from an infected person or animal or a reservoir to a susceptible host, either directly or indirectly through an intermediate animal host, vector, or the inanimate environment.

Controlled free pratique means permission for a carrier to enter a U.S. port, disembark, and begin operation under certain stipulated conditions.

Detention when applied to carriers, animals, articles, or things means the temporary holding on a voluntary or involuntary basis of such carriers, animals, articles, or things, until the completion of such sanitary measures as may be required under this part.

Director means the Director, Centers for Disease Control and Prevention, Department of Health and Human Services or another authorized representative as approved by the Director or the Secretary.

Disinfection means the killing of infectious agents or inactivation of their toxic products outside the body of a person or on the surface of a thing by direct exposure to chemical or physical agents.

Disinfestation means any chemical or physical process serving to destroy or remove undesired small animal forms, particularly arthropods or rodents.

Disinsection means the operation in which measures are taken to kill the insect vectors of human disease.

Educational purpose means use in the teaching of a defined educational program at the university level or equivalent.

Exhibition purpose means use as a part of a display in a facility comparable to a zoological park or in a trained animal act. The animal display must be open to the general public at routinely scheduled hours on 5 or more days of each week. The trained animal act must be routinely scheduled for multiple performances each week and open to the general public except for reasonable vacation and retraining periods.

Emergency contact information means the following information pertaining to a person (other than the passenger or crewmember) or an entity (such as a business) that has the ability to contact the passenger or crewmember on an emergency basis:

(i) The full name (first, last, middle initial, suffix) of the person or business name of the entity;

(ii) The permanent address; and

(iii) A phone number (either home, work, or mobile).

Flight information means for each airline operating a flight on an international voyage destined for a U.S. port (including any intermediate stops between the flight's origin and final destination) the airline name, flight number, city of arrival, date of arrival, date of departure, seat number for any passenger or crewmember, arrival gate, and arrival terminal.

Hearing officer means a person designated by the Director or the Secretary to conduct administrative hearings under this part or another authorized representative as approved by the Director or the Secretary.

Ill person means a person who:

(i) Has a temperature of 100.4 °F (or 38 °C) or greater accompanied by one or more of the following: rash, swelling of the lymph nodes or glands, headache with neck stiffness, or changes in level of consciousness or cognitive function; or

(ii) Has a temperature of 100.4 °F (or 38 °C) or greater that has persisted for more than 48 hours; or

(iii) Has diarrhea, defined as the occurrence in a 24-hour period of three or more loose stools or of stools in an amount greater than normal (for the person); or

(iv) Has one or more of the following: severe bleeding, jaundice, or severe, persistent cough accompanied by bloody sputum, respiratory distress; or a temperature of 100.4 °F (or 38 °C) or greater; or

(v) Displays other symptoms or factors that are suggestive of communicable disease, which the Director may describe in an order as the Director determines necessary.

Infectious agent means an organism (*e.g.,* bacteria, fungus, helminth, prion, protozoan, rickettsia, virus, or bioengineered variant thereof) that is capable of producing infection or infectious disease.

International health regulations means the International Health Regulations of the World Health Organization, adopted by the Fifty-Eighth World Health Assembly in 2005, and as may be further amended and ratified by the United States.

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 such person begins his/her voyage.

Medical monitoring means close medical or other supervision of a person or group of persons on a voluntary or involuntary basis to permit prompt recognition of infection or illness.

Military services means the U.S. Air Force, U.S. Army, the U.S. Coast Guard, the U.S. Marine Corps, the U.S. Navy, and any National Defense Reserve Fleet vessels engaged in military operations at the direction of the Department of Defense.

Possession means, in addition to Puerto Rico, any other possession of the United States.

Provisional quarantine means the detention on an involuntary basis of an arriving person or group of arriving persons reasonably believed to be infected with or exposed to a quarantinable disease until a quarantine order has been issued or until the Director determines that provisional quarantine is no longer warranted.

Public health emergency, as used in this part, means

(i) Any disease event as determined by the Director with either documented or significant potential for regional, national, or international disease spread or with actual or potential interference with the free movement of people or goods between States and possessions within the United States or other countries or sovereignties; or

(ii) Any disease event designated as a public health emergency by the Secretary pursuant to section 319(a) of the Public Health Service Act (42 U.S.C. 247d(a)).

Quarantine means the holding on a voluntary or involuntary basis, including the isolation, of a person or group of persons in such place and for such period of time as the Director deems necessary to prevent the spread of infection or illness.

Quarantinable disease means any of the communicable diseases listed in an Executive Order, as provided under section 361 of the Public Health Service Act. Executive Order 13295, of April 4, 2003, as amended by Executive Order 13375 of April 1, 2005, contains the current revised list of quarantinable diseases, and may be obtained at *http://www.cdc.gov* and *http://www.archives.gov/federal_register.* If this Order is amended, HHS will enforce that amended order immediately and update that Web site.

Sanitary measures means:

(i) When applied to carriers, animals, articles, or things: Detention; destruction of animals, articles, or things that the Director deems to be sources of dangerous infection to human beings; disinfection; disinfestations; disinsection; export; fumigation; pest extermination; seizure; or any other measure or combination of measures whether voluntary or involuntary that the Director deems necessary to prevent the introduction, transmission, or spread of communicable diseases; or

(ii) When applied to a person or group of persons, the killing of infectious agents (or vectors capable of conveying infectious agents) outside the body by direct exposure to any chemical, physical, or other process designed to destroy such infectious agents.

Scientific purpose means use for scientific research following a defined protocol and other standards for research projects as normally conducted at the university level. The term also includes the use for safety testing, potency testing, and other activities related to the production of medical products.

Ship means any ship commercially operated by a shipline, regardless of an individual ship's flag or registry or the shipline's principal place of business, that carries passengers or cargo under regular schedules arriving in or departing from the United States, but does not include ships that operate between Canadian ports and ports on Puget Sound or on the Great Lakes and connected waterways.

Ship Sanitation Control Certificate means a certificate issued under the instructions of the Director, in the form prescribed by the International Health Regulations, unless the Director determines otherwise, recording the evidence of a public health risk found on board during an inspection and the successful completion of any sanitary measures taken.

Ship Sanitation Control Exemption Certificate means a certificate issued under the instructions of the Director, in the form prescribed by the International Health Regulations, unless the Director determines otherwise, recording that the ship had been inspected and found to be free of infection and contamination, including vectors and reservoirs.

Shipline means any shipline operating ships commercially, regardless of an individual ship's flag or registry or the shipline's principal place of business, carrying passengers or cargo under regular schedules arriving in or departing from the United States.

Shipline's agent means any person who is authorized to act for or in place of the owner or operator of a ship for the purposes of carrying out the shipline's responsibilities described in this part.

State means, in addition to the several States, only the District of Columbia.

U.S. port means any seaport, airport, or border crossing point under the control of the United States.

United States means the States and possessions of the United States.

Vector means an animal (including insects) or thing which conveys or is capable of conveying infectious agents from a person or animal to another person or animal.

§ 71.2 Designation of yellow fever vaccination centers; Yellow fever or other validation stamps.

(a) *Designation of yellow fever vaccination centers.* (1) The Director is responsible for the designation of yellow fever vaccination centers authorized to issue certificates of vaccination. This responsibility may be delegated by the Director to the health department of a State or possession, with their consent, with respect to yellow fever vaccination activities of non-Federal medical, public health facilities, and licensed physicians functioning within the respective jurisdictions of a health department of a State or possession. Designation may be made upon application and presentation of evidence satisfactory to a health department of a State or possession to whom such responsibility has been delegated by the Director that the applicant has adequate facilities and professionally trained personnel for the handling, storage, and administration of a safe, potent, and pure yellow fever vaccine. Medical facilities of Federal agencies are authorized to obtain yellow fever vaccine without being designated as a yellow fever vaccination center by the Director, but shall comply with instructions issued by the Director for the administration, handling, monitoring, recordkeeping, and storage of yellow fever vaccine.

(2) A designated yellow fever vaccination center shall comply with instructions issued by the Director or by an officer or employee of a health department of a State or possession to whom such responsibility has been delegated by the Director for the administration, handling, monitoring, recordkeeping, and storage of yellow fever vaccine. If a designated center fails to comply with such instruction, after notice to such center, the Director or, for non-Federal centers, a health department of a State or possession may revoke designation.

(b) *Validation stamps.* International Certificates of Vaccination against yellow fever issued for vaccinations performed in the United States and other validation stamps as required by the Director shall be validated by:

(1) The Seal of the Public Health Service;

(2) The Seal of the Department of State;

(3) The stamp of the Department of Defense;

(4) The stamp issued to the National Aeronautics and Space Administration;

(5) The stamp issued by the health department of a State or possession to whom such responsibility has been delegated by the Director; or

(6) An official stamp of a design and size approved by the Director for such purpose.

(c) When authorized by the Director, certificates of vaccination and validation stamps may be issued and authenticated by electronic means.

§ 71.3 Vaccination clinics.

(a) The Director may establish vaccination clinics, through contract or otherwise, authorized to issue certificates of vaccination and administer vaccines and/or other prophylaxis.

(b) A vaccination clinic established by the Director shall collect and maintain, for such time as determined by the Director, the following information from vaccine recipients:

(1) Gender;

(2) Age;

(3) Vaccination date;

(4) Vaccine lot number;

(5) Prior vaccinations;

(6) Reason for vaccination (*e.g.*, post-exposure, pre-exposure, member of high risk group, general vaccination);

(7) Concurrent vaccinations;

(8) Vaccine Adverse Events Reporting System Report/Adverse Event Report Number; and

(9) Verification that the vaccine conferred immunity (if applicable).

(c) In addition to the requirements in paragraph (b) of this section, a vaccination clinic established by the Director shall comply with such additional recordkeeping requirements and other instructions that the Director may issue for the safe administration, handling, monitoring, and storage of vaccines.

(d) In the event of a public health emergency, the Director may waive or modify any of the requirements in paragraph (b) of this section.

(e) When authorized by the Director, certificates of vaccination and validation stamps may be issued and authenticated by electronic means.

§ 71.4 Bills of health.

The Director, to the extent permitted by law and in consultation with such other federal agencies as the Director may deem necessary, may require a carrier at any foreign port clearing or departing for any U.S port to obtain or deliver a bill of health from a United States consular or medical officer designated for such purpose.

§ 71.5 Suspension of entries and imports from designated places.

Whenever the Director determines that by reason of the existence of any communicable disease in a foreign country there is serious danger of the introduction of such disease in the United States, and that this danger is so increased by the introduction of persons or property from such country that a suspension of the right to introduce such persons or property is required in the interest of the public health, the Director, to the extent permitted by law and in consultation with such other federal agencies as the Director may deem necessary, may prohibit, in whole or in part, the introduction of persons and property from such countries or places for such period of time as the Director may designate through order.

§ 71.6 Report of death or illness on board flights.

(a) Any airline operating flights on an international voyage destined for a U.S. port shall, pursuant to the written plan required under § 71.7, report any deaths or ill persons that occur on board to the Director as soon as such occurrences are made known to the aircraft commander and, where possible, at least one hour before arrival.

(b) The Director may order airlines operating flights on an international voyage destined for a U.S. port to disseminate to passengers and crew public health notices, recommended public health measures, and other information that the Director deems necessary for the purposes of preventing the introduction, transmission, or spread of communicable diseases. Such information shall be disseminated at the time and in a manner specified in the Director's order.

(c) The provisions of paragraphs (a) and (b) of this section shall also apply to airlines operating flights on an international voyage between airports of a possession and a State of the United States or among possessions of the United States.

§ 71.7 Written plan for reporting of deaths or illness on board flights and designation of an airline agent.

(a) Within 90 days of the final publication of this rule, any airline operating flights on an international voyage destined for a U.S. port shall develop a written plan sufficient to ensure the reporting of any deaths or ill persons on board flights as required by § 71.6.

(b) The written plan shall include the full name (*i.e.*, first, last, middle initial, suffix), official title, business telephone number, and e-mail address (if available), of an airline agent who shall serve as a point of contact between the Director and the airline concerning reports of deaths or ill persons on board flights.

(c) The written plan shall include policies and procedures necessary to facilitate communication between the Director and the airline agent on a 24-hour basis, 7 days a week.

(d) Within 90 days of final publication of this rule, copy of the written plan shall be submitted to the Director.

(e) Airlines shall implement the written plan within 180 days of the final publication of this rule.

(f) Airlines shall review the written plan one year after implementation and annually thereafter. The review shall include drills or exercises to test and evaluate the effectiveness of the written plan unless the airline has reported any deaths or ill persons on board under § 71.6 in the prior 365 days. Airlines shall revise the plan as necessary after any review. Any revisions of the written plan shall be submitted to the Director within 60 days.

(g) Airlines that intend to commence operations after the effective date in paragraph (a) shall submit a written plan meeting the requirements of this section to the Director before commencing operations. The airline shall implement the written plan by the later of the following dates: either 180 days after the publication of the final rule, or upon commencement of operations.

(h) The provisions of paragraphs (a) through (g) of this section shall also apply to airlines operating flights on an international voyage between airports of a possession and a State of the United States or among possessions of the United States.

§ 71.8 Report of death or illness on board ships.

(a) Any shipline operating ships on an international voyage destined for a U.S. port shall report to the quarantine station or to another authorized representative of the Director, at or nearest the port at which the ship will arrive, the occurrence, on board, of any death or any ill person among passengers or crew as soon as such occurrences are made known to the ship's commander and, where possible, at least 24 hours before arrival.

(b) In addition to paragraph (a) of this section, the shipline, shall also report any death or any ill person among passengers or crew (including those who have disembarked or have been removed) on board ships during the 15-day period preceding the date of expected arrival at a U.S. port or during the period since departure from a U.S. port (whichever period of time is shorter).

(c) Any shipline operating ships traveling from one U.S. port to another while on an international voyage shall report immediately to the quarantine station or other authorized representative at the next port of call, station, or stop, the occurrence of any case or suspected case of a communicable disease and shall take such measures to prevent the spread of disease as the Director directs.

(d) Any shipline with ships at a U.S. port shall report immediately to the quarantine station or other authorized representative at or nearest the port the occurrence, on board, of any death or any ill person among passengers or crew during stays in port.

(e) In addition to paragraphs (a) through (d) of this section, the shipline must report to the quarantine station or other authorized representative 24 hours before a ship's arrival the number of cases (including zero) of diarrhea, febrile respiratory disease, febrile rash illness, or febrile neurologic illness in passengers and crew recorded in the ship's medical log during the current cruise. All cases of diarrhea that occur after the 24-hour report must also be reported at least 4 hours before arrival.

(f) The Director for purposes of preventing the introduction, transmission, or spread of communicable diseases may order shiplines operating ships on an international voyage destined for a U.S. port to disseminate to passengers and crew public health notices, recommended public health measures, and other public health information. Such information shall be disseminated at the time and in a manner specified in the Director's order.

(g) The provisions of paragraphs (a) through (f) of this section shall additionally apply to shiplines operating ships traveling between a possession and a State of the United States or among possessions of the United States.

§ 71.9 Written plan for reporting of deaths or illness on board ships and designation of a shipline's agent.

(a) Within 90 days of the final publication of this rule, any shipline operating ships on an international voyage destined for a U.S. port shall develop a written plan sufficient to ensure the reporting of any deaths or ill persons as required by § 71.8.

(b) The written plan shall include the full name (i.e., first, last, middle initial, suffix), official title, business telephone number, and e-mail address (if available), of a shipline's agent who shall serve as a point of contact between the Director and the shipline concerning reports of deaths or ill persons on board ships.

(c) The written plan shall include policies and procedures necessary to facilitate communication between the Director and the shipline's agent on a 24-hour basis, 7 days a week.

(d) A copy of the written plan shall be submitted to the Director.

(e) Within 90 days of the final publication of this rule, shiplines shall implement the written plan.

(f) Shiplines shall review the written plan one year after implementation and annually thereafter. The review shall include drills or exercises to test and evaluate the effectiveness of the written plan unless the shipline has reported any deaths or ill passengers under § 71.8 in the prior 365 days. Shiplines shall revise the plan as necessary after any review. Any revisions of the written plan shall be submitted to the Director within 60 days.

(g) Shiplines that intend to commence operations after the effective date in paragraph (a) of this section shall submit a written plan meeting the requirements of this section to the Director before commencing operations. The shipline shall implement a written plan by the later of the following dates: either 180 days after final publication of this rule, or upon commencement of operations.

(h) The provisions of paragraphs (a) through (g) of this section shall also apply to shiplines operating ships on an international voyage between ports of a possession of the United States or between ports of a possession and a State of the United States.

§ 71.10 Passenger information.

(a) Any airline operating flights or shipline operating ships on an international voyage destined for a U.S. port shall, pursuant to the written plan approved under § 71.11, solicit from each passenger (or head of household if traveling with a minor) and crewmember traveling on an international voyage destined for a U.S. port the information contained in the data fields specified in paragraph (e) of this section.

(b) Any information obtained by the airline or shipline pursuant to paragraph (a) of this section shall be maintained by the airline or shipline for 60 days from the end of the voyage.

(c) For each passenger (or head of household if traveling with a minor) and crewmember traveling on an international voyage destined for a U.S. port, the airline or shipline may solicit the information in paragraph (e) of this section from such person's authorized agent.

(d) Within 12 hours of a request by the Director to the airline's or shipline's agent, the airline or shipline, pursuant to the written plan approved under § 71.11, shall transmit to the Director in an electronic format the data fields specified in paragraph (e) of this section.

(e) The data fields, as applicable to the individual passenger (or head of household if traveling with a minor) or crew member, shall include the following:

(1) Full name (first, last, middle initial, suffix);

(2) Emergency contact information;

(3) E-mail address;

(4) Current home address (street, apartment #, city, state/province, postal code);

(5) Passport number or travel document number, including the issuing country or organization;

(6) Name of traveling companions or group;

(7) Flight information or ports of call;

(8) Returning flight (date, airline number, and flight number) or returning ports of call; and

(9) At least one of the following current phone numbers in order of preference: mobile, home, pager, or work.

(f) In addition to data fields specified in paragraph (e) of this section, when necessary to prevent the introduction, transmission, or spread of communicable diseases, the Director through order may also require that airlines or shiplines transmit additional information in the airline's or shipline's possession.

(g) The provisions of paragraphs (a) through (f) of this section shall also apply to airlines operating flights and shiplines operating ships on an international voyage between ports of a possession of the United States or between ports of a possession and a State of the United States.

(h) Information collected solely in order to comply with this regulation may only be used for the purposes for which it is collected.

(i) Airlines operating flights and shiplines operating ships on an international voyage destined for a U.S. port shall ensure that passengers are informed of the purposes of this information collection at the time passengers arrange their travel.

§ 71.11 Written plan for passenger information and designation of an airline or shipline agent.

(a) Within six months of the final publication of this rule, any airline operating flights or shipline operating ships on an international voyage destined for a U.S. port shall develop a written plan sufficient to ensure electronic transmission of passenger and crew information as required by § 71.10.

(b) The written plan shall include:

(1) Policies and procedures for the transmission of data in an electronic format available to the airline or shipline and CDC using industry standards for data encoding, transmission, and security, within 12 hours of a request by the Director to the airline's or shipline's agent;

(2) The full name (i.e., first, last, middle initial, suffix), official title, business telephone number, and e-mail address (if available), of an airline agent or shipline agent who shall serve as a point of contact between the Director and the airline or shipline concerning requests for and transmission of passenger and crew manifest data;

(3) Policies and procedures necessary to facilitate communication between the Director and the airline's or shipline's agent on a 24-hour basis, 7 days a week;

(4) Policies and procedures for soliciting the information contained in the data fields required by § 71.10 from the passenger (or head of household if traveling with a minor), crewmember, or such persons' authorized agent; and

(5) Policies and procedures for maintaining responsive information obtained by the airline or shipline in an electronic database for 60 days from the end of the voyage as required by § 71.10.

(c) Within 180 days of final publication of this rule, a copy of the written plan shall be submitted to the Director.

(d) Airlines and shiplines shall implement the written plan within 2 years of the final publication of this rule. Within 60 days of submission, airlines and shiplines shall conduct drills or exercises to test and evaluate the effectiveness of the written plan and revise the plan as necessary after any drill or exercise. Any revisions to the written plan shall be submitted to the Director within 60 days.

(e) Airlines and shiplines shall review the written plan one year after implementation and annually thereafter. The review shall include drills or exercises to test and evaluate the effectiveness of the written plan unless the airline or shipline has transmitted passenger and crewmember information under § 71.10 in the prior 365 days. Airlines shall revise the plan as necessary after any review. Any revisions of the written plan shall be submitted to the Director within 60 days.

(f) Airlines and shiplines that intend to commence operations after the effective date in paragraph (a) of this section shall submit a written plan meeting the requirements of this section to the Director before commencing operations. The airline or shipline shall implement the written plan by the later of the following dates: either 2 years after the final publication of this rule, or upon commencement of operations.

(g) Pending the development or implementation of the written plan as required by this section, the Director, through order, may require that airlines and shiplines transmit to the Director, in a format available to both the airline or shipline and the Director, any of the information required by § 71.10 that may be in the airline's or shipline's possession.

(h) The provisions of paragraphs (a) through (g) of this section shall also apply to airlines operating flights and shiplines operating ships on an international voyage between ports of a possession of the United States or between ports of a possession and a State of the United States.

§ 71.12 Inspections.

(a) Carriers arriving at a U.S. port from a foreign country or on an international voyage in traffic between U.S. ports are subject to detention and inspection to determine the existence of any rodent, insect, or other vermin infestation, contaminated food or water, or other unsanitary conditions, that may require sanitary measures for the prevention of the introduction, transmission, or spread of communicable disease.

(b) The Director may detain and inspect a carrier arriving at a U.S. port from a foreign country when the Director determines that a threat of introduction, transmission, or spread of communicable disease into the United States exists, as may occur, for instance, when the carrier has on board ill persons.

(c) Carriers on an international voyage that are in traffic between U.S. ports shall be subject to detention and inspection when there occurs on board, among passengers or crew, any death, or when there is any ill person, or when the Director reasonably believes that illness may be caused by unsanitary conditions.

(d) The provisions of paragraphs (a) through (c) of this section shall additionally apply to carriers traveling between a possession and State or among possessions of the United States.

§ 71.13 Sanitary measures.

(a) Whenever the Director reasonably believes that any carrier arriving at a U.S. port from a foreign country or on an international voyage in traffic between U.S. ports or animal, article, or thing on board the carrier is or may be infected or contaminated with a communicable disease, the Director may, in consultation with such other federal agencies as appropriate:

(1) Inspect the carrier, animal, article, or thing on board the carrier, and/or

(2) Order the carrier, or other entity specified in the order, to apply such sanitary measures as the Director deems necessary to prevent the introduction, transmission, or spread of communicable diseases.

(b) CDC shall not bear the expense of any sanitary measures required or ordered by the Director. The carrier or other entity specified in the order issued pursuant to 71.13(a) shall bear the responsibility for the application of such measures.

(c) Sections 71.13(a) and 71.13(b) shall not preclude any entity ordered to conduct sanitary measures pursuant to § 71.13(b) from arranging to have such measures conducted by other entities through contractual or other arrangements, or from seeking reimbursement for any costs associated with sanitary measures through contractual or other arrangements.

(d) The Director may apply such sanitary measures to persons who have not been infected with or exposed to a quarantinable disease, upon their consent, as may be required to destroy the presence of infectious agents or vectors.

§ 71.14 Detention of carriers.

(a) The Director, in consultation with such other federal agencies as the Director deems necessary, may require detention of a carrier and all things onboard the carrier until the completion of the measures outlined in this part that the Director determines to be necessary to prevent the introduction, transmission, or spread of communicable diseases.

(b) The owner of the carrier shall bear any expenses relating to the detention of the carrier; or, in the case of animals, articles, or things on board the carrier, such expense shall be borne by the owners thereof.

(c) Director may issue a controlled free pratique to the carrier stipulating what sanitary measures are to be met, but such issuance does not prevent the periodic boarding of a carrier and the inspection of persons and records to verify that the conditions have been met for granting the pratique.

§ 71.15 Carriers of U.S. military services.

(a) Carriers belonging to or operated by the military services of the United States may be exempted from detention and inspection if the Director is satisfied that they have complied with regulations of the military services which also meet the requirements of the regulations in this part. (For applicable regulations of the military services, see Army Regulation No. 40–12, Air Force Regulation No. 161–4, Secretary of the Navy Instruction 6210.2, and Coast Guard Commandant Instruction 6210.2).

(b) Notwithstanding exemption from detention and inspection of carriers under this section, animals, articles, or things on board shall be required to comply with the applicable requirements of subpart B of this part.

§ 71.16 Screenings to detect ill persons.

The Director may at U.S. ports or other locations, conduct screenings of persons or group of persons to detect the presence of ill persons. Such screenings may be conducted through visual inspection, electronic temperature monitors, or other means determined appropriate by the Director to detect the presence of ill persons.

§ 71.17 Provisional quarantine of arriving persons.

(a) The Director may provisionally quarantine an arriving person or group of arriving persons who the Director reasonably believes to be infected with or exposed to a quarantinable disease.

(b) Provisional quarantine shall commence upon:

(1) The service of a written provisional quarantine order;

(2) A verbal provisional quarantine order; or

(3) Actual movement restrictions placed on the person or group of persons.

(c) Provisional quarantine shall end three business days after provisional quarantine commences, except that the person or group of persons shall be released earlier if the Director determines that provisional quarantine is no longer warranted.

(d) In the event that the Director determines that it is necessary to provisionally quarantine a person or group of persons beyond three business days, then the Director shall serve the person or group of persons with a written quarantine order in accordance with this part.

(e) A person or group of persons subject to provisional quarantine may be offered medical treatment, prophylaxis, or vaccination, as the Director deems necessary to prevent the transmission or spread of the disease; such persons may refuse such medical treatment, prophylaxis, or vaccination, but remain subject to provisional quarantine.

(f) Nothing in this section shall be construed to limit the Director's ability to detain a person or group of persons on a voluntary basis or offer such persons medical treatment, prophylaxis, or vaccination on a voluntary basis.

§ 71.18 Provisional quarantine orders.

(a) Provisional quarantine orders shall be served by the Director at the time that provisional quarantine commences or as soon thereafter as the circumstances reasonably permit either through personal service or, in circumstances where the Director deems it necessary or desirable, by posting or publishing the order in a conspicuous location.

(b) In circumstances where the Director deems public posting or publishing necessary, the Director may omit the names and/or identities of persons and take other measures respecting the privacy of persons.

(c) The provisional quarantine order shall be in writing, signed by the Director, and include the following information:

(1) A statement setting forth the Director's reasonable belief that the arriving person or group of arriving persons is infected with or exposed to a quarantinable disease based on information available to the Director at the time, such as travel history, clinical manifestations, and any other evidence of infection or exposure;

(2) The suspected quarantinable disease;

(3) A statement advising the arriving person or group of arriving persons that they may be placed under provisional quarantine for three business days and that at the end of such period they shall be released or, if determined by the Director, served with a quarantine order;

(4) A statement advising the person or group of persons that they shall be released earlier if the Director determines that provisional quarantine is no longer warranted;

(5) The location of provisional quarantine;

(d) When authorized by the Director, provisional quarantine orders may be issued and signed by electronic means.

§ 71.19 Quarantine.

(a) The Director may issue a quarantine order whenever the Director reasonably believes that an arriving person or group of arriving persons is infected with or exposed to a quarantinable disease based on, but not limited to, any of the following: clinical manifestations, diagnostic tests or other medical tests, epidemiologic information, laboratory tests, physical examination, or other evidence of exposure or infection;

(b) In accordance with the Director's quarantine order, the Director may offer medical treatment, prophylaxis, or vaccination, as the Director deems necessary to prevent the transmission or spread of the disease.

(c) Persons offered treatment, prophylaxis, or vaccination may refuse, but remain subject to quarantine.

(d) The Director's quarantine order may include the quarantine of an arriving person or group of arriving persons who refuse examination, medical treatment, prophylaxis, or vaccination, or for whom the Director determines that such examination, medical treatment, prophylaxis, or vaccination is medically contra-indicated or not reasonably available.

(e) The length of quarantine shall not exceed the period of incubation and communicability, as determined by the Director, for the quarantinable disease.

(f) Nothing in this section shall be construed to limit the Director's ability to quarantine a person or group of persons on a voluntary basis.

§ 71.20 Content of quarantine order.

(a) Quarantine orders shall be in writing, signed by the Director, and contain the following:

(1) The identity of the arriving person or group of arriving persons to be quarantined;

(2) The location where the arriving person or group of arriving persons will be quarantined;

(3) The date and time at which quarantine commences and ends;

(4) The suspected quarantinable disease;

(5) A statement that the Director reasonably believes that the arriving person or group of arriving persons are infected with or exposed to a quarantinable disease;

(6) A statement regarding the basis for the Director's reasonable belief that the arriving person or group of arriving persons are infected with or exposed to a quarantinable disease, e.g., clinical manifestations, physical examination, laboratory tests, diagnostic tests or other medical tests, epidemiologic information, or other evidence of exposure or infection;

(7) A statement that the arriving person or group of arriving persons shall comply with conditions of quarantine, including, but not limited to examination, medical monitoring, medical treatment, prophylaxis, or vaccination, or other conditions of quarantine deemed by the Director to be necessary to prevent the transmission or spread of communicable disease;

(8) A statement that persons may refuse examination, medical monitoring, medical treatment, prophylaxis, or vaccination, but that such persons remain subject to quarantine; and

(9) A statement that persons under quarantine, any time while the quarantine order is in effect, may request that the Director hold a hearing to review the quarantine order.

(b) When authorized by the Director, quarantine orders may be issued and signed by electronic means.

§ 71.21 Service of quarantine order.

(a) A copy of the quarantine order shall be personally served on the person or group of persons at the time that quarantine commences or as soon thereafter as the Director determines that the circumstances reasonably permit.

(b) In circumstances where the Director deems it necessary or desirable, the quarantine order may be posted or published in a conspicuous location, except that the Director may omit the names and/or identities of persons and take other measures respecting the privacy of persons.

§ 71.22 Medical examination and monitoring.

(a) The Director may order medical examination or monitoring of an arriving person or group of arriving persons that the Director reasonably believes to be infected with or exposed to a quarantinable disease.

(b) Arriving persons subject to medical examination or monitoring shall provide the Director with such information as the Director may order, including, but not limited to, familial and social contacts, travel itinerary, medical history, place of work, and vaccination status.

(c) Arriving persons subject to medical monitoring shall report for such further medical examinations and comply with other conditions of monitoring as the Director orders.

(d) Arriving persons may refuse medical examination or monitoring, but remain subject to provisional quarantine or quarantine provided that if quarantined such persons may request a hearing in accordance with § 71.23.

(e) Nothing in this section shall be construed to limit the Director's ability to conduct medical examinations or place arriving persons under medical monitoring on a voluntary basis or from engaging in other methods of voluntary disease surveillance.

§ 71.23 Hearings.

(a) Upon the request of an arriving person or group of arriving persons under quarantine, at any time while the quarantine order is in effect, the Director shall hold a hearing to review the quarantine order within one business day of the request.

(b) Requests for a hearing by the person or groups of persons under quarantine shall be limited to genuine and substantial issues of fact in dispute.

(c) The Director shall provide notice of the hearing to the arriving person or group of arriving persons under quarantine through any method that the Director determines to be reasonably designed to notify the person or group of persons that such a hearing has been scheduled.

(d) The Director shall designate a hearing officer to review the medical or other evidence of exposure or infection available to the Director and make findings as to which arriving person or group of arriving persons are infected with or exposed to a quarantinable disease and recommendations concerning which arriving person or group of arriving persons should be released or remain in quarantine.

(e) An arriving person or group of arriving persons in quarantine may authorize a representative to submit evidence concerning whether the person or group is infected with or exposed to a quarantinable disease;

(f) The Director shall take such measures that the Director determines to be reasonably necessary to allow an arriving person or group of arriving persons in quarantine to communicate with their authorized representatives. Such measures, for example, may include the establishment of video-conferencing facilities, e-mail terminals, telephone or cellular phone services, and other similar devices or technologies.

(g) The hearing officer may order a medical examination of the arriving person or group of arriving persons in quarantine when, in the hearing officer's judgment, such a medical examination would be necessary or desirable for a determination of whether the arriving person or group of arriving persons are infected with or exposed to a quarantinable disease, provided that such arriving persons may refuse such examination.

(h) The hearing officer shall, based upon his or her review of the evidence of exposure or infection made available to the hearing officer, make findings and a written recommendation to the Director as to which, if any, arriving person or group of arriving persons should be released or remain in quarantine.

(i) The Director, based upon the hearing officer's findings and written recommendation the administrative record shall within one business day after the conclusion of the hearing order the release or continued quarantine of the arriving person or group of arriving persons in quarantine.

(j) The Director may issue additional instructions and guidelines as the Director deems necessary governing the conduct of hearings.

(k) The quarantine order shall be deemed final either when the Director has accepted or rejected the hearing officer's written recommendation or three business days after the request for a hearing, whichever comes first.

§ 71.24 Care and treatment of arriving persons.

(a) Arriving persons subject to medical examination and monitoring, provisional quarantine, or quarantine in accordance with this part may receive care and treatment at the expense of the Director subject to paragraphs (b) through (f) of this section.

(b) Payment for such expenses shall be in the Director's sole discretion and subject to the availability of appropriations.

(c) Any payment of expenses 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 only be paid by the Director after all third-party payers have made payment in satisfaction of their obligations.

(d) Payment shall be limited to those amounts the hospital or medical facility would customarily bill the Medicare system using the International Classification of Diseases, Clinical Modification (ICD–CM), and relevant federal regulations promulgated by the Centers for Medicare and Medicaid Services in existence at the time of billing.

(e) For quarantinable diseases, payment shall be limited to costs for services and items reasonable and necessary for the care and treatment of the person for the time period that begins when the Director refers the person to the hospital or medical facility and ends when, as determined by the Director, the period of provisional quarantine or quarantine expires.

(f) For diseases other than those described in paragraph (e) of this section, such payment shall be limited to costs for services and items reasonable and necessary for care and treatment of the person for the time period that begins when the Director refers the person to the hospital or medical facility and ends when the person's condition is diagnosed, as determined by the Director, with a non-quarantinable disease.

§ 71.25 Arriving foreign nationals.

(a) The Director, in consultation with the U.S. Department of State as may be necessary, shall advise an arriving foreign national under provisional quarantine or quarantine of such person's right to have the Director notify the consular post of the foreign state of such person's provisional quarantine or quarantine and to have any communications forwarded to the consular post without delay. In circumstances where required by international legal obligation, the Director shall, in consultation with the U.S. Department of State as may be necessary, directly notify the consular post of the foreign state of its arriving foreign nationals' provisional quarantine or quarantine.

(b) When requested by the consular officer of the foreign state and in a manner that the Director determines to be practicable, the Director, in consultation with the U.S. Department of State as may be necessary, shall allow the consular officer to have access to the foreign national under provisional quarantine or quarantine for purposes of conversing and corresponding with the foreign national and arranging for the foreign national's legal representation.

(c) Any foreign national subject to provisional quarantine or quarantine shall have the same rights as provided for other arriving persons subject to provisional quarantine or quarantine elsewhere in this part.

§ 71.26 Administrative record.

A person's administrative record shall, where applicable, consist of the provisional quarantine and/or quarantine order, and any medical, laboratory, epidemiologic, or other information in support thereof, evidence submitted by the person under provisional quarantine and/or quarantine, written findings and recommendation of the hearing officer, and hearing transcript, if any, or summary notes of the proceeding.

§ 71.27 Food, potable water, and waste: U.S. seaports and airports.

(a) Every seaport and airport shall have a supply of potable water from a watering point approved by the Commissioner of Food and Drugs, FDA, in accordance with standards established in 21 CFR parts 1240 and 1250.

(b) All food and potable water taken on board a ship or aircraft at any seaport or airport intended for human consumption thereon shall be obtained from sources approved in accordance with regulations cited in paragraph (a) of this section.

(c) Aircraft inbound or outbound on an international voyage shall not discharge over the United States any excrement, waste water or other polluting materials. Arriving aircraft shall discharge such matter only at servicing areas approved under regulations cited in paragraph (a) of this section.

§ 71.28 Health documents in international traffic.

(a) The Director may perform rodent infestation inspections, when requested by a shipline and at the shipline's own expense, and issue certificates, in a form prescribed by the Director, concerning the absence of rodents and other vermin on board ships.

(b) Unless otherwise determined by the Director, and in accordance with Articles 37 and 38 of the International Health Regulations, as may be further amended and ratified by the United States, the Maritime Declaration of Health and the Health Part of the Aircraft General Declaration, shall not be required as a condition of arrival at a U.S. port.

(c) The Director, upon the request of a shipline, may issue a Ship Sanitation Control Exemption Certificate or a Ship Sanitation Control Certificate, in accordance with Article 39 of the International Health Regulations, as may be further amended and ratified by the United States, or in another format prescribed by the Director.

§ 71.29 Special provisions relating to airports: Office, examination, and quarantine facilities.

(a) Each U.S. airport which receives international traffic shall provide without cost to the Government suitable office, examination, quarantine and other exclusive space for carrying out the Federal responsibilities under this part.

(b) Each U.S. airport which receives international traffic shall identify to the nearest quarantine station or other authorized representative on a yearly basis, or at other intervals as determined by the Director, space which is suitable for the quarantine of an arriving person or group of persons under guidelines or instructions issued by the Director.

§ 71.30 Establishment of institutions, hospitals and stations.

(a) The Director, with the approval of the Secretary, may, from time to time, select sites suitable for, and establish such institutions, hospitals, and stations in the States and possessions of the United States as the Director, with the approval of the Secretary, deems necessary or desirable for carrying out the functions in this part.

(b) The Director may enter into voluntary agreements with public or private institutions as the Director deems necessary or desirable for carrying out the functions in this part.

§ 71.31 Penalties.

Persons in violation of this part are subject to a fine of no more than $250,000 or one year in jail, or both, or as otherwise provided by law. Violations by organizations are subject to a fine of no more than $500,000 per event or as otherwise provided by law.

§ 71.32 Implementation through order.

The Director may implement any of the provisions of this part through order issued and signed by the Director.

§ 71.33 Appeals of actions required pursuant to §§ 71.13 or 71.14.

If the Director requires export or destruction of animals, articles, or things pursuant to § 71.13 or detention of a carrier pursuant to § 71.14, the owner of the animals, articles, or things thereof, or, the carrier owner may appeal. The appeal must be in writing and be submitted to the Director within 2 business days. The appeal must state the reasons for the appeal and show that there is a genuine and substantial issue of fact in dispute. The Director will issue a written response to the appeal, which shall constitute final agency action. This opportunity for an appeal shall not preclude the Director from acting immediately to exercise actions authorized under §§ 71.13 or 71.14.

Subpart B—Importations

§ 71.51 Dogs and cats.

(a) *Definitions.* As used in this section the term:

Cat means all domestic cats.

Confinement means restriction of a dog or cat to a building or other enclosure at a U.S. port, en route to destination and at destination, in isolation from other animals and from persons except for contact necessary for its care or, if the dog or cat is allowed out of the enclosure, muzzling and keeping it on a leash.

Dog means all domestic dogs.

Owner means owner or agent.

Valid rabies vaccination certificate means a certificate which was issued for a dog not less than 3 months of age at the time of vaccination and which:

(1) Identifies a dog on the basis of breed, sex, age, color, markings, and other identifying information.

(2) Specifies a date of rabies vaccination at least 30 days before the date of arrival of the dog at a U.S. port.

(3) Specifies a date of expiration which is after the date of arrival of the dog at a U.S. port. If no date of expiration is specified, then the date of vaccination shall be no more than 12 months before the date of arrival at a U.S. port.

(4) Bears the signature of a licensed veterinarian.

(b) *General requirements for admission of dogs and cats*—(1) Inspection by Director. The Director shall inspect all dogs and cats which arrive at a U.S. port, and admit only those dogs and cats which show no signs of communicable disease as defined in § 71.1.

(2) Examination by veterinarian and confinement of dogs and cats. When, upon inspection, a dog or cat does not appear to be in good health on arrival (e.g., it has symptoms such as emaciation, lesions of the skin, nervous system disturbances, jaundice, or diarrhea), the Director may require prompt confinement and give the owner an opportunity to arrange for a licensed veterinarian to examine the animal and give or arrange for any tests or treatment indicated. The Director will consider the findings of the examination and tests in determining whether or not the dog or cat may have a communicable disease. The owner shall bear the expense of the examination, tests, and treatment. When it is necessary to detain a dog or cat pending determination of its admissibility, the owner shall provide confinement facilities which in the judgment of the Director will afford protection against any communicable disease. The owner shall bear the expense of confinement. Confinement shall be subject to conditions specified by the Director to protect the public health.

(3) *Record of sickness or death of dogs and cats and requirements for exposed animals.* (i) The carrier responsible for the care of dogs and cats shall maintain a record of sickness or death of animals en route to the United States and shall submit the record to the quarantine station at the U.S. port upon arrival. Dogs or cats which have become sick while en route or are dead on arrival shall be separated from other animals as soon as the sickness or death is discovered, and shall be held in confinement pending any necessary examination as determined by the Director.

(ii) When, upon inspection, a dog or cat appears healthy but, during shipment, has been exposed to a sick or dead animal suspected of having a communicable disease, the exposed dog or cat shall be admitted only if examination or tests made on arrival reveal no evidence that the animal may be infected with a communicable disease. The provisions of paragraph (b)(2) of this section shall be applicable to the examination or tests.

(4) *Sanitation.* When the Director finds that the cages or other containers of dogs or cats arriving in the United States are in an insanitary or other condition that may constitute a communicable disease hazard, the dogs or cats shall not be admitted in such containers unless the owner has the containers cleaned and disinfected.

(c) *Rabies vaccination requirements for dogs.* (1) A valid rabies vaccination certificate is required at a U.S. port for admission of a dog unless the owner submits evidence satisfactory to the Director that:

(i) If a dog is less than 6 months of age, it has been only in a country determined by the Director to be rabies-free (a current list of rabies-free countries may be obtained from the Division of Quarantine, Center for Prevention Services, Centers for Disease Control, Atlanta, GA 30333); or

(ii) If a dog is 6 months of age or older, for the 6 months before arrival, it has been only in a country determined by the Director to be rabies-free; or

(iii) The dog is to be taken to a research facility to be used for research purposes and vaccination would interfere with its use for such purposes.

(2) Regardless of the provisions of paragraph (c)(1) of this section, the Director may authorize admission as follows:

(i) If the date of vaccination shown on the vaccination certificate is less than 30 days before the date of arrival, the dog may be admitted, but must be confined until at least 30 days have elapsed since the date of vaccination;

(ii) If the dog is less than 3 months of age, it may be admitted, but must be confined until vaccinated against rabies at 3 months of age and for at least 30 days after the date of vaccination;

(iii) If the dog is 3 months of age or older, it may be admitted, but must be confined until it is vaccinated against rabies. The dog must be vaccinated within 4 days after arrival at destination but no more than 10 days after arrival at a U.S. port. It must be kept in confinement for at least 30 days after the date of vaccination.

(3) When a dog is admitted under paragraph (c)(2) of this section, the Director shall notify the health department or other appropriate agency having jurisdiction at the point of destination and shall provide the address of the specified place of confinement and other pertinent information to facilitate surveillance and other appropriate action.

(d) *Certification requirements.* The owner shall submit such certification regarding confinement and vaccination prescribed under this section as may be required by the Director.

(e) *Additional requirements for the importation of dogs and cats.* Dogs and cats shall be subject to such additional requirements as may be deemed necessary by the Director or to exclusion if coming from areas which the Director has determined to have high rates of rabies.

(f) *Requirements for dogs and cats in transit.* The provisions of this section shall apply to dogs and cats transported through the United States from one foreign country to another, except as provided below:

(1) Dogs and cats that appear healthy, but have been exposed to a sick or dead animal suspected of having a communicable disease, need not undergo examination or tests as provided in paragraph (b)(3) of this section if the Director determines that the conditions under which they are being transported will afford adequate protection against introduction of communicable disease.

(2) Rabies vaccination is not required for dogs that are transported by aircraft or ship and retained in custody of the carrier under conditions that would prevent transmission of rabies.

(g) *Disposal of excluded dogs and cats.* A dog or cat excluded from the United States under the regulations in this part shall be exported or destroyed. Pending exportation, it shall be detained at the owner's expense in the custody of the U.S. Customs Service at the U.S. port.

§ 71.52 Turtles, tortoises, and terrapins.

(a) *Definitions.* As used in this section the term:

Turtles includes all animals commonly known as turtles, tortoises, terrapins, and all other animals of the order Testudinata, class Reptilia, except marine species (Families Dermochelidae and Cheloniidae).

(b) *Importation; general prohibition.* Except as otherwise provided in this section, live turtles with a carapace length of less than 4 inches and viable turtle eggs may not be imported into the United States.

(c) *Exceptions.* (1) Live turtles with a carapace length of less than 4 inches and viable turtle eggs may be imported into the United States, provided that such importation is not in connection with a business, and the importation is limited to lots of fewer than seven live turtles or fewer than seven viable turtle eggs, or any combinations of such turtles and turtle eggs totaling fewer than seven, for any entry.

(2) Seven or more live turtles with a carapace length of less than 4 inches, or seven or more viable turtle eggs or any combination of turtles and turtle eggs totaling seven or more, may be imported into the United States for bona fide scientific or educational purposes or for exhibition when accompanied by a permit issued by the Director.

(3) The requirements in paragraphs (c)(1) and (c)(2) of this section shall not apply to the eggs of marine turtles excluded from these regulations under § 71.52(a).

(d) *Application for permits.* Applications for permits to import turtles, as set forth in paragraph (c)(2) of this section, shall be made by letter to the Director, and shall contain, identify, or describe, the name and address of the applicant, the number of specimens, and the common and scientific names of each species to be imported, the holding facilities, the intended use of the turtles following their importation, the precautions to be undertaken to prevent infection of members of the public with Salmonella and Arizona bacteria, and any other information and assurances the Director may require.

(e) *Criteria for issuance of permits.* A permit may be issued upon a determination that the holder of the permit will isolate or otherwise confine the turtles and will take such other precautions as may be determined by the Director to be necessary to prevent infection of members of the public with Salmonella and Arizona bacteria and on condition that the holder of the permit will provide such reports as the Director may require.

(f) *Interstate regulations.* Upon admission at a U.S. Port, turtles and viable turtle eggs become subject to Food and Drug Administration Regulations (21 CFR 1240.62) regarding general prohibition.

(g) *Other permits.* Permits to import certain species of turtles may be required under other Federal regulations (50 CFR parts 17 and 23) protecting such species.

§ 71.53 Nonhuman primates.

(a) *Definitions.* As used in this section the term:

Importer means any person or corporation, partnership, or other organization, receiving live nonhuman primates from a foreign country within a period of 31 days, beginning with the importation date, whether or not the primates were held for part of the period at another location. The term importer includes the original importer and any other person or organization receiving imported primates within the 31-day period.

Nonhuman primates means all nonhuman members of the Order Primates, including, but not limited to, animals commonly known as monkeys, chimpanzees, orangutans, gorillas, gibbons, apes, baboons, marmosets, tamarin, lemurs, and lorises.

(b) *General prohibition.* No person or organization may import live nonhuman primates into the United States unless registered as an importer in accordance with applicable provisions of this section.

(c) *Uses for which nonhuman primates may be imported and distributed.* Live nonhuman primates may be imported into the United States and sold, resold, or otherwise distributed only for bona fide scientific, educational, or exhibition purposes. The importation of nonhuman primates for use in breeding colonies is also permitted provided that all offspring will be used only for scientific, educational, or exhibition purposes. The maintenance of nonhuman primates as pets, hobby, or an avocation with occasional display to the general public is not a permissible use.

(d) *Registration of importers.* (1) Importers of nonhuman primates shall register with the Director in a manner prescribed by the Director.

(2) Documentary evidence that an importer will use all nonhuman primates solely for the permitted purposes is required.

(3) Registration shall include certification that the nonhuman primates will not be shipped, sold, or otherwise transferred to other persons or organizations without adequate proof that the primates will be used only for the permitted purposes.

(4) Registration shall be for 2 years, effective the date the application for registration is approved by the Director.

(5) Registration may be renewed by filing a registration application form with the Director not less than 30 days nor more than 60 days before expiration of the current registration.

(e) *Recordkeeping and reporting requirement for registered importers.* (1) Importers shall maintain records on each shipment of imported nonhuman primates received. The record on each shipment shall include the number of primates received, species, country of origin, date of importation, the number of primates in the shipment that die within 90 days after receipt, and cause(s) of deaths. If any primates in the shipment are sold or otherwise distributed within 90 days after receipt, the record shall include the number of primates in each shipment or sale, the dates of each shipment or sale, and the identity of the recipients. In addition, the record shall contain copies of documents that were presented to the importer to establish that the recipient would use the primates solely for the permitted purposes. The records shall be maintained in an organized manner in a central location at or in close proximity to the importer's primate holding facility. The records shall be maintained for a period of 3 years and shall be available for inspection by the Director at any time.

(2) Importers shall report to the Director by telephone within 24 hours the occurrence of any illness in nonhuman primates that is suspected of being yellow fever, monkeypox, or Marburg/Ebola disease.

(3) Importers also shall report to the Director by telephone within 24 hours the occurrence of illness in any member of their staff suspected of having an infectious disease acquired from nonhuman primates.

(f) *Disease control measures.* Upon receipt of evidence of exposure of nonhuman primates to a communicable disease that may constitute a threat to public health, the Director may provide for or require examination, treatment, detention, isolation, seizure, or destruction of exposed animals. Any measures required shall be at the owner's expense.

(g) *Disposal of excluded nonhuman primates.* Nonhuman primate(s) excluded from the United States by provisions of this section shall, at the owner's option and expense, be exported, destroyed, or given to a scientific, educational, or exhibition facility under arrangements approved by the Director. If the owner fails to dispose of the nonhuman primate by one of the approved options or fails to select a method of disposal within 7 days, the Director will select the method of disposal. Pending disposal, the nonhuman primate(s) shall be detained at the owner's expense in custody of the U.S. Customs Service at the U.S. port.

(h) *Revocation of an importer's registration.* (1) An importer's registration may be revoked by the Director, upon notice to the importer holding such registration, if the Director determines that the importer has failed to comply with any applicable provisions of this section. The notice shall contain a statement of the grounds upon which the revocation is based.

(2) The importer may file an answer within 20 days after receipt of the notice. Answers shall admit or deny

specifically, and in detail, each allegation in the notice. Allegations in the notice not denied by answer shall be deemed admitted. Matters alleged as affirmative defenses shall be separately stated and numbered. Failure of the importer to file an answer within 20 days after receipt of the notice may be deemed an admission of all allegations of fact recited in the notice.

(3) The importer shall be entitled to a hearing with respect to the revocation upon filing a written request, either in the answer or in a separate document, with the Director within 20 days after the effective date of revocation. Failure to request a hearing shall be deemed a waiver of hearing and as consent to the submission of the case to the Director for decision based on the written record. The failure both to file an answer and to request a hearing shall be deemed to constitute consent to the making of a decision on the basis of available information.

(4) As soon as practicable after the completion of any hearing conducted pursuant to the provisions of this section, the Director shall render a final decision. A copy of such decision shall be served on the importer.

(5) An importer's registration which has been revoked may be reinstated by the Director upon inspection, examination of records, conference with the importer, and receipt of information and assurances of compliance with the requirements of this section.

(i) *Other permits.* In addition to the requirements under this section, permits to import certain species of nonhuman primates may also be required under other Federal regulations (50 CFR parts 17 and 23) protecting such species.

§ 71.54 Etiological agents, hosts, and vectors.

(a) A person may not import into the United States, nor distribute after importation, any etiological agent or any arthropod or other animal host or vector of human disease, or any exotic living arthropod or other animal capable of being a host or vector of human disease unless accompanied by a permit issued by the Director.

(b) Any import coming within the provisions of this section will not be released from custody prior to receipt by the District Director of the U.S. Customs Service of a permit issued by the Director.

§ 71.55 Dead bodies.

(a) The remains of a person who died of a communicable disease may not be brought into a U.S. port unless it has been:

(1) Placed in a hermetically sealed casket;

(2) Cremated; or

(3) Accompanied by a permit issued by the Director.

(b) The Director may inspect human remains brought into a U.S. port and condition their further importation upon such requirements that the Director may deem necessary through order to prevent the introduction, transmission, and spread of communicable diseases.

§ 71.56 African rodents and other animals that may carry the monkeypox virus.

(a) *What actions are prohibited? What animals are affected?* (1) Except as provided in paragraphs (a)(2) and (a)(3) of this section,

(i) You must not import or attempt to import any rodents, whether dead or alive, that were obtained, directly or indirectly, from Africa, or whose native habitat is Africa, any products derived from such rodents, any other animal, whether dead or alive, whose importation the Director has prohibited by order, or any products derived from such animals; and

(ii) You must not prevent or attempt to prevent the Centers for Disease Control and Prevention (CDC) from causing an animal to be quarantined, re-exported, or destroyed under a written order.

(2) The prohibitions in paragraph (a)(1) of this section do not apply if you have written permission from CDC to import a rodent that was obtained, directly or indirectly, from Africa, or whose native habitat is Africa, or an animal whose importation the Director has prohibited by order.

(i) To obtain such written permission from CDC, you must send a written request to Division of Global Migration and Quarantine, National Center for Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Rd., Atlanta, GA 30333. You may also fax your request to the Division of Global Migration and Quarantine (using the same address in the previous sentence) at 404–498–1633.

(ii) Your request must state the reasons why you need an exemption, describe the animals involved, describe the number of animals involved, describe how the animals will be transported (including carrying containers or cages, precautions for handlers, types of vehicles used, and other procedures to minimize exposure of animals and precautions to prevent animals from escaping into the environment), describe any holding facilities, quarantine procedures, and/or veterinarian evaluation involved in the animals' movement, and explain why an exemption will not result in the spread of monkeypox within the United States. Your request must be limited to scientific, exhibition, or educational purposes.

(iii) We will respond in writing to all requests, and we also may impose conditions in granting an exemption. If we deny your request, you may appeal that denial. Your appeal must be in writing and be submitted to the CDC official whose office denied your request, and you must submit the appeal within two business days after you receive the denial. Your appeal must state the reasons for the appeal and show that there is a genuine and substantial issue of fact in dispute. We will issue a written response to the appeal, which shall constitute final agency action.

(3) The prohibitions in paragraph (a) of this section do not apply to products derived from rodents that were obtained, directly or indirectly, from Africa, or whose native habitat is Africa, or products derived from any other animal whose importation the Director has prohibited by order if such products have been properly processed to render them noninfectious so that they pose no risk of transmitting or carrying the monkeypox virus. Such products include, but are not limited to, fully taxidermied animals and completely finished trophies; and they may be imported without written permission from CDC.

(b) *What actions can CDC take?* (1) To prevent the monkeypox virus from spreading and becoming established in the United States, we may, in addition to any other authorities under this part:

(i) Issue an order causing an animal to be placed in quarantine,

(ii) Issue an order causing an animal to be re-exported,

(iii) Issue an order causing an animal to be destroyed, or

(iv) Take any other action necessary to prevent the spread of the monkeypox virus.

(2) Any order causing an animal to be quarantined, re-exported, or destroyed will be in writing.

(c) *How do I appeal an order?* If you received a written order to quarantine or re-export an animal or to cause an animal to be destroyed, you may appeal that order. Your appeal must be in writing and be submitted to the CDC official whose office issued the order, and you must submit the appeal within 2 business days after you receive the order. Your appeal must state the reasons for the appeal and show that there is a genuine and substantial issue of fact in dispute. We will issue a written response to the appeal, which shall constitute final agency action.

Dated: November 21, 2005.

Michael O. Leavitt,

Secretary.

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