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 C.F.R 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 USC 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	No

	international flights	
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 C.F.R. 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 USC 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 §§ 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 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 USC 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 § 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 §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 § 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	Proposed Regulation
Section	**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 designation 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 Responsibility 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
	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