

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	No. of Respondents	Annual Frequency per Response	Total No. 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	2740
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	3135	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.