DRAFT

Regulatory Impact Analysis of Proposed 42 CFR Part 70 and 42 CFR Part 71

Control of Communicable Diseases
Notice of Proposed Rulemaking (NPRM)

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Submitted to:

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EXECUTIVE SUMMARY

The Public Health Service Act (42 U.S.C. §264) authorizes the Secretary of Health and Human Services (HHS) to make and enforce regulations as necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States and from one state or possession into another. The Secretary has delegated this responsibility to the Centers for Disease Control and Prevention (CDC). CDC learned during the SARS outbreak that its ability to track potentially infected individuals was severely hampered by a lack of timely information.

CDC is proposing a rule that requires timely access to crew and passenger data from international air and water carriers and interstate air carriers, as well as sanitary measures to mitigate or prevent the effects of a disease outbreak from natural or terrorist origin. It is also updating the regulations to codify due process procedures to protect individual liberties and relationships with tribal nations.

The primary cost impact of the proposed rule is the collection and maintenance of crew manifest data and passenger information. The economic analysis focused on air and water carriers that are likely to modify computer systems and collect passenger information to come into compliance. Secondarily affected industries, such as Global Distribution Systems and travel agencies that may need to reprogram their systems in order to meet airline requirements are also analyzed.

Although some of the data sought by CDC may at some future time be collected by industry or other government agencies, plans for such data collection are not close to being final. Furthermore, CDC requires data that that are not currently being collected. These data will need to be integrated with existing databases, which cannot currently accept the data fields CDC requires. This situation drives the analytical assumptions for two scenarios that provide bounding estimates of costs and impacts. The first scenario assumes that the affected airlines and cruise lines will be able to access data collected by travel agencies and others (the Point of Sale scenario) and the second scenario assumes that this will not be possible, and thus the carriers will need to collect data when passengers arrive for ticketing and/or boarding (the Point of Departure scenario). Both of these scenarios assume that: (1) the various carriers, Global Distribution Systems, and travel agencies will need to undertake substantial reprogramming efforts, (2) reprogramming costs are primarily a function of the need to add these fields but are relatively invariant with respect to the number of fields added, and (3) CDC will need to collect these data themselves and will not be able to depend on other government agencies to collect the data.

Tables ES-1, ES-2, and ES-3 summarize the estimated annualized costs and benefits associated with the proposed rule under the two scenarios as well as the midpoint between the two scenarios. The benefits of the rule are measured in terms of the number of deaths and illnesses prevented by rapid intervention. The costs and benefits of the rule are considered over a 10-year period.

The options analyzed require the collection of crew manifest and passenger information from a range of flights and passenger vessel trips. The options cover the following flights and vessel trips:

- Option 1: International passenger flights only (arrivals) and passenger vessel trips from non-U.S. locations (International Only)

- Option 2: International passenger flights and vessel trips and domestic passenger flights into and out of large and medium airport hubs (International plus Large and Medium Hubs)

- Option 3: International flights and vessel trips and all domestic passenger flights (International plus All Domestic)

Table ES-1. Annualized Discounted Value of Costs and Benefits of the Point of Sale (POS) Scenario over a 10-Year Planning Period

Parameter	Option 1 International Only		Option 2 International plus Medium and Large Hubs		Option 3 International plus All Domestic	
	Total Cost and Benefit	Incremental Net Benefit	Total Cost and Benefit	Incremental Net Benefit	Total Cost and Benefit	Incremental Net Benefit
At 7 percent discount rate						
Costs	$185.5		$495.0		$535.3	
Benefits	$1,070		$1,263		$1,274	
Net Benefit	$884.5	--	$768.0	($116.5)	$738.7	($29.3)
At 3 percent discount rate						
Costs	$165.7		$475.0		$515.3	
Benefits	$1,033		$1,220		$1,231	
Net Benefit	$867.3	--	$745.0	($122.3)	$715.7	($29.3)

Table ES-2. Annualized Discounted Value of Costs and Benefits of the Point of Departure (POD) Scenario over a 10-Year Planning Period

Parameter	Option 1 International Only		Option 2 International plus Medium and Large Hubs		Option 3 International plus All Domestic	
	Total Cost and Benefit	Incremental Net Benefit	Total Cost and Benefit	Incremental Net Benefit	Total Cost and Benefit	Incremental Net Benefit
At 7 percent discount rate						
Costs	$262.9		$793.8		$865.2	
Benefits	$1,070		$1,263		$1,274	
Net Benefit	$807.1	--	$469.2	($337.9)	$408.8	($60.4)
At 3 percent discount rate						
Costs	$244.1		$774.7		$846.1	
Benefits	$1,033		$1,220		$1,231	
Net Benefit	$788.9	--	$445.3	($343.6)	$384.9	($60.4)

Table ES-3. Annualized Discounted Value of Costs and Benefits of the Midpoint between the POS and POD Scenario over a 10-Year Planning Period

Parameter	Option 1 International Only		Option 2 International plus Medium and Large Hubs		Option 3 International plus All Domestic	
	Total Cost and Benefit	Incremental Net Benefit	Total Cost and Benefit	Incremental Net Benefit	Total Cost and Benefit	Incremental Net Benefit
At 7 percent discount rate						
Costs	$224.2		$644.4		$700.3	
Benefits	$1,070		$1,263		$1,274	
Net Benefit	$845.8	--	$618.6	($227.2)	$573.7	($44.9)
At 3 percent discount rate						
Costs	$204.9		$624.9		$680.7	
Benefits	$1,033		$1,220		$1,231	
Net Benefit	$828.1	--	$595.1	($233.0)	$550.3	($44.8)

CDC also examined the potential economic impacts of the rule. CDC found that under the Point of Sale scenario, no airlines, vessels or other, secondarily affected entities (e.g., travel agencies) would incur costs exceeding one percent of average revenues for the proposed option. Under the Point of Departure Scenario, however, two airlines might incur costs exceeding one percent of revenues. Also, one firm might incur costs in excess of baseline net income. The relatively low projected impacts to the airline industry, however, are at least somewhat offset by the poor baseline financial condition of the industry. Twenty of the 52 airlines for which net income data are available, had negative net income for the period analyzed.

CDC also performed small business and civil justice analyses, as well as addressing the requirements of the Unfunded Mandates Reform Act.

SECTION 1. INTRODUCTION

1.1 BACKGROUND AND AUTHORITY

The Public Health Service Act (42 U.S.C. §264) authorizes the Secretary of Health and Human Services (HHS) to make and enforce regulations as necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States and from one state or possession into another. The Secretary has delegated this responsibility to the Centers for Disease Control and Prevention (CDC).

Quarantine and isolation are age-old measures that have been used effectively to contain the spread of diseases. Federal quarantine regulations are currently promulgated in 42 CFR Parts 70 and 71; part 70 concerns interstate matters while Part 71 deals with foreign arrivals. These regulations were last substantially updated in 1985. (Part 70 underwent a technical revision in 2000, when the regulation was transferred from the Food and Drug Administration to CDC. In response to the emergence of severe acute respiratory syndrome—SARS—in 2003, HHS amended Parts 70.6 and 71.3 to refer to Executive Order 13295 listing the communicable diseases subject to quarantine.) Changes in technology, civil rights, global travel, and the nature of communicable disease threats in the intervening 20 years necessitate an update to the regulation.

CDC, acting on lessons learned during the SARS outbreak, is proposing to update its regulations to adequately address quarantine and medical examinations in the 21st century and clarify administrative and due process procedures for the future. The regulatory analysis in this document summarizes the key changes between the current and proposed regulations, the estimated costs of those changes, and the economic impacts of those costs. The report also estimates the monetary benefits associated with the proposed rule, compares the rule's estimated costs and benefits, and summarizes how the proposed rule meets various legislative and executive requirements.

1.2 NEED FOR THE REGULATION

The regulatory philosophy and principles given in Executive Order 12866, "Regulatory Planning and Review," include an analysis on the need for the proposed regulatory action. The need for the regulation is driven by a demonstrated market failure. An externality exists when one person's or party's actions impose uncompensated costs to other parties. By exposing fellow travelers to potential illness and possible death, an ill traveler imposes uncompensated costs on the fellow travelers, travel providers, and the individuals that they, in turn, might expose. Due to the national and international nature of travel and the transmission of communicable diseases, regulation at the Federal level is the most appropriate mechanism for protecting public health.

The need for the regulation became evident during the SARS outbreak when CDC realized it had an unacceptable situation—the time required to track passengers was longer than the incubation period of the SARS virus (Smolinski et al., 2003; Rothstein et al., 2003; GAO, 2004). The Government Accountability Office (GAO) report also 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." With this proposed regulation, CDC is taking the first steps to respond to the GAO recommendation and rectify a situation unacceptable for the protection of public health.

The overall intent of the proposed regulation is to update the regulations in five major areas:

- Clarify administrative procedures to ensure due process rights to quarantined individuals.
- Mandate that carriers maintain and provide to CDC manifest and other passenger information in electronic formats.
- Expand requirements for reporting sick passengers.
- Clarify coordination with state and tribal authorities.
- Clarify the list of communicable diseases applicable to 40 CFR Parts 34, 70, and 71.

The proposed new sections on due process codify existing practices rather than delineating new procedures for CDC. A section-by-section comparison of the current and proposed regulations is provided in Section 2.

1.3 RELATIONSHIP TO OTHER ONGOING DATA COLLECTION EFFORTS

While CDC's focus is stopping the spread of death and sickness from diseases carried by individuals into the United States and from one state or possession into another, the Department of Homeland Security (DHS) focuses on stopping the spread of death and destruction from terrorist activities. CDC's procedures for stopping the transmission and spread of disease are applicable to both naturally occurring and terrorist-induced outbreaks. Some DHS activities, particularly those of U.S. Customs and Border Protection (CBP) and the Transportation Security Administration (TSA), also involve collecting passenger information to protect public health and safety.

Airlines routinely collect Passenger Name Record (PNR) information from all passengers. PNR varies from airline to airline (69 FR 57353), but core information—such as full name, contact phone number, mailing address, and travel itinerary—is generally, but not consistently, collected. Section 1.3.1 discusses data collected from international flights, while Section 1.3.2 discusses developments for data collection on domestic flights. Section 1.3.3 discusses how these efforts affect the cost estimates for the proposed rule.

1.3.1 International Flights

APIS (Advance Passenger Information System) is a database system developed in 1988 that collects data on passengers and crewmembers before they arrive in or leave the United States. The air carrier must submit crewmember data prior to a flight's departure and passenger data within 15 minutes of departure in electronic form to APIS. Sea carriers have a different time frame for reporting (CBP, 2005a). In 2002, the United Nations approved a standard message set called UN/EDIFACT (United Nations Electronic Data Interchange for Administration, Commerce, and Trade). Manifest data are now being submitted using the UN/EDIFACT format (CBP, 2004a). Large airlines generate the manifests from the PNR data and submit the manifests to APIS. That is, under current practices, a subset of PNR data is extracted and sent to APIS. CBP is assisting small carriers by providing guidance, rules to minimize APIS transmission errors, a spreadsheet template for data entry, and an executable file that translates the spreadsheet into a "formatted text only" that can be read by APIS. The manifest file can be sent as an email attachment to CBP (CBP, 2004b, 2005b).

On July 9, 2004, CBP issued a general notice in the Federal Register that the European Union had issued an "adequacy finding" for the transfer of PNR data to CBP (CBP, 2004c). The document on which the finding was based describes the use and measures taken to protect the privacy of the information.

Attachment A lists 34 PNR data elements required by CBP from the carriers. These include parameters of interest for CDC, such as name, other names, address, contact telephone numbers, email address, travel itinerary information, and seat assignment.

CDC is currently developing a Memorandum of Understanding with DHS regarding access to PNR data for the purpose of mitigating health impacts from communicable diseases. Because this process has not been completed at the time of the proposal, CDC developed two basic scenarios—one where the agency has access to the PNR data and one where it does not (see Section 2.3 for details). Note that CBP intends to hold the data in online form for 7 days and with manual access for 3.5 years (Paragraph 15). For comparison, Sections 70.3 and 71.6 identify a 60-day retention period during which manifest data can be recovered and sent in electronic form to CDC.

1.3.2 Domestic Flights

On September 24, 2004, TSA announced that it is establishing "Secure Flight," a next generation system of domestic passenger prescreening (TSA, 2004a). Secure Flight will be the successor to the currently used system for passenger screening, the Computer-Assisted Passenger Prescreening System (CAPPS). Secure Flight will involve the comparison of information in the PNRs to names in the Terrorist Screening Database (TSDB) and apply a version of the existing CAPPS rule set to other PNR data to identify indicators associated with suspicious travel behavior. TSA identified seven elements of interest: passenger name, reservation date, travel agency or agent, travel itinerary information, form of payment, flight number, and seating location. Again, this information might overlap some of that sought by CDC for the purposes of protecting public health, but this program is still only in proposal stages, and the final form of the information to be collected is not certain.

TSA has requested PNR data from domestic aircraft operators for all flight segments flown during the month of June 2004 in order to test the Secure Flight system (TSA, 2004b). TSA also conducted a privacy impact assessment for the Secure Flight testing phase (TSA, 2004c), concluding that TSA's record systems are safeguarded in accordance with the Federal Information Management Act of 2002 (Public Law 107-347). In addition to using standard procedures (e.g., a secure facility, password protection, protections against reverse engineering, and controlled access), TSA notes it intends to protect privacy by limiting the purpose and anticipated retention time for the information. That is, TSA focuses Secure Flight's PNR data usage solely on potential terrorism and not other law enforcement purposes (to address concerns about "mission creep" by TSA). TSA has stated that the data will be held for a limited time after completion of a passenger's itinerary but does not specify what that time is, only that TSA is working on a records retention schedule with the National Archives and Records Administration. As with APIS for international flights, the limited scope for using the information might limit CDC's ability to access Secure Flight information, even if the program were finalized quickly.

1.3.3 Effect on Cost and Impact Analysis for Proposed CDC Regulations

Although some of the information for international passengers sought by CDC might be collected by other government agencies at some point in the future, it is by no means certain. If such data collection began soon, covered the data fields CDC requires, and CDC could gain access to this information, the incremental cost to industry of complying with the manifest requirements could be reduced. However, any such data collection program outside CDC's purview is too uncertain at this time to consider as a likely scenario.

Rather than using an assumption that costs will be minimal due to access to other government databases, the main analysis in this Regulatory Impact Analysis (RIA) assumes that the airlines share data

with the GDSs and travel agencies, minimizing duplicate information gathering and streamlining the data collection process. This scenario is discussed in Section 3.

We also investigate a more pessimistic scenario in which we assume that the air carriers will have to collect the data for CDC from the passengers directly at check-in or before boarding. This analysis generates higher cost estimates.

1.4 PRIVACY CONCERNS

CDC has always protected personal data collected for the purpose of mitigating health impacts and currently handles all data in accordance with the Federal Information Management Act of 2002 (FIMA). While the method of data collection and, possibly, the volume of data collected might change under the proposed regulation, CDC already incurs the costs of complying with FIMA privacy protection costs. As such, CDC is forecast to incur a very modest increase in costs to protect privacy under the proposed rule.

1.5 REPORT ORGANIZATION

This regulatory analysis report is organized as follows:

- Section 2—Current and Proposed Rules
  Provides background information on the rule as currently written, outlines current practices, and discusses requirements in the proposed rule that would add to the costs of current practices. The section also introduces the options on which CDC is focusing and two data gathering scenarios under which the options will be analyzed.

- Section 3—Cost Analysis
  Provides a brief overview of the cost elements considered, the values used, and how the information is integrated to project the estimated cost of the rule.

- Section 4—Impact Analysis
  Examines the impacts of the compliance cost estimates on the affected entities. Due to limited financial information, the analysis primarily examines variations of a revenue test (e.g., the ratio of annualized costs to annual revenues).

- Section 5—Initial Regulatory Flexibility Analysis
  Divides the affected community into "small" and "large" based on the Small Business Administration's size standards and repeats the impact analysis for the small businesses. The results enable CDC to state whether or not the proposed rule will have a significant impact on a substantial number of small businesses.

- Section 6—Benefits Analysis
  Summarizes the methodology and findings by which CDC identifies, qualifies, quantifies, and—where possible—monetizes the benefits associated with the proposed rule.

- Section 7—Comparison of Costs and Benefits
  Compares the costs and benefits of the proposed regulation, as required by Executive Order 12866.

- Section 8—Unfunded Mandates Reform Act Analysis and Civil Justice Review

Shows how the analysis meets the legislative requirements of the Unfunded Mandates Reform Act and Executive Order 12988, "Civil Justice Reform."

1.6 REFERENCES

CBP (U.S. Customs and Border Protection). 2005a. Advance Passenger Information System (APIS) fact sheet. <http://www.cbp.gov/xp/cgov/travel/inspections_carriers_facilities/apis/apis_factsheet.xml>. Accessed March 3, 2005.

CBP (U.S. Customs and Border Protection). 2005b. Advance Passenger Information System (APIS). <http://www.cbp.gov/xp/cgov/travel/inspections_carriers_facilities/apis/>. Accessed March 3, 2005.

CBP (U.S. Customs and Border Protection). 2004a. U.S. passenger list (PAXLST). Message implementation guidelines. UN/EDIFACT message set. Advance passenger information for airlines. Document Number OIT-SDD-TB-UN_EDIFACT_AIR. June.

CBP (U.S. Customs and Border Protection). 2004b. APIS-TSA crew reporting guideline. Document Number 2050026-S2-CARRIER-GUIDE-1.31. April.

CBP (U.S. Customs and Border Protection). 2004c. Undertakings of the Department of Homeland Security Bureau of Customs and Border Protection regarding the handling of Passenger Name Record data. Fed. Reg. 69:41543-41547. July 9.

GAO (U.S. General Accounting Office). 2004. Emerging infectious diseases: Asian SARS outbreak challenged international and national responses. GAO-04-564. Washington, DC. April.

Rothstein, M.A. et al. 2003. Quarantine and isolation: Lessons learned from SARS. A report to the Centers for Disease Control and Prevention, Institute for Bioethics, Health Policy, and Law. University of Louisville School of Medicine. November.

Smolinski, M.S., M.A. Hamburg, and J. Lederberg, eds. 2003. Microbial threats to health: Emergence, detection, and response. Washington, DC: The National Academies Press. March.

TSA (Transportation Security Administration). 2004a. Privacy Act of 1974; system of records; Secure Flight test records. Fed. Reg. 69:57345-57348. September 24.

TSA (Transportation Security Administration). 2004b. Reports, forms, and recordkeeping requirements: Agency information collection activity under OMB review; Secure Flight test phase. Fed. Reg. 69:57342-573445. September 24.

TSA (Transportation Security Administration). 2004c. Privacy impact assessment; Secure Flight test phase. Fed. Reg. 69:57352-57355. September 24.

SECTION 2. CURRENT AND PROPOSED RULES

Economic analysis of regulation is based on the concept of incremental change: what would happen without a rule versus what would happen with it. Thus, the current regulatory milieu provides a base case against which the changes in behavior precipitated by the new rule are compared. Firms may have costs of compliance, i.e., spending for goods and systems that they would not have purchased in the base case, and society may reap benefits in the form of greater social welfare than under the base case. To estimate these economic effects, ERG compared the proposed rule section by section with the existing rule and identified likely sources of costs. Two policy options and two implementation scenarios were developed to consider alternative methods to improve contact tracing and assess their relative costs. This section summarizes the sources of costs in the proposed rule and discusses alternative options.

2.1 SECTION BY SECTION COMPARISON OF CURRENT AND PROPOSED RULE

Overall, the proposed rule seeks to:

- Clarify administrative procedures to ensure due process rights to quarantined individuals.
- Mandate that carriers maintain and provide to CDC manifest and other passenger information in electronic formats.
- Expand requirements for reporting sick passengers.
- Clarify coordination with state and tribal authorities.
- Clarify the list of communicable diseases applicable to 40 CFR Parts 70 and 71.

Table 2-1 provides a section-by-section comparison based on the section numbering of the proposed rule. The table summarizes the requirements under current and proposed rules, and indicates likely incremental cost impacts. Many provisions of the proposed rule codify practices that have evolved over the years. As these practices are part of current practice at CDC and in the industry, their codification does not impose new costs upon society. Italics in the “Incremental Cost Impact” column indicate provisions that do not impose new costs.

Table 2-1. Analysis of the Proposed Interstate and Foreign Quarantine Regulations: Current and New Requirements

Section	Title	Current Requirement	New Requirement	Incremental Cost Impact
42 CFR Part 70				
2	Report of death or illness on board flights	(70.4) Vessels and conveyances must report illness. Notify the local health authority only.	Air carriers only must report illness Notify the Director (i.e., quarantine center via a control tower) and the local state health department.	Lower costs for carriers who no longer need to notify. Negligible: the control tower can call the quarantine station and the local state health department.
3	Written plan for reporting of deaths or illness on board flights and designation of an airline agent	None.	Within 90 days of the rule, interstate airlines shall develop a written plan regarding the reporting of disease.	Initial cost of producing plan, plus updates.
4	Passenger information	None.	Carriers engaged in interstate travel shall maintain passenger and crew information for 60 days from the end of the voyage. Information is maintained and transmitted electronically.	Cost to carriers to produce, maintain, and communicate information to CDC.
5	Written plan for passenger information and designation of an airline agent.	None.	Within 6 months, interstate airlines shall develop a written plan regarding passenger information.	Initial cost of developing plan, plus updates.
6	Travel permits	(70.5) Traveling individuals must obtain a travel permit if they are in the incubation or communicable period of cholera, plague, smallpox, typhus or yellow fever.	Travel permits are required for traveling individuals who are in the qualifying stage of any quarantinable disease (as defined by the regulation).	Cost to an additional number of individuals who do not currently require travel permits. Burden to carriers of added measures to prevent the spread of disease for more passengers.
9	Vaccination clinics	(70.9) The Director may establish vaccination clinics through contract or otherwise. A vaccination fee may be charged to individuals not enrolled in Medicare Part B.	Same. In addition, the clinic shall comply with recordkeeping requirements for the safe handling of vaccines	Possible additional recordkeeping requirements.

Table 2-1. Analysis of the Proposed Interstate and Foreign Quarantine Regulations: Current and New Requirements

Section	Title	Current Requirement	New Requirement	Incremental Cost Impact
10	Establishment of institutions, hospitals and stations	None.	The Director may select and establish sites, hospitals, and stations suitable for quarantine, care and treatment; and enter into voluntary agreements with public or private institutions as necessary.	*Codifies current practice.*
11	Sanitary measures	None.	The carrier shall bear the expense of applying sanitary measures (e.g., fumigation, disinfection) as may be required by the director. If sanitary measures are applied to something on the carrier, then the owner of the thing bears the expense.	*Clarifies current practice: the carrier or shipper bears the cost of any necessary sanitary measures.*
12	Detention of carriers affecting interstate commerce	None.	The carrier shall bear the expenses of detention of the carrier. The owners of things on board the carrier shall bear the expense of detaining their things.	*Codifies current practice.*
15	Provisional quarantine orders	None.	Where the Director deems it necessary, detention (of people) orders are posted or published publicly, or electronically.	*Codifies current practice.*
17	Content of quarantine order	None.	(Specifies the documentation included in the order). Written or electronic.	*Codifies current practice.*
18	Service of quarantine order	None.	A copy is served to the person or persons. May be posted or published.	*Codifies current practice.*
19	Medical examination and monitoring	None.	Arriving persons may be subject to medical examination or monitoring and shall provide the Director with documentation of family, work and medical history.	*Codifies current practice.*
20	Hearings	None.	A person being detained can request a hearing. If so, the person is notified. The Director shall designate a hearing officer to review evidence of exposure or infection. The person requesting a hearing bears the expense of legal council. The hearing officer may order a medical examination. The hearing officer then makes a written recommendation to the Director who may issue additional instructions and guidelines.	*Codifies current practice.*

Table 2-1. Analysis of the Proposed Interstate and Foreign Quarantine Regulations: Current and New Requirements

Section	Title	Current Requirement	New Requirement	Incremental Cost Impact
21	Care and treatment of persons	None.	Individuals are responsible for the medical costs incurred after diagnosis.	*Clarification, not a cost of the proposed changes.*
22	Foreign nationals	None.	By request, foreign national can have the Director notify the foreign state of detention or quarantine, forward communications, and arrange consultation between the foreign national and the consular officer.	*Clarification, not a cost of the proposed changes.*
23	Administrative record		(Summary of paperwork above: detention and quarantine order, medical information supporting the order, evidence for a hearing, written findings and recommendation of the hearing, and hearing transcript or summary notes of the proceeding.)	*Covered above.*
25	Measures in the event of inadequate local control.	(70.2) Director may take measures when state efforts are inadequate. Director does not explicitly have jurisdiction over Indian Tribes.	Same, in addition, the Director has jurisdiction over Indian Tribes to take whatever measures necessary in preventing the spread of disease.	*Codifies current practice.*
27	Indian country	None.	The Director may detain, quarantine or examine persons in Indian country with the concurrence of the Director of the Indian Health Service and after consulting with the affected Tribes.	*Clarification of authority*.
28	Special powers in time of war	None.	The Director may, without making a requisite finding, in time of war, apprehend, detain, or release persons, in the qualifying stage of a quarantinable disease; and a probable source of infection to members of the military services.	*Clarification of authority*.
29	Penalties	None.	Persons violating this part are subject to $250,000 or less in fines, 1 year in prison, or both. Organizations in violation are subject to $500,000 or less in fines.	*Incremental penalties of violating the proposed rule are not a social cost.*
31	Appeals of actions required pursuant to 70.6, 70.7, 70.11 or 70.12	None.	Owners of animals or articles to be exported or destroyed may file an appeal.	*Voluntary; no cost.*

Table 2-1. Analysis of the Proposed Interstate and Foreign Quarantine Regulations: Current and New Requirements

Section	Title	Current Requirement	New Requirement	Incremental Cost Impact
42 CFR Part 71				
3	Vaccination clinics	The Director may establish vaccination clinics.	The Director may establish vaccination clinics through contract or otherwise. The clinic shall comply with recordkeeping requirements for the safe handling of vaccines. Certificates of vaccination and validation stamps may be issued and authenticated by electronic means.	Recordkeeping requirements, vaccination certification
4	Bills of health	A bill of health is not required of a carrier from a foreign port to a U.S. port.	The Director may require a carrier at any foreign port, destined for a U.S. port, to obtain or deliver a bill of health from a US consular or medical officer.	*Codifies current practice.*
5	Suspension of entries and imports from designated places	None.	The Director may prohibit the introduction of persons or property from places where there exists a communicable disease and a danger of its introduction to the United States.	*Codifies current practice.*
6	Report of death or illness on board flights	(b)The commander of an aircraft shall immediately report a death or illness.	(a)Any airline on international voyage to U.S. shall report deaths or illness as soon as known or 1 hour prior to arrival. (b)The Director may order airlines to disseminate public health notices to passengers and crew.	*Codifies current practice.*
7	Written plan for reporting of deaths or illness on board flights and designation of an airline agent	None.	Within 90 days of the rule, airlines on international voyage shall develop a written plan regarding the reporting of disease.	Initial cost of producing plan, plus updates.

Table 2-1. Analysis of the Proposed Interstate and Foreign Quarantine Regulations: Current and New Requirements

Section	Title	Current Requirement	New Requirement	Incremental Cost Impact
8	Report of death or illness on board ships.	(a)A ship destined for a U.S. port shall immediately report any death or illness occurring within 15 days of arrival, or since departure from a U.S. port (whichever time is shorter). (c)A ship of 13 passengers or more must report cases of diarrhea.	(a)Any ship destined for a U.S. port on international voyage shall report any death or illness at least 24 hours before arrival. (b)Any shipline on international voyage shall additionally report any death or ill person during the 15 day period preceding arrival or during the period since departure from a U.S. port (whichever time is shorter). (c)Any ships traveling between U.S. ports on international voyage shall report suspected or verified cases of communicable disease at the next port/stop and take measure to prevent its spread. (d)Any shipline at a U.S. port shall immediately report any death or ill person during stays in port. (e)A shipline must report cases of diarrhea (4 hours prior to arrival), febrile respiratory disease, febrile rash illness or febrile neurological illness (24 hours prior to arrival). (f)The Director may order dissemination of public health notices and other information to passengers and crew of ships on international voyage to a U.S. port. (g)Sections a-e apply to shiplines with ships traveling between a possession and a state.	*Codifies current practice. Clarifies when and to whom the reports must be made; no new requirements beyond current practice.*

Table 2-1. Analysis of the Proposed Interstate and Foreign Quarantine Regulations: Current and New Requirements

Section	Title	Current Requirement	New Requirement	Incremental Cost Impact
9	Written plan for reporting of deaths or illness on board ships and designation of a shipline's agent	None.	Within 90 days of the rule, shiplines on international voyage shall develop a written plan regarding the reporting of disease.	Initial cost of producing plan, plus updates.
10	Passenger information	None.	Airlines and shiplines on international voyage (including between a state and a possession) shall maintain passenger and crew information for 60 days from the end of the voyage. Information is maintained and transmitted electronically.	Cost of creating, maintaining, and delivering passenger information.
11	Written plan for passenger information and designation of an airline or shipline agent.	None.	Within 6 months, airlines and shiplines shall develop a written plan regarding passenger information.	Initial cost of developing plan, plus updates.
12	Inspections	Carriers arriving at a U.S. port may be inspected, detained, or issued a controlled free pratique. (General provisions under 71.31) Also, Carriers, on an international voyage, which are in traffic between U.S. ports, shall be subject to inspection … when there occurs on board, among passengers or crew, any death, or any ill person, or when illness is suspected to be caused by unsanitary conditions, under 71.48.	Carriers arriving at a U.S. port from a foreign country are subject to detention and inspection. No mention is made to a controlled free pratique. Additionally, carriers on an international voyage, which are in traffic between U.S. ports, are subject to detention and inspection when there is an illness or death, or illness-causing conditions are suspected. (Applies between states and possessions also).	*Codifies current practice.*

Table 2-1. Analysis of the Proposed Interstate and Foreign Quarantine Regulations: Current and New Requirements

Section	Title	Current Requirement	New Requirement	Incremental Cost Impact
13	Sanitary measures	None.	The carrier shall bear the expense of applying sanitary measures (e.g., fumigation, disinfection) as may be required by the director. If sanitary measures are applied to something on the carrier, then the owner of the thing bears the expense.	*Codifies current practice.*
14	Detention of carriers	None.	The carrier shall bear the expenses of detention of the carrier. The owners of things on board the carrier shall bear the expense of detaining their things. The Director may issue a controlled free pratique.	*Codifies current practice.*
15	Carriers of U.S. military services	Service carriers were explicitly exempt from inspection, but not detention.	Service carriers are explicitly exempt from both detention and exemption.	*Codifies current practice.*
18	Provisional quarantine orders	None.	Where the Director deems it necessary, detention (of people) orders are posted or published publicly, or electronically.	*Codifies current practice.*
20	Content of quarantine order	None.	(Specifies the documentation included in the order.) Written or electronic.	*Codifies current practice.*
21	Service of quarantine order	None.	A copy is served to the person or persons. May be posted or published.	*Codifies current practice.*
22	Medical examination and monitoring	None.	Arriving persons may be subject to medical examination or monitoring and shall provide the Director with documentation of family, work and medical history.	*Codifies current practice.*
23	Hearings	None.	A person being detained can request a hearing. If so, the person is notified. The Director shall designate a hearing officer to review evidence of exposure or infection. The person requesting a hearing bears the expense of legal council. The hearing officer may order a medical examination. The hearing officer then makes a written recommendation to the Director who may issue additional instructions and guidelines.	*Codifies current practice.*

Table 2-1. Analysis of the Proposed Interstate and Foreign Quarantine Regulations: Current and New Requirements

Section	Title	Current Requirement	New Requirement	Incremental Cost Impact
24	Care and treatment of arriving persons	None.	Individuals are responsible for the medical costs incurred after diagnosis.	*Codifies current practice.*
25	Arriving foreign nationals	None.	By request, foreign national can have the Director notify the foreign state of detention or quarantine, forward communications, and arrange consultation between the foreign national and the consular officer.	*Codifies current practice.*
26	Administrative record		(Summary of paperwork above: detention and quarantine order, medical information supporting the order, evidence for a hearing, written findings and recommendation of the hearing, and hearing transcript or summary notes of the proceeding.)	*Codifies current practice.*
28	Health documents in international traffic	The inspection and issuance of Ship Sanitation Control and Ship Sanitation Control Exemption certificates was not explicitly an expense incurred by ships.	The inspection and issuance of and Ship Sanitation Control exemption certificates is now explicitly an expense incurred by ships.	*Codifies current practice.*
29	Special provisions relating to airports: office, examination, and quarantine facilities	Each U.S. airport with international traffic shall provide an examination, quarantine and other exclusive space for carrying out the Federal responsibilities under this part.	Additionally, each U.S. airport with international traffic shall identify to the nearest quarantine station or other authorized representative of the Director on a yearly basis a space which is suitable for the quarantine of an arriving person or group of persons.	The language regarding isolation space does not change between the old and new regulations. An incremental cost may exist if the CDC outlines the requirements of an isolation space.
30	Establishment of institutions, hospitals and stations	None.	The Director may select and establish sites suitable for, and establish, hospitals and stations and enter into voluntary agreements with public or private institutions as necessary.	*Codifies current practice.*
31	Penalties	Persons pay $1,000 or 1 year in prison or both.	Persons violating this part are subject to $250,000 or less in fines, 1 year in prison, or both. Organizations in violation are subject to $500,000 or less in fines.	*Incremental penalties of violating the proposed rule are not social costs.*

Table 2-1. Analysis of the Proposed Interstate and Foreign Quarantine Regulations: Current and New Requirements

Section	Title	Current Requirement	New Requirement	Incremental Cost Impact
33	Appeals of actions required pursuant to 71.13 or 71.14	None.	The owner of an article or animal may file an appeal in writing.	Voluntary; no costs.
55	Dead bodies	(a) The remains of a person who died of a communicable disease must be embalmed and hermetically sealed, cremated or accompanied by a permit.	A hermetically sealed body is no longer required to be embalmed.	Removing the embalming requirement may reduce costs.
			The Director may condition the importation of a body upon requirements deemed necessary.	The Director's additional importation requirements could increase the cost of delivering a body in certain circumstances; cost not estimated.

2.2 IDENTIFIED COSTS

As Table 2-1 shows, several costly activities that are required but not specifically mentioned under the current regulation are now clearly defined. Among these are the issue of who is responsible for the costs of detention and sanitary measures. The new regulation makes clear that these costs are to be borne by the carrier and the owner of the goods transported. As this has been the standard—albeit uncodified—practice in the past, detention and sanitation costs are not considered costs of the proposed rule. Vaccination clinics are directed to comply with recordkeeping requirements under the proposed rule. As standard medical practice requires similar recordkeeping, this is not considered a substantial cost of the rule. The provision that the Director may establish quarantine sites and enter into agreements with hospitals for quarantine purposes codifies current practice; thus no costs or benefits are attributed to this provision.

The proposed regulation allows a person to appeal a decision concerning destruction of animals or property. In considering the economic impacts of this provision, ERG judged that persons are unlikely to appeal unless they expect to be successful. Thus, the value of the property multiplied by the probability of a successful appeal is expected to be greater than the cost of the appeal. Because it is a new provision, there are no data by which to estimate the frequency and cost of appeal. Thus, even though the provisions are likely to provide a net benefit for the proposed rule, ERG includes neither costs nor benefits for these provisions in this analysis.

The major new cost of the proposed regulation is creation and maintenance of additional passenger information, including home, emergency contact, and itinerary information. Under current regulations, the airlines do not typically collect this information in an easily accessible format, nor do they maintain it for the proposed 60-day period. If the airlines can coordinate with Global Distribution Systems and travel agencies to collect the information CDC needs, the data collection effort may become invisible to the traveler and a simple programming problem for the airlines. This is the “Point of Sale” scenario, discussed in Section 3. However, if a wholly separate information collection must be undertaken at departure, this process could add to check-in times, generating real and opportunity costs for carriers and passengers. This is the “Point of Departure” scenario evaluated in Section 3

In addition to requiring electronic manifests and passenger data, CDC is broadening the definition of who needs a travel permit to anyone in the qualifying stage of a quarantinable illness. This change expands the number of people who will need to obtain permits. Carriers will also be obligated to keep permitted travelers from infecting others on the trip and preventing or cleaning up contamination of equipment. ERG has not developed quantitative estimates of these costs but anticipates that they will be small. ERG forecasts that the number of incremental requests for travel permits is modest. Requests arise infrequently because the requirement pertains to individuals who know they are in the qualifying stage of a quarantinable disease. No quantitative data allowing a forecast of this element was identified in the research.

2.3 OPTION DEVELOPMENT

The base case reflects the expected course of events in the absence of the proposed rule. ERG assumed that in the absence of the proposed rule, the existing quarantine rules would continue to be in force. Thus, the CDC’s response to future outbreaks would be similar to its response to the SARS outbreak in 2003. Contact information would be traced manually and quarantine would be only partially effective. Similar traveler information systems, such as APIS and Secure Flight, would go forward with little involvement from CDC.

The proposed rule defines a basic set of information to be collected from all passengers. The information includes permanent addresses, email addresses, emergency contact information, phone numbers, itinerary, and other information prescribed by the Director. Even this basic data set is greater than the information currently collected. The incremental costs of collecting, storing, and producing this information on demand in contrast with the no-action base case represent the compliance costs of the proposed rule.

CDC determined that there are options that could be constructed resulting in varying numbers of passengers for which information would be gathered, providing a range of option costs and benefits. Ideally, CDC would want to trace all passengers on passenger flights and vessels arriving from non-U.S. locations and all those on domestic passenger flights through all connecting flights to address both foreign-based and domestic outbreaks of disease. Should this option not be implementable, CDC would want to trace all foreign-inbound passengers through most of their connecting flights, and trace some domestic passengers traveling between larger airport hubs in the U.S. At a bare minimum, CDC would need information from arriving foreign passengers to at least their initial destination in the U.S.

2.4 REFERENCES

OMB, 2004. Office of Management and Budget. Regulatory Analysis. Circular A-4. September 17.

SECTION 3. COST ANALYSIS

This section provides an overview of the cost analysis. Section 3.1 briefly profiles the industries most likely to be affected by the rule—the airline and cruise ship industries. Section 3.2 outlines the differences between current and proposed requirements to identify components that will result in incremental costs to affected parties. Section 3.3 describes the cost values used in the analysis and explains how the information is integrated to project the estimated cost of the rule. Section 3.4 summarizes the projected total costs of the rule.

3.1 PROFILE OF AIRLINE AND CRUISE SHIP INDUSTRIES

3.1.1 Airline Industry Profile

3.1.1.1 Overview of Air Carrier Types

The Department of Transportation (DOT) and Federal Aviation Administration (FAA) classify commercial air carriers according to the size of the aircraft and type of service provided. Air carriers operating aircraft with more than 60 seats are classified as large certificated carriers (in reference to the financial certificate of approval necessary from DOT for them to operate). Large certificated carriers are further categorized as major (revenues exceeding $1 billion), national (revenues greater than $100 million but less than $1 billion), large regional (revenues between $20 million and $100 million) and medium regional (revenues less than $20 million; BTS, 1998; DOT, 2005).

Carriers operating aircraft with 60 seats or fewer may be classified as small certificated carriers, commuter airlines, or air taxis. The distinction between these three classes is not clear cut. Commuter airlines offer some minimum scheduled air service between at least two cities.[1] Small certificated carriers tend to provide the same type of service and use the same type of aircraft as commuter airlines, but for somewhat complex legal reasons have chosen to obtain DOT fitness certificates rather than registering with FAA as commuter airlines. (In this analysis, small certificated and commuter airlines were considered to be more or less identical.) Air taxis are legally able to operate the same type of aircraft as small certificated airlines and commuter airlines; the primary distinction is that air taxis offer almost exclusively on-demand service (BTS, 1998; DOT, 2005).[2]

3.1.1.2 Air Carrier Operations

Commercial Air Carriers

All commercial air carriers must periodically report operational and financial data to DOT. ERG used these airline-generated data to compile Table 3-1, which characterizes operations by airline type (BTS, 2005c). Table 3-1 presents air carrier information for the most recent 12-month period for which complete data are available (July 1, 2003 through June 30, 2004). The left-hand columns present data for all airline operations, including cargo-only flights, interstate and intrastate passenger flights, and both

[1] For consistency, we use DOT's definition of commuter airlines. These should not be confused with the popular image of commuter airlines as the smaller "feeder" airlines often associated with major airlines (e.g., American Eagle, Continental Express, Delta Connection). Some of these airlines are large certificated carriers, earning annual revenues in excess of $1 billion.

[2] The proposed rule is intended to cover scheduled air service providers. The data from DOT may reflect airlines involved strictly in charter or other on-demand service. It is not possible using these data to distinguish those airlines that provide only this type of service from similar airlines that also provide some scheduled air service. To be conservative, no airlines reported in the DOT data were removed from the analysis on this basis.

departures and arrivals of overseas flights. The right-hand columns present data for the subset of airline operations likely to be affected by this rule; that is, cargo-only flights and departures of foreign-bound flights are excluded.

The relative significance of the largest airlines is apparent in Table 3-1. The major airlines likely to be covered by this rule account for about 75 percent of passengers and 57 percent of flights and thus will bear the largest burden of the rule. Because these 13 airlines average 40.2 million passengers and 454,000 potentially affected flights per year, they have by far the largest and most complex computer infrastructures that may require modification in response to the rule. Furthermore, these airlines as a group were among the earliest airlines to computerize (and indeed were pioneers in the development of these systems, such as American Airline's development of the SABRE reservation system). Therefore, they probably have many legacy systems that will be relatively difficult to modify (Delta, 2005).

At the other end of the scale are the small certificated and commuter airlines. Some small certificated and commuter airlines do not carry passengers. DOT data show that while 73 small certificated and commuter airlines operated in the July 2003 through June 2004 time period, only 47 of those are likely to be affected by the rule. The relative size of these airlines is reflected in the fact that while they carry less than 3 percent of passengers likely to be affected by the rule, they account for over 15 percent of potentially affected flights under CDC's most inclusive option (see Section 3.2.2). These potentially affected airlines average about 12 passengers per flight. While it is difficult to characterize the information technology (IT) infrastructure and resources for this group of airlines, they appear to have relatively simple computer systems, at least when compared to the large airlines (FR, 2003; Pace, 2005; Sun Country, 2005).

Codeshare Air Carriers

A significant subgroup of commercial air carriers are regional airlines that have code-sharing partnerships with other airlines. Although some of these airlines are direct subsidiaries of other airlines, most are independently owned, but carry passengers under contract for other airlines using those airlines' identity codes. (This happens, for example, when one books a flight on American Airlines but boards a smaller plane with "American Eagle Airlines" on the tail fin.) Some "codeshare" airlines are under contract to multiple parent airlines (RAA, 2005).

Codeshare airlines are a diverse group, and range from airlines with 10 million or more passengers per year and annual revenues exceeding $1 billion (and thus are classified as major airlines in their own right) to small certificated and commuter airlines that fly fewer than 500,000 passengers per year and earn less than $50 million in annual revenues. Distinguishing codeshare airlines from other airlines is relevant to this rule because these airlines do not generally have their own reservation systems; all reservations are made with, and flight manifests are generated by, the parent airlines (Franz, 2005). Therefore, they will not incur costs to reprogram their reservation systems under the proposed rule. Based on the Regional Airline Association Web site, airline Web sites, and other information, we estimate that 23 codeshare airlines fly exclusively under other airlines' codes (RAA, 2005). While it is possible that the parent airline may try to pass some of its reprogramming costs through to the codeshare airline, this will not affect the projected costs of the rule.

3.1.1.3 Air Carrier Finances

Table 3-2 summarizes operations and financial data for the airlines that are most likely to be affected by the proposed rule (BTS 2005a, 2005b, 2005c). Operationally, the dominance of major airlines in average passengers flown per year is clear. On average, major airlines fly almost 10 times more passengers per year than the next largest group of airlines (national) and almost 100 times more than

Table 3-1. U.S. Flights and Passengers Carried by Airline Type, July 1, 2003 - June 30, 2004.

Airline Type	All Flights*					Non-Ca		
	Number of Airlines	Passengers		Flights		Number of Airlines	Passengers	
		Total	Percent	Total	Percent		Total	P
Major	15	552,595,548	72.4%	6,579,007	55.6%	13	522,768,869	
National	29	117,876,007	15.4%	2,689,894	22.7%	24	113,906,070	
Large regional	23	6,082,166	0.8%	128,823	1.1%	12	5,130,150	
Medium regional	14	2,592,449	0.3%	91,407	0.8%	8	2,478,234	
Small certificated/commuter	73	19,337,955	2.5%	1,725,043	14.6%	47	18,901,042	
Cargo only	1	0	0.0%	70,960	0.6%	0	—	
Foreign flag	135	64,924,489	8.5%	551,266	4.7%	113	32,823,205	
Total	290	763,408,614	100%	11,836,400	100%	217	696,007,570	

*All departures from U.S. airports (including territories and protectorates) to U.S. and foreign airports, plus departures from foreign air
**Excludes departures of cargo-only flights and departures of passenger-carrying flights from U.S. airports to foreign airports.

Table 3-2. Flights, Passengers, and Financial Information for Airlines Affected by CDC's Most Inclusive Regulatory Through June 30, 2004**

Airline Type	Number of Airlines	Average		Revenue ($millions)			N
		Passengers	Flights	Average	Max	Min	Average
Major	13	40,212,990	453,686	$6,857	$18,303	$1,132	$(3
National	24	4,746,086	105,622	$512	$1,145	$125	$
Regional	12	427,513	4,989	$87	$199	$25	$(0
Medium regional	8	309,779	8,825	$30	$80	$2	$(0
Small certificated/commuter*	47	402,150	33,604	$53	$350	$0.4	I
Foreign flag	113	290,471	2,113	NA	NA	NA	I

*Revenue for 31 small certificated carriers and commuters taken from Dun & Bradstreet or estimated from similar airlines based on av
**Excludes departures of cargo-only flights and departures of passenger-carrying flights from U.S. airports to foreign airports.

small certificated and commuter airlines. Average revenues for major airlines exceed those for smaller airlines by an even larger margin (13 times larger than national airline average revenues and 130 times larger than average small certificated and commuter airline revenues).[3]

Average net income is negative for all groups except national airlines. Among major airlines, six of 13 companies earned negative net income between July 2003 and June 2004. Overall, 20 of the 55 airlines for which net income figures were available had negative net income in this period. It is possible that the airline industry has still not recovered from the financial impact of 9/11 or the SARS epidemic, although the prevalence of negative net income in this industry may also reflect structural problems within the industry.

3.1.2 Cruise Ship Industry Profile

The cruise ship industry is the primary affected segment of the industry that provides international water transportation to passengers. The well-known portion of this industry comprises large to very large foreign firms, best typified by the "big three" of the global industry: Carnival, Royal Caribbean, and Star Cruises. Also included in this group are some smaller cruise lines that serve similar markets or niche markets (markets characterized by particular passenger interests or profiles, such as ultra-luxury and educational).

A second, much smaller segment comprises small operations that provide shorter-distance international water transportation to passengers in such areas as the Great Lakes, the Pacific Northwest, Maine to Canada, and Florida to Mexico, Bahamas, or Caribbean locations. These operations may own small to very small cruise ships carrying, for example, from fewer than 20 passengers to several hundred passengers. Finally there are also lines that own and operate ferries, with or without berths, which carry passengers between, for example, Seattle, WA, and Vancouver, B.C., Canada, or Ohio and Ontario, Canada. The sections that follow profile the major cruise ship industry, then briefly discuss the smaller operations that may be less well known to the general public.

3.1.2.1 Definition of Cruise Markets

Cruise markets can be defined in two ways: the location where the cruise is primarily marketed or the departure location of the ship. The cruise line industry itself defines "market" to mean where the cruise lines market their cruises, not the cruises' origins or destinations. This definition can cause confusion: for example, a Mediterranean cruise primarily marketed to North American passengers would be considered part of the North American market. The other definition, based on departure location, is used by analysts covering the industry. Under this system, a ship departing from San Juan, Puerto Rico, would be counted as part of the North American market without regard to the makeup of the passengers[4].

When considering the cruise industry, one must remember that the home country of the cruise ship company has nothing to do with the markets in which it operates. Since ships are mobile, cruise ship companies locate their headquarters to take advantage of favorable tax, maritime registry, and other laws.

[3] DOT collects financial data from small certificated and commuter airlines but publishes it only after a 3-year delay (DOT, 2005). Therefore, the revenue figures for these airlines were estimated using the average revenue per passenger from medium regional airlines and multiplying by total passengers flown for each airline. ERG did not try to estimate operating margin or net income for this group of airlines.

[4] ERG relied on data primarily from the cruise line industry, so the passenger data used reflects the North American market. The vast majority of the North American market is associated with entrances to U.S. ports and any overcounting of passengers (e.g., counting passengers that cruise exclusively in the Mediterranean) is offset by passengers from other market areas also entering U.S. ports.

Additionally, companies are under no obligation to fly on their ships the flag of the country where their headquarters is located. As with headquarter locations, companies flag their vessels in countries that provide the best combination of cost and legal environment. For example, the *Norwegian Star* sails in Canada and Alaska, is registered in the Bahamas, and is owned by Star Cruises, a Malaysian company. The vast majority of major cruise lines are foreign-owned or affiliated with foreign parents.

3.1.2.2 World and North American Cruise Market

In 2004, the world cruise ship fleet consisted of about 250 vessels with a capacity of just under 13 million people. This count of vessels includes 10 new, very large ships that have increased industry capacity by 12 percent, or more than a million passengers (Cruise Industry News, 2004). Capacity is generally divided among three areas: North America, Europe, and Asia. Of these, North America dwarfs all others with 74 percent of global capacity. At 23 percent, Europe controls the second largest share, while Asia is the smallest market with only 3 percent of capacity (Deutsche Bank, 2004).

The North American market is served by 128 ships containing 192,000 berths with a total capacity of almost 10 million people (Deutsche Bank, 2004). As noted earlier, these ships may or may not actually visit U.S. ports, since these data correspond to where the cruise is marketed rather than where it departs from, but many do visit U.S. ports. The big three in the North America cruise market, as well as the world cruise market, are Carnival, Royal Caribbean, and Star Cruises. These three handle over 92 percent of the passengers in the North American market.

The Caribbean is the single largest cruising area. Unlike most other markets, the Caribbean hosts cruise ships year round. In 2002, this market accounted for 40 percent of worldwide capacity and about 60 percent of North American capacity (USB Warburg, 2003). Other large cruising areas include Europe and the Mediterranean, and Asia and the South Pacific. Alaska represents the fourth largest market globally and the second largest portion of the North American market, with approximately 8 percent of the global market in 2002 (USB Warburg, 2003).

3.1.2.3 The Medium-to-Small Cruise and Ferry Industries Serving International Ports

Like the major cruise lines, discussed above, these smaller lines are also predominantly foreign-owned. These lines tend to serve the niche markets and generally operate older, smaller vessels. (Some of these are built to order; others are purchased from the major lines as they acquire newer, larger, state-of-the-art ships.) Some of the niche markets that these lines serve are passengers seeking educational cruises, such as those specializing in ecological, cultural, or historical experiences. Others provide very small, exclusive, luxury cruises, focusing on parties of passengers numbering well under 100. Still others operate dive/cruise vacations. This is a very disparate group of operations whose lines may or may not be counted in the economic data on the North American cruise line market.

The primary areas of operation can be highly localized, such as between California and Mexico, between U.S. and Canadian ports along the St. Lawrence River, and between Florida and the Bahamas. They can also be as far-flung as any of the major lines' areas of operation. ERG has identified 7 cruise lines in this category. More lines were identified, but these others were eliminated from the affected cruise line group either because they had no U.S. ports of call listed (for example, they cruise only in European waters) or generally did not appear to offer passenger services when relocating ships from, for example, Maine to the Caribbean during seasonal transfers. In theory, any vessel could become an affected vessel, because ships are inherently mobile. Nevertheless, the general itineraries of the lines as currently posted on Web sites were considered the likeliest indicator of whether they were likely to be affected by the proposed regulation in the near future.

There are also ferry lines linking U.S. and foreign ports. ERG has identified eight ferry lines that operate internationally. The primary areas of operation are the Great Lakes, the Gulf of Mexico, Maine to Canada, and the Pacific Northwest. Some ferries are passenger-only, some serve passengers with vehicles, and some combine the cruise line/ferry concept. Two affiliated lines are good examples of this last category: the Scotia Prince Line, which provides overnight accommodations and car shipping services between Maine and Canada, and the Yucatan Express Line, which provides the same services between Florida and Mexico.

3.1.2.4 Financial Overview of the Cruise Line Industry

Most of the largest cruise lines are members of the International Council of Cruise Lines (ICCL). These cruise lines currently number 16, although most of these are subsidiaries of the "big three." The 16 ICCL members are Carnival, Celebrity, Costa, Crystal Cruises, Cunard, Disney Cruise Lines, Holland America, Norwegian Cruise Lines (NCL), NCL America, Orient, Princess, Radisson Seven Seas, Royal Caribbean, Seabourn Cruise Lines, Silversea, and Windstar. Carnival owns Costa, Cunard, Holland America, Princess, Seabourn, and Windstar. Royal Caribbean owns Celebrity. Star Cruises owns NCL, NCL America, and Orient. Only Silversea, Radisson, and Disney are not affiliated with the "big three."

Another 16 cruise lines or ferry lines are not members of ICCL, but *are* large operations or are foreign owned or affiliated and thus are not characterized as small for small business analysis purposes. (See Section 5 for more information on definitions of small businesses.)

Small lines were identified on the basis that (1) they serve U.S. ports and (2) they have itineraries with at least one international destination. They are also U.S. corporations. These lines number only 25, of which five are ferry lines.

Table 3-3 presents limited financial data, to the extent it is available, at the parent company level for corporations that are not foreign owned or affiliated. Financial data are presented only for U.S. firms, first, because financial information on foreign firms is either unavailable or is not necessarily available in terms comparable to U.S. financial reporting terms. Furthermore, no impact analysis on foreign firms is undertaken, although costs to these firms are accounted for, since it is possible that costs could ultimately fall on U.S. consumers. The counts discussed above—16 ICCL members, 16 additional large or foreign cruise lines, and 25 small cruise or ferry lines—are used in the cost analysis. Financial data for only the 10 lines shown in Table 3-3, however, are used to characterize the three types of U.S. firms (ICCL firms, other large firms, and small firms) in the impact analysis.

3.2 COMPARISON OF CURRENT REGULATORY REQUIREMENTS TO PROPOSED RULE

3.2.1 Components of the Proposed Rule Imposing Incremental Costs on Industry

Table 2-1 (See Section 2) provided a section-by-section comparison of the proposed rule with current practices. Incremental cost impacts of these changes are associated with passenger information requirements and various administrative paperwork and opportunity costs. The proposed regulation does not currently add new requirements to the mandated isolation and quarantine space at airports. Airlines, airports, cruise ships and passengers bear the bulk of costs. The sections below discuss the implications of these requirements, which add time to the current data collection for airline and cruise line needs, as well as time to prepare data for potential submission to CDC.

Table 3-3. Available Financial Data for U.S. Cruise Lines

Cruise Line	Number of Ships	Number of Berths	Parent Corporation	Revenues ($millions)	Operating Earnings ($millions)	Net Income ($millions)
U.S. ICCL Members						
Radisson Seven Seas	6	2,614	Carlson Companies	$400	NA	NA
Disney Cruise Lines	2	4,800	Disney	$30,752	3,739	2,345
Other Large U.S. Cruise Lines						
Oceania Cruises, Inc	3	1368	Oceania Cruises, Inc	$49	NA	NA
Small U.S. Cruise and Ferry Lines						
Lindblad Expeditions	6	442	Lindblad Expeditions	$51	NA	NA
Glacier Bay Cruiseline	4	209	BB Acquisition L.L.C.	$7.5	NA	NA
Cruise West	8	719	Travel West	$52	NA	NA
Seadream Yacht Club	2	220	Seadream Yacht Club	$5.6	NA	NA
Nekton Diving Cruises	2	68	Nekton Diving Cruises	$3.2	NA	NA
Star Clippers	2	170	Star Clippers	$17.8	NA	NA
Discovery Cruises	1	NA	Discovery Cruises	$1	NA	NA

NA=Not Available. Most U.S. cruise lines are privately held and this information is not publicly available.

3.2.2 Options and Scenarios Examined

To project the costs and impacts of the proposed rule, ERG examined three regulatory options, as discussed in Section 2. These are:

- Option 1: International passenger flights only (arrivals) and passenger vessel trips from non-U.S. locations (International Only)

- Option 2: International passenger flights and vessel trips and domestic passenger flights into and out of large and medium airport hubs (International plus Large and Medium Hub)

- Option 3: International flights and vessel trips and all domestic passenger flights (International plus All Domestic)

The large and medium hub airports are those as defined by CDC (see the Preamble to the proposed rulemaking). CDC has defined 33 large hubs and 36 medium hubs, for a total of 69 airports covered under Option 2.

Table 3-4 presents the estimated number of affected airlines and passengers under each option. The projected costs of the rule are primarily a function of the number of airlines that must perform computer reprogramming tasks, and the number of passengers from whom information must be obtained. As demonstrated in Table 3-4, the regulation affects most airlines under Option 1. Thereafter, the number of affected airlines increases relatively little, but the number of affected passengers increases more than 10-fold. Thus, the increase in costs from Option 1 to Options 2 and 3 will primarily be associated with

passenger data collection costs (essentially an operating cost), while the one-time reprogramming costs, akin to capital costs in this context, are largely incurred under Option 1.

Table 3-4. Estimated Number of Airlines and Passengers Affected by Option

Airline Type	Option 1 International Only		Option 2 International plus Large and Medium Hubs		Option 3 International plus All Domestic	
	Airlines	Passengers (millions)	Airlines	Passengers (millions)	Airlines	Passengers (millions)
Major	12	29.80	13	488.28	13	522.77
National	24	3.96	24	87.32	24	113.91
Regional	11	0.97	12	3.90	12	5.13
Medium regional	5	0.11	8	1.12	8	2.48
Small/commuter	19	0.43	47	9.88	47	18.90
Foreign	113	32.07	113	32.83	113	32.89
Total	184	67.35	217	623.33	217	696.07

ERG investigated two data collection scenarios. ERG projects that much of the passenger data will eventually be collected in a decentralized manner at the point of sale, which suggests lower costs to industry. However, there are currently legal and logistical obstacles that would need to be addressed before this option could be implemented. Conversely, centralized data collection at the point of departure may be inefficient and costly. This scenario represents a worst-case scenario for the method of compliance. Therefore, ERG developed cost estimates for both scenarios and presents the results as a range of potential costs. In the long run, ERG expects the efficiencies associated with decentralized point of sale data collection will provide industry with incentive to move towards that means of data collection.

Decentralized data collection at the point of sale assumes carriers can link into centralized databases such as APIS, or travel industry databases such as those controlled by GDS companies. Some data elements required under this rule are already collected by travel agents, the airlines themselves, and by intermediaries such as Travelocity and Orbitz when passengers book directly through the Internet (i.e., at the point of sale). Furthermore, missing data elements can be entered directly by passengers when purchasing the tickets through the Internet. By accessing already provided data, and having passengers directly provide missing information when purchasing their tickets through the Internet, data collection costs to industry as a whole (airlines and travel booking firms) are likely to be lower than costs when data is collected at the point of departure.

Under the POS scenario, airlines and cruise lines would need to reprogram their computer systems. The primary component of these reprogramming costs appears to be the need to add database fields to the carriers' computer systems to handle the additional data collected, regardless of how or who collects the data, (Delta, 2005). In addition, linking outside databases and modifying Web-based data collection systems may result in some additional reprogramming costs. These potential additional costs, however, could not be usefully distinguished given the broad nature of reprogramming cost estimates we received from industry.

ERG assumes that the POS scenario can largely be implemented, but recognizes that there are impediments to setting up this approach. For example, Amadeus, one of the four dominant GDS companies, is foreign owned and stores collected passenger information in Germany; it is governed by German law regarding data sharing and privacy. Complete implementation of the POS scenario would

thus require changes in international law. Therefore, ERG also examined costs under an alternative "Point of Departure" (POD) scenario.

The POD scenario assumes that airlines and cruise lines will not have access to centralized databases such as APIS, nor will carriers have access to data from other travel industry sectors such as GDSs or travel agencies. Therefore, airlines will need to obtain address and contact information from all passengers for whom they do not already have this information. Furthermore, it is assumed there is no automated means for collecting or updating the key passenger data that may change for every trip (e.g., emergency contact information). Thus, carriers will need to collect the missing information at the point of departure. The cost of data collection is the biggest difference between this scenario and the POS scenario. The same costs for reprogramming and archiving/administrative tasks will be incurred under both scenarios for each option. However, there will be additional opportunity costs for passengers under the POD scenario, since information currently being provided to travel agencies, for example, may have to be provided again to the airlines at check-in (e.g., permanent address).

Under the POD scenario, travel agencies and GDSs are, by definition, unaffected. That is, travel agencies and GDSs are not collecting any relevant incremental information; airlines are forced to assemble all relevant data. To the extent that travel agencies or GDSs actually do compile and share relevant passenger information, compliance costs are reduced and move towards the POS option costs.

ERG uses the POD scenario to estimate an upper bound, and the POS scenario to estimate a lower bound on data collection costs incurred under the proposed rule. Actual regulatory costs should fall between these two estimates; the exact point within this range will depend on the ability of carriers to overcome the legal and logistical barriers associated with the POS scenario.

3.3 INCREMENTAL COSTS TO INDUSTRY OF DATA COLLECTION

This section presents the assumptions and costs for the three options discussed above under both scenarios. Four cost items are discussed. Section 3.3.1 discusses the cost of time to collect incremental passenger information; Section 3.3.2 presents the cost to reprogram computer systems, including airline and cruise line computers, and GDS and other travel booking computers, such as those at travel agencies. All costs are calculated on a pre-tax basis and all are considered to be in 2004 dollars.

3.3.1 Cost Item 1: Cost of Time to Collect Incremental Passenger Information

This section presents ERG's estimates of the incremental time needed by industry to collect additional information from passengers to meet the requirements of this rule. ERG based its assumptions concerning the incremental time needed to collect this information on estimates reported by industry to DHS for its proposed implementation of Section 231 of the Enhanced Border Security and Visa Reform Act of 2002 (which requires similar temporary address information), industry comments on that proposed rule, and industry discussions with CDC concerning development of this rule (FR, 2003; IATA, 2003; Qantas, 2003; Volpe, 2004). Industry comments, which were broadly consistent, suggest that it would take 30 to 45 seconds per passenger to obtain temporary address information.

3.3.1.1 Assumptions under the POS Scenario

Under the POS Scenario, ERG assumes that most passengers would be able to input their information directly into a database as they make their reservations. This database may belong to the airline if the passenger is a frequent flier or is booking the flight directly, or it may belong to the GDS if the passenger is booking through Travelocity or a similar Web-based system. For the purpose of

developing this cost estimate, ERG assumes (as noted previously) that the legal and logistical barriers to airlines accessing these databases are removed. Information available from these databases may include: permanent address, telephone numbers, email address, passport or visa numbers, and simple itinerary (departure city and gate, arrival city and gate, flight number, and seat assignment) (Delta, 2005; Volpe, 2004).

The only industries judged to be affected by incremental data collection costs are travel agencies and other similar reservation-booking services. Although the majority of passengers will directly enter all necessary information when booking through the airlines or Web-based systems, those booking through travel agencies will still need additional data entered for them by the travel agent. ERG makes the following assumptions:

- Industry sources indicate that 40 percent of passengers book directly through airlines; of the remaining 60 percent, we assumed that half use Web-based systems and half (30 percent) use travel agents. The percentage of bookings through travel agents has shown a marked decline over recent years due to the use of the Internet by passengers to book their travel directly, so data collection costs associated with travel agencies should decline over time.

- Travel agencies are estimated to need an additional 45 seconds per passenger to gather information from passengers to cover the new data requirements. Travel agencies already collect much of the information required, but a few pieces of information might not be universally collected. These might include email address, passport information, and emergency contact information. This information was considered equivalent to the amount of information that would need to be gathered for an address. In reality, the time needed to collect data might decline because databases will build up over time with repeat customers and the additional information needed at subsequent visits will be smaller than the initial visit.

3.3.1.2 Assumptions under the POD Scenario

Under the POD Scenario, ERG assumes that airlines, through their own databases, including APIS, will have access to some information for frequent fliers and others who book directly with the airline. This information includes: permanent address, telephone numbers, email address, passport or visa numbers, and simple itinerary (departure city and gate, arrival city and gate, flight number, and seat assignment) (Delta, 2005; Volpe, 2004). Airline passengers who are not frequent fliers, and all cruise ship passengers, will need to have this information collected prior to boarding. All passengers, including frequent fliers, will need to provide updated emergency contact names and phone numbers, and possibly email addresses, at the time of departure. ERG assumes:

- 30 seconds are required to collect emergency contact information from all passengers.

- An additional 30 seconds, on average, is necessary to confirm an existing or provide a revised permanent address, email address, and telephone number for each frequent flier or direct booker, and, if applicable, to identify groups or flying companions and provide passport information, if applicable.

- For non-frequent flier and cruise ship passengers, 1 minute is necessary to gather permanent address and telephone number, email address, and, if applicable, information on group or flying companions, and passport information. Added to the 30 seconds for emergency contact information, this totals 1.5 minutes per non-frequent flier passenger.

- The percentage of frequent fliers/direct bookers is greatest for major and foreign airlines, declining as size of airline declines. Major and foreign airlines are expected to have access to permanent address information for 70 percent of their passengers (Delta, 2005). This percentage is 60 percent for national airlines, 50 percent for regional airlines, 40 percent for medium regional airlines, and 30 percent for small certificated/commuter airlines.

Thus, frequent fliers will require an additional minute in the check-in process while others will require 1.5 minutes.

A key concern of industry is the potential for delay associated with the additional time needed for passenger check-in if data were collected at the point of departure (Qantas, 2003; Volpe, 2004). To minimize the potential for delay, ERG assumed that:

- Air carriers would need to hire additional workers to gather this information at the point of departure. It is envisioned that the information would be input using portable hand-held workstations (costing $400 each), allowing workers to minimize delays by collecting the data while passengers are in line for check-in or waiting to board. Therefore, no additional queuing time and no impact on terminal space are assumed.

- Codeshare airlines will incur data collection costs as described for other airlines. It is possible that at least some of these costs will be borne by the parent airline, but the extent to which that may happen is unclear.

- Additional computers are not necessary for check-in at cruise lines, since passengers have several hours over which they may board.

We expect carriers would develop more efficient systems of data collection, but this model suggests that carriers could gather the necessary information without causing delays. We assumed a wage rate of $14.68 per hour, which is the average for an airline customer service representative multiplied by a factor of 1.4 to account for benefits (BLS, 2005).

3.3.1.3 Costs of Data Collection

Table 3-5 presents the costs of data collection for the three options under each of the two scenarios. Because the number of passengers from whom information must be gathered increases as the option number increases, the costs of data collection increase proportionately. These costs range from $5.2 million to $316.3 million, depending on option and scenario. These costs are likely to be overestimated to the extent they fail to account for passengers taking connecting flights or for group travel.[5]

Data collection costs under the POD scenario are 6 to 12 times larger than data collection costs under the POS scenario. This reflects the fact that for each option, more passengers have to provide data under the POD scenario, but more data has to be provided as well. That is, under the POD scenario,

[5] For example, costs are estimated using the number of passengers on each non-stop flight between two airports; for some passengers, however, a single trip may be composed of two or more flight segments for which information will only need to be provided a single time. Similarly, the time needed to provide all information collectively for a group or family traveling together is probably significantly less than the time needed to collect the same information from each individual member of the group.

frequent fliers are the only group of passengers for whom industry can save data collection time by accessing previously provided information.

In addition, the burden of data collection costs is distributed quite differently under the POD scenario than the POS scenario. Under the POS scenario, data collection costs are borne by travel agencies; under the POD scenario, all data collection costs are borne by the carriers.

Table 3-5. Total Costs of Proposed Options by Cost Type and Affected Entity (in millions, $2004)

	Option 1 Scenario		Option 2 Scenario		Option 3 Scenario	
Cost Item by Affected Entity	**POS**	**POD**	**POS**	**POD**	**POS**	**POD**
Airlines						
Data Collection	$0	$26.81	$0	$248.19	$0	$278.05
Reprogramming	$105.87	$105.87	$107.50	$107.50	$107.50	$107.50
Archiving/Administration	$0.68	$0.68	$0.71	$0.71	$0.71	$0.71
Total	$106.55	$133.36	$108.22	$356.41	$108.22	$386.27
Cruiseships						
Data Collection	$0	$38.26	$0	$38.26	$0	$38.26
Reprogramming	$0.61	$0.61	$0.61	$0.61	$0.61	$0.61
Archiving/Administration	$0.14	$0.14	$0.14	$0.14	$0.14	$0.14
Total	$0.75	$39.01	$0.75	$39.01	$0.75	$39.01
GDS						
Data Collection	$0	$0	$0	$0	$0	$0
Reprogramming	$2.97	$0	$2.97	$0	$2.97	$0
Archiving/Administration	$0	$0	$0	$0	$0	$0
Total	$2.97	$0	$2.97	$0	$2.97	$0
Travel Agencies						
Data Collection	$5.19	$0	$48.04	$0	$53.65	$0
Reprogramming	$2.44	$0	$2.44	$0	$2.44	$0
Archiving/Administration	$0	$0	$0	$0	$0	$0
Total	$7.64	$0	$50.48	$0	$56.09	$0
Total, Industry						
Data Collection	$5.19	$65.07	$48.04	$286.45	$53.65	$316.31
Reprogramming	$111.89	$106.48	$113.52	$108.11	$113.52	$108.11
Archiving/Administration	$0.82	$0.82	$0.85	$0.85	$0.85	$0.85
Total	$117.90	$172.36	$162.41	$395.41	$168.02	$425.27
Passengers						
Opportunity Costs	$67.60	$90.52	$332.62	$398.40	$367.29	$439.92
Total Social Costs	$185.50	$262.89	$495.03	$793.81	$535.31	$865.19

3.3.2 Cost Item 2: Reprogramming Costs

3.3.2.1 Assumptions

All options investigated involve potentially substantial reprogramming by carriers so that a variety of information from several different databases can be automatically linked to the information being compiled elsewhere and saved electronically with the manifest. There are no substantive differences between carrier reprogramming requirements under the POD scenario and the POS scenario, therefore carrier reprogramming costs under the two scenarios are assumed to be identical. GDS and travel

agencies, however, incur reprogramming costs under the POS scenario that are not incurred under the POD scenario.

Discussions with Delta Airlines (Delta, 2005) indicate that reprogramming might cost a major airline anywhere from $5 million to $15 million. Smaller airlines indicate that their IT systems are smaller and more flexible than those of major airlines so their reprogramming costs should be substantially lower (Airline Web Sites, 2005; FR, 2003; Pace, 2005; Sun Country, 2005). This is partially because smaller airlines' operations are less complex than those of major airlines, but also because major airlines are burdened with substantial legacy IT systems, which are more difficult to reprogram. Therefore, ERG assumed:

- Major and foreign airlines will each incur reprogramming costs of $10 million, and these costs are assumed to trend downwards as airline size decreases: $5 million is assumed for national airlines; $1 million for regional airlines; $100,000 for medium regional airlines; and $10,000 for small certificated/commuter airlines. This principal cost estimate is an approximation based on discussions with several airlines and their rough projections of reprogramming efforts. (Given the uncertainty around this estimate, this estimate might be refined based on further research and information provided in public comments to the proposed regulation.) Reprogramming costs were not extended to one group of very small intrastate airlines where passenger volumes were so low (e.g., a few hundred passengers per year) as to suggest that electronic interactions with other airlines would be limited.

- Codeshare airlines will incur zero reprogramming costs, because they do not have their own reservation systems: they piggyback off the parent airlines' reservation and flight manifest systems (Franz, 2005). It is possible, however, that the parent airline may try to pass some of its reprogramming costs through to the codeshare airline.

- Large cruise lines that are ICCL members and other large or foreign lines are assigned a cost of $125,000, based on information presented in support of proposed 8 CFR Parts 217, 231, and 251 (FR, 2003). Costs similar to those for small airlines ($10,000) are assigned to small cruise lines and ferries.

- Companies that own and operate GDS will incur reprogramming costs to accept additional data fields from Web-based systems as well as from travel agencies under the POS scenario. ERG estimates that four major GDS systems dominate the U.S. market, and these companies will each incur reprogramming costs on the order of $5 million.

- Travel agencies and other tour-booking companies will incur reprogramming costs of $1,000 each to update their Web links with the GDS under the POS scenario. ERG estimates that about 18,000 establishments will incur these costs.

Reprogramming costs are one-time costs, so they are annualized at 7 percent over 10 years.

3.3.2.2 Total Costs of Cost Item 2

Using the above assumptions and information on number of airlines and cruise lines presented earlier, ERG estimates that reprogramming tasks will cost the airlines $105.9 million to $107.5 million on an annualized basis for each scenario depending on option. For cruise lines, the estimated costs of reprogramming total $0.6 million (annualized). Under the POS scenario, GDSs, travel agencies, and similar operations will incur costs totaling $5.4 million, regardless of option. Total costs to industry for

reprogramming are therefore estimated to be $106.5 million to $113.5 million on an annualized basis (see Table 3-5). Industry reprogramming costs are lower under the POD scenario than the POS scenario because GDS and travel agencies do not perform reprogramming under that scenario.

3.3.3 Cost Item 3: Archiving and Other Administrative Costs Assumptions

3.3.3.1 Assumptions

Major airlines tend to keep flight manifests in electronic format for only a few days because their intensive flight operations would otherwise result in massive storage requirements (United, 2005; Volpe, 2004). The proposed rule requires manifests to be kept in electronic format for up to 60 days. Therefore, airlines will have to store manifests electronically rather than simply dumping them from the system. These archiving and administrative requirements have identical cost implications under the two scenarios.

- ERG assumes that incremental costs will be incurred for archiving and administrative time. Included in archiving is the administrative cost to archive and store the data on each flight and cruise on a daily, weekly, and monthly basis. Archiving and administrative time also includes any time needed to interface with CDC, to provide written plans for reporting incidents and preparing and delivering manifests and other passenger information, and to prepare data to send to CDC. This time estimate also includes the time to respond to 10-12 routine requests per month for passenger lists that CDC anticipates. It is assumed that once systems are reprogrammed, compiling and transmitting passenger lists will take little time. It is also assumed that an airline database manager or equivalent level staff is in charge of these tasks and that the time needed varies by size of airline or cruise line. Major, national, and foreign airlines are expected to require 5 percent of a full-time-equivalent employee to handle these tasks; regional airlines are assigned 3 percent of an FTE per year; medium regional airlines, 2 percent; and small certificated/commuter airlines, 1 percent. For cruise lines, ICCL members are assigned 5 percent, other large and foreign lines are assigned 3 percent, and small lines and ferries are assigned 1 percent. The average wage for this occupation is taken to be $31.43; fully loaded, this is $44.00 per hour (BLS, 2005). Any costs savings resulting from differences in numbers of passengers among the options considered are considered minimal, so the cost to archive and administer the collected data is assumed not to vary among the options.

- No incremental archive storage space is assumed because it is estimated that a week's data collection comprising only the data required by CDC would entail about 20 gigabytes of space at the largest airlines, with all other airlines and cruise lines needing substantially less space. Backup tapes with 50-gigabyte storage space are available; ERG assumes that this is the standard size used by the largest airlines. This would mean that four tapes per month would be needed at most, for a maximum of 12 tapes over a 3-month period. The tapes could be recycled as they "aged off." It is assumed the tapes can be stored on shelf space currently available. Since tapes can be reused for a number of years, the cost to purchase tapes is considered minimal.

- Because the GDS and travel agencies are not responsible for saving or submitting manifests, they incur no archiving or administrative costs.

3.3.3.2 Total Costs of Cost Item 3

Using the assumptions outlined above and the numbers of lines discussed earlier, ERG estimates that the costs of archiving and administrative tasks will total $676,000 to $715,000 for airlines per year,

depending on option and $140,000 per year for cruise lines (see Table 3-4), for a total of about $816,000 to $855,000 per year, depending on option.

3.3.4 Cost Item 4: Opportunity Costs of Increased Passenger Time to Provide Information

3.3.4.1 Assumptions

Passengers also incur an opportunity cost for the time they must use in providing the information to the carriers. For the POS scenario, ERG assumed that:

- It takes an average of 1 minute for passengers to provide the required additional information to travel agents, on web forms, or to airlines/cruise lines when travel is booked. This represents the incremental time experienced by passengers to provide the information that is not currently collected (for example, passport information or emergency contact information). It includes an additional 15 seconds over the time estimated for travel agencies to account for additional time for passengers to locate information and to account for the small increment of time, on average, over all passengers, for those needing additional time to fill in new information fields on Web sites.

Under the POD scenario, non-frequent flier passengers are assumed to need additional time to provide personal information even though much of that information is already collected by travel agencies, Web site travel booking services, and the airlines. Essentially, both passengers and carriers require more time when information is collected at the point of departure because some of that information must be provided twice (once when purchasing the ticket, and again when departing). The lower time estimate for data collection under the POS scenario represents a benefit of information sharing among the airlines, travel agencies, and GDSs. ERG assumed that:

- It takes an average of 1.5 minutes for passengers to provide the required additional information to airlines/cruise lines when information is only collected at the point of departure.

- The opportunity cost of passenger time is set at a value of passenger time recommended by the Federal Aviation Administration (FAA-APO, 2003) of $28.60. The opportunity cost to passengers makes up the non-industry social costs of the rule.

3.3.4.2 Total Costs of Cost Item 4

Given the above assumptions and the total number of passengers on airlines and estimated for cruise lines, ERG estimates that the opportunity costs to passengers of providing additional data total $67.6 million to $440.0 million annually, depending on option and scenario.

3.4 PROJECTED NATIONAL COSTS OF THE PROPOSED RULE

ERG discounted future costs to their present value using the 7 percent discount rate recommended by OMB. Costs are annualized so that options with costs occurring in different years can be compared. Table 3-6 presents the range and the midpoint of the range of annualized national costs of the options under each scenario. ERG uses the midpoint of the range for each option in the cost benefit comparison presented in Section 7. Projected annualized costs of the rule range from $185.5 million to $865.2 million per year over 10 years (including foreign carriers).

Table 3-6. Projected Annualized National Costs of the Proposed Rule (millions, 2004 dollars)

Affected Entity	Option 1 Scenario		Option 2 Scenario		Option 3 Scenario	
	POS: Lower Estimate	POD: Upper Estimate	POS: Lower Estimate	POD: Upper Estimate	POS: Lower Estimate	POD: Upper Estimate
Airlines	$106.5 - $133.4		$108.2 - $356.4		$108.2 - $386.3	
Cruise Lines	$0.7 - $39.0		$0.7 - $39.0		$0.7 - $39.0	
Travel Agencies	$7.6 - $0		$50.5 - $0		$56.1 - $0	
GDS	$3.0 - $0		$3.0 - $0		$3.0 - $0	
Total, Industry	**$117.9 - $172.4**		**$162.4 - $395.4**		**$168.0 - $425.3**	
Opportunity Costs, Passengers	$67.6 - $90.5		$332.6 - $398.4		$367.3 - $439.9	
Total with Opportunity Costs	**$185.5 - $262.9**		**$495.0 - $793.8**		**$535.3 - $865.2**	
Foreign Carriers	$80.5 - $93.2		$80.5 - $93.5		$80.5 - $93.6	
Total, excluding Foreign Carriers	**$105.0 - $169.6**		**$414.6 - $700.3**		**$454.8 - $771.6**	
Midpoint of Range						
Airlines	$120.0		$232.3		$247.2	
Cruise Lines	$19.9		$19.9		$19.9	
Travel Agencies	$3.8		$25.2		$28.0	
GDS	$1.5		$1.5		$1.5	
Total, Industry	**$145.1**		**$278.9**		**$296.6**	
Opportunity Costs, Passengers	$79.1		$365.5		$403.6	
Total with Opportunity Costs	**$224.2**		**$644.4**		**$700.3**	
Foreign Carriers	$86.9		$87.0		$87.0	
Total, excluding Foreign Carriers	**$137.3**		**$557.4**		**$613.2**	

3.5 ALTERNATIVE ASSUMPTION ON ARCHIVING AND ADMINISTRATION COSTS

The costs to the airlines of ongoing tasks associated with managing the passenger manifest data remain subject to considerable uncertainty. As an alternative estimate of operating costs, ERG assumes that the airlines would incur operating costs that are 10 percent of their initial reprogramming costs; that is, as much as $1 million per year for the largest airlines and $500,000 per year for national airlines. This assumption yields similar or lower costs for the smaller airlines, but does allow for the potential of ongoing complexity in compliance tasks and for the possibility of unforeseeable complications for large airlines. (This estimate will be refined should further research and information provided in public comments provide additional data.)

Under this assumption in Option 3 (International and All Domestic), costs to the airlines increase by about $75 million per year. Total national costs of Option 3 rise to $610.1 million, an increase of about 14 percent. Total airline costs would rise to $183.0 million per year, compared with the $108.2 million estimated in Section 3.4. Nevertheless, the results of impact analyses on the airlines as presented in Section 4 remain largely unchanged—none of the airlines' estimated post-compliance financial situations reach the thresholds defined as significant regulatory impacts.

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SECTION 4: PROJECTED IMPACTS ON AFFECTED FIRMS

4.1 METHODOLOGY FOR ANALYZING IMPACTS ON AFFECTED FIRMS

4.1.1 Analysis of Airlines

The Bureau of Transportation Statistics (BTS) collects and disseminates substantial financial data for airlines. Up-to-date financial information is available for 55 large certificated carriers, including revenues, operating margin, and net income. For small certificated and commuter airlines, however, BTS withholds publication of financial data for three years. ERG either obtained revenues from Dun & Bradstreet for this group of 49 airlines, or estimated revenues based on total passengers flown and the average revenue per passenger earned by medium regional airlines.

For airlines, ERG calculated: (1) annualized compliance costs as a percentage of revenues, and (2) the number of airlines for which the projected costs of the rule exceed net income. For airlines without net income data, only compliance costs as a percentage of revenues are calculated.

4.1.2 Analysis of Cruise Lines, GDSs, and Travel Agencies

A significant number of cruise line companies are foreign-owned, and thus have no financial data available. Revenues are available for 10 domestic companies operating cruise ships. ERG identified 7 small-business-owned cruise lines without foreign affiliation that have publicly available revenue data.

A revenue test is conducted for all domestic cruise lines using actual revenues or average revenues by size. Where additional financial data are available, ERG conducts a similar analysis to that conducted for the airlines, as discussed above in Section 4.1.1.

For GDSs and travel agencies, ERG uses average revenues for these entities as presented in Census (U.S. Census Bureau, 2004). ERG conducts a revenue test on these entities; net income data are not available.

4.2 COMPLIANCE COSTS BY FIRM TYPE

Table 4-1 and 4-2 present the total annualized compliance costs calculated for each type of airline, cruise line, and other affected entity under the POS scenario and POD scenario, respectively. Costs projected for any individual airline might deviate substantially from the average for the category because: (1) codeshare airlines do not incur reprogramming costs, and (2) especially among smaller airlines, the number of passengers flown per year can differ significantly between airlines in the same size class. Major and foreign large airlines incur the highest cost on average, compared to smaller classes. This is largely because reprogramming costs are much higher for these groups, due to the prevalence of difficult-to-reprogram legacy computer systems under the POS scenario and because, under the POD scenario, they also handle the vast majority of passengers.

4.3 RESULTS OF IMPACT ANALYSIS

4.3.1 Compliance Costs as a Percent of Revenues

Of the 104 airlines with revenue data available or imputed, no airlines are projected to incur costs in excess of 1 percent of revenues under any of the options examined under the POS scenario.[6] ERG found a similar result for cruise lines, travel agencies, and GDSs under all options and under either scenario.

Table 4-1. Total Projected Average Compliance Costs by Industry and Size Class, POS Scenario

	Total Annualized Costs ($millions)					
	Option 1		Option 2		Option 3	
	International Arrivals Only		International Arrivals and Large and Medium Hubs		International Arrivals and All Domestic Flights	
Affected Entity	Number of Lines	Annualized Cost per Line	Number of Lines	Annualized Cost Per Line	Number of Lines	Annualized Cost per Line
Major	9	$1,428,351	10	$1,428,351	10	$1,428,351
Major Codeshare	3	$4,576	3	$4,576	3	$4,576
National	16	$716,464	16	$716,464	16	$716,464
National Codeshare	8	$4,576	8	$4,576	8	$4,576
Regional	11	$145,123	12	$145,123	12	$145,123
Medium Regional	5	$16,068	7	$16,068	7	$16,068
Medium Codeshare	0	N/A	1	$1,830	1	$1,830
Foreign, Large	30	$1,428,351	30	$1,428,351	30	$1,428,351
Foreign, Medium	49	$716,464	49	$716,464	49	$716,464
Foreign, Small	34	$73,934	34	$73,934	34	$73,934
Small/commuter airlines	11	$2,339	34	$2,339	34	$2,339
Small Codeshare	8	$915	13	$915	13	$915
Average Annualized Cost Per Airline	**184**	**$579,074**	**217**	**$498,689**	**217**	**$498,689**
Cruise Lines						
Large lines (ICCL Members)	16	$22,373	16	$22,373	16	$22,373
Other large lines	16	$20,543	16	$20,543	16	$20,543
Small lines	25	$2,339	25	$2,339	25	$2,339
Average Annualized Cost Per Cruse Lines	**57**	**$13,073**	**57**	**$13,073**	**57**	**$13,073**

[6] One small airline, for which direct revenue data were unavailable, showed impacts exceeding 1 percent of revenues when revenues were extrapolated from passengers carried. However, the airline carried so few passengers that ERG believes the extrapolation method results in an unreliable estimate of revenues in this case.

Table 4-1. Total Projected Average Compliance Costs by Industry and Size Class, POS Scenario

Affected Entity	Total Annualized Costs ($millions)					
	Option 1		Option 2		Option 3	
	International Arrivals Only		International Arrivals and Large and Medium Hubs		International Arrivals and All Domestic Flights	
	Number of Lines	Annualized Cost per Line	Number of Lines	Annualized Cost Per Line	Number of Lines	Annualized Cost per Line
Other						
Large Travel Agencies	50	$83,193	50	$768,784	50	$858,484
Small Travel Agencies	17,120	$203	17,120	$704	17,120	$769
GDS	4	$711,888	4	$711,888	4	$711,888
Other Tour Booking Firms	835	$142	835	$142	835	$142
Average Annualized Cost Per Agency booking agencies	**18,009**	**$288**	**18,009**	**$2,968**	**18,009**	**$3,279**

Table 4-2. Total Projected Average Compliance Costs by Industry and Size Class, POD Scenario

Affected Entity	Option 1		Option 2		Option 3	
	International Arrivals Only		International Arrivals and Large and Medium Hubs		International Arrivals and All Domestic Flights	
	Number of Lines	Annualized Cost per Line	Number of Lines	Annualized Cost per Line	Number of Lines	Annualized Cost per Line
Airlines						
Major	9	$2,690,112	10	$19,610,138	10	$20,576,088
Major Codeshare	3	$135,349	3	$3,554,830	3	$4,866,386
National	16	$778,036	16	$2,060,823	16	$2,325,733
National Codeshare	8	$84,929	8	$1,805,240	8	$2,642,431
Regional	11	$182,995	12	$284,352	12	$328,292
Medium Regional	5	$26,168	7	$44,824	7	$105,302
Medium Codeshare	0	NA	1	$300,179	1	$481,468
Foreign, Large	30	$1,763,801	30	$1,772,788	30	$1,773,499
Foreign, Medium	49	$765,757	49	$766,112	49	$766,125
Foreign, Small	34	$82,375	34	$82,797	34	$82,804
Small/commuter	11	$5,466	34	$17,593	34	$48,306
Small Codeshare	8	$21,435	13	$312,643	13	$553,467
Average Annualized Cost Per Airline	184	$724,768	217	$1,642,433	217	$1,780,033
Cruise Lines						
Large lines (ICCL members)	16	$2,222,652	16	$2,222,652	16	$2,222,652
Other large lines	16	$152,070	16	$152,070	16	$152,070

Small lines	25	$40,403	25	$40,403	25	$40,403
Average Annual Cost Per Cruse Lines	**57**	**$684,309**	**57**	**$684,309**	**57**	**$684,309**
Other						
Large Travel Agencies	0	NA	0	NA	0	NA
Small Travel Agencies	0	NA	0	NA	0	NA
GDS	0	NA	0	NA	0	NA
Other Tour Booking Firms	0	NA	0	NA	0	NA
Average Annualized Cost Per Agency	**0**	**NA**	**0**	**NA**	**0**	**NA**

Under the POD, scenario, however, some impacts are estimated. Option 1 results in 1 airline with costs estimated to exceed 1 percent of revenues, while two airlines are expected to exceed the 1 percent threshold under Option 2. Option 3 results in 4 airlines with estimated costs projected to exceed 1 percent of revenues.

Under either scenario, there are 19 airlines that were not analyzed in the impact analysis because no financial data were available. These airlines predominately fly intrastate routes only, and generally fly only a few hundred passengers per year. ERG believes that these very small airlines will not experience any major impacts, since passengers data collection will likely be handled without any significant programming costs. For such firms, the presumed $10,000 per year in reprogramming costs was judged to be excessive and to overstate the complexity of recordkeeping operations.

4.3.2 Compliance Costs Relative to Net Income

A total of 20 of the 52 airlines with net income data available reported negative net income over the July 2003 to June 2004 time period used for this analysis. This may reflect that the airline industry has not yet fully recovered from the impacts of 9/11 and the SARS epidemic, although ongoing structural problems might also be indicated. In addition, the price of jet fuel has increased significantly over the past year, offsetting industry cost-cutting strategies in other areas.

ERG examined the impact on net income among the 32 airlines with positive net income in the baseline. For one airline, projected compliance costs are projected to exceed net income figures under each option. Because baseline net income data are not readily available for the other industries, net income analysis was not performed for cruise lines, travel agencies, and GDSs.

4.4 REFERENCES

U.S. Census Bureau. 2004. Travel arrangement and reservation services: 2002. Economic Census 2002, administrative and support and waste management and remediation services, industry series, EC 02-561-05. Issued September, 2004.

SECTION 5. INITIAL REGULATORY FLEXIBILITY ANALYSIS

5.1 INTRODUCTION TO THE INITIAL REGULATORY FLEXIBILITY ANALYSIS

This section considers the proposed regulation's effects on small entities, as required by the Regulatory Flexibility Act (RFA; 5 U.S.C. et seq.; Public Law 96-354) amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA; Public Law 104-121). The RFA establishes, as a principle of regulation, that agencies should tailor regulatory and informational requirements to the size of entities, consistent with the objectives of a particular regulation and applicable statutes. The act requires an agency to prepare an initial regulatory flexibility analysis (IRFA) for any rule subject to notice-and-comment rulemaking unless the agency can certify that the rule will not have a "significant impact on a substantial number of small entities." Small entities include small businesses, small organizations, and small governmental jurisdictions.

Because the proposed rule may involve small airlines and cruise lines, CDC has undertaken this IRFA rather than certifying no significant impact. The analysis is presented as follows.

Section 5.2 outlines the initial assessment of small businesses in the industries affected by the proposed regulations.

Section 5.3 summarizes the steps taken to comply with the RFA.

Section 5.4 presents the data, methodology, and results of the IFRA.

5.2 INITIAL ASSESSMENT OF THE NUMBER OF SMALL ENTITIES AFFECTED

The RFA defines a small entity as a "small not-for-profit organization, small governmental jurisdiction, or small business" (5 USC Sec. 601). The principal small-entity impact of the proposed quarantine regulations will fall on small airlines and small cruise lines. The majority of these operations are undertaken by private businesses, so the small entity analysis focuses on small businesses engaged in domestic and international air passenger transport and international passenger transport by ship. Travel agencies and reservation services may also be affected by the proposed rule, depending on how it is implemented.

5.2.1 Airlines

The RFA requires (with some exceptions) that "small" be defined according to the size standards established by the Small Business Administration (SBA). SBA's standards are based on either the number of employees or annual revenues (13 CFR 121), depending on NAICS classifications. According to SBA definitions, businesses within NAICS 481111, Scheduled Passenger Air Transportation, are small if they employ fewer than 1,500 employees; businesses in NAICS 438112, Deep Sea Passenger Transportation, are small if they employ fewer than 500 employees (SBA, 2005).

According to the Department of Transportation, which collects employment data on domestic airlines, there are 43 airlines that have fewer than 1,500 employees (U.S. Department of Transportation, BTS, 2005a and 2005b). The remaining 32 airlines where employment size is unknown were assumed to be small for this analysis. ERG also determined that 19 airlines serving very few passengers per year also had no financial data whatsoever. These airlines were not directly analyzed, but given that they serve only a few hundred passengers per year, costs and impacts are expected to be very small.

5.2.2 Cruise Lines

Most cruise lines operating internationally are either foreign or large, or both. SBA definitions of "small" preclude foreign-owned firms as small businesses with few exceptions.[7]

ERG made directed searches for cruise lines using trade associations, Web sites, and other sources of information to determine which cruise lines met the size criteria and were likely to be affected by the proposed rule (those lines that appear to be incorporated in the U.S., are likely to be small, have itineraries with at least one U.S. port visit and one international visit, and are not affiliated with any large or foreign firm). ERG also investigated various ferry and charter boat companies that operate in key areas where international travel might be possible for smaller vessels, e.g., the Great Lakes, the Pacific Northwest, the Gulf of Mexico, or Florida. Smaller vessels, including ferries, can operate in these areas with easy access to foreign ports. After accounting for all smaller vessels and their firms that show U.S. to foreign port itineraries, the count of small firms (not establishments) is estimated to be 20.

The total count of all small affected firms analyzed in the two directly affected industries (airlines and cruise lines) is therefore 91.

5.2.3 Travel Agencies and Global Distribution Systems

ERG assumes that GDSs and travel agencies will need to revise their Web sites or data entry systems, and travel agencies will need to collect additional passenger information. Thus, these firms will also be secondarily affected by the proposed rule.

There are 21,679 small travel agency establishments owned by firms in NAICS industry 561510 (U.S. Census Bureau, 2004).[8] The largest 50 firms own 4,559 of these establishments (U.S. Census Bureau, 2004). ERG assumed that the other 17,120 establishments are single-establishment firms. The average revenues calculated for all establishments other than those owned by the 50 largest firms are about $300,000 annually. SBA defines small businesses in this category as those having revenues below $3 million per year, so we assumed that all 17,120 remaining firms are small businesses.

The number of GDSs and other booking agencies is estimated to be 839, of which 703 are small (U.S. Census Bureau, 2004) based on SBA's small business definition for this group (NAICS 561599) of $6 million per year in revenues. There are 2,569 establishments owned by firms within NAICS 561599. Of this group, 400 do not report a specific product line; for those, we needed to impute the number of relevant firms in the total group. Of the 2,169 establishments reporting a product line code, 631 are identified as providing airline seat reservations for international travel and 839 are identified as providing airline seat reservations for domestic travel. We assume those providing international travel are included

[7] Only those firms with a substantial contribution to the U.S. economy might be relevant, but foreign firms with a substantial contribution to the U.S. economy are very unlikely to meet the size standard. SBA also defines a small business at the highest level of corporate organization, and solid evidence of corporate affiliation can be considered. Thus, for example, a firm incorporated in Greece that has an office in Miami would not be defined as small, since it would be considered a foreign firm. A small firm whose CEO is a corporate officer of a large firm would be considered affiliated with that large firm and would not be considered a small firm.

[8] According to this source, the number of travel agencies has dropped from 1997. This is at least partly due to the rise in the direct use of the internet by passengers for booking travel.

in the count of those providing domestic travel. Thus, out of the 2,169 establishments for which we have a product line, 839 (or 39 percent) are believed to be GDSs or other booking agencies that may be affected.

The largest 50 firms own 719 establishments. The remaining firms own 1,850 establishments. As for travel agencies, we assumed these establishments to be single-establishment firms. They are also assumed to be small, as they are associated with average annual revenues of about $1.5 million—well below the SBA's $6 million cutoff figure. Based on the estimate that 39 percent of establishments in this industry are GDSs or other booking agencies, ERG estimates that 703 small firms may provide some type of GDS service to the airlines and would be affected by the proposed regulation.

5.3 COMPLIANCE WITH RFA REQUIREMENTS

As required by Section 603 of the RFA, as amended by SBREFA, an IRFA has been conducted. By reference, the IRFA includes Section 1, a discussion of the problems the proposed rule will solve as well as the objectives and legal basis for the proposal. The IRFA also includes a description and estimate of the following:

- The number of small businesses that will be affected (see Section 5.2).
- The reporting, recordkeeping, and other compliance requirements of the proposed rule (see Section 4).
- Any Federal rules that may duplicate, overlap, or conflict with the proposed rule (see Section 1).
- Any significant regulatory alternatives to the rule that would accomplish the stated objectives of the applicable statutes and minimize impacts to small business (see Section 5.4.1).
- Section 607 of the RFA further notes that to comply with the IRFA requirements, the agency must "provide either a quantifiable or numerical description of the effects of a proposed rule or alternatives to the proposed rule, or more general descriptive statements if quantification is not practicable or reliable." Accordingly, an economic analysis of the impacts on small businesses has been prepared. It is presented in Section 5.4.

5.4 ANALYSIS OF SMALL BUSINESS IMPACTS

5.4.1 Options Considered

CDC considered three options, each increasing the number of flights and passengers that would be affected. Option 1, covering only incoming international flights reduced the number of affected small airlines, since many of the smallest airlines do not have international itineraries. Option 2 increased the number of firms, passengers, and flights among small airlines, but the option does provide some reduction in passengers and flights compared with Option 3. CDC did not develop an option that specifically exempted small airlines from the requirements because it was felt that this would not adequately protect human health. Although small airlines serve at most 5 to 10 percent of potentially affected passengers, this is still as many as 35 million passengers a year and as many as 2.2 million flights (22 percent of all flights) for which CDC would not be able to trace in the event of an outbreak (see Table 5-1).

Table 5-1. Number of Affected Small Entities by Option Compared to Large Entities

Airline Type	Option 1			Option 2			Option 3		
	Airlines	**Flights**	**Passengers**	**Airlines**	**Flights**	**Passengers**	**Airlines**	**Flights**	**Passengers**
Large Businesses									
Major	11	224,351	29,204,074	12	5,005,544	478,983,038	12	5,534,009	510,735,551
National	15	67,419	2,320,969	15	1,538,604	77,447,464	15	2,210,878	101,595,705
Large Regional	0	0	0	0	0	0	0	0	0
Medium Regional	0	0	0	0	0	0	0	0	0
Small Certificated/ Commuter	2	3,510	87,732	2	104,525	2,356,769	2	183,883	4,120,263
Total Large	28	295,280	31,612,775	29	6,648,673	558,787,271	29	7,928,770	616,451,519
Small Businesses									
Major	1	18,138	600,307	1	279,708	9,298,250	1	363,912	12, 033,318
National	9	13,657	1,637,018	9	245,804	9,870,431	9	324,056	12,310,365
Large Regional	11	8,644	972,302	12	43,647	3,899,484	12	59,866	5,130,150
Medium Regional	5	3,588	113,325	8	39,972	1,121,296	8	70,601	2,478,234
Small Certificated/ Commuter	17	32,299	345,366	45	478,816	7,521,799	45	1,395,517	14,780,779
Total Small	43	76,326	3,668,318	75	1,087,947	31,711,260	75	2,213,952	34,699,528
Total	71	371,606	35,277,093	104	7,736,620	590,498,531	104	10,142,722	663,184,365
% of Total Small	61%	21%	10%	72%	14%	5%	72%	22%	5%

5.4.2 Overview of Costs and Impacts on Small Businesses

The costs falling on small businesses under the POS scenario include the costs to reprogram systems for both small airlines, cruise lines, and travel agencies; the costs to collect data from passengers, which fall on the travel agencies and GDS operations; and the costs to manage and archive data and provide data to CDC, which are exclusively costs to the airlines and cruise lines. Under this scenario, the majority of the costs to the airlines and cruise lines are the costs for reprogramming. These costs are estimated to range from $10,000 per firm to $10 million per firm (the firms defined as small encompass all of the types of airlines, from one major airline to numerous small commuter airlines. Many of the smaller airlines are codeshare airlines, which do not have their own reservation systems, and will not directly incur programming costs. While larger airlines might pass some of the reprogramming costs on to their codeshare partners, the larger airlines are also dependent upon small airlines to fill in the gaps in their itineraries. Also, many of the smaller airlines and cruise lines have much more modern software for handling passenger data and would therefore be much more flexible than the software used by larger airlines (see Section 3.1.1.2). Thus, the large airlines shoulder a very large share of the costs of this proposed regulation. Of the $27.7 million (POS scenario) to $262.9 million (POD scenario) projected annualized costs to U.S.-owned airlines (that is, excluding costs to foreign airlines) under Option 2, approximately 75 percent to 90 percent of the costs will be incurred by large airlines.

Under the POD scenario, the costs to small airlines and cruise lines are greater than those of the POS scenario, since it is assumed that the costs of gathering passenger data fall directly on the airlines and cruise lines themselves. Relatively fewer small airlines operate frequent flier programs, thus the

incremental cost of gathering passenger data may be, on average, somewhat greater on a per-passenger basis than the costs to the large airlines. However, there are some mitigating factors. First, these costs are proportional to the number of passengers handled and, thus, tend to vary by size of firm, with the very smallest firms generally handling the smallest numbers of passengers. Second, as the number of passengers handled is reduced, some of the logistical difficulties that can be more than proportionate to numbers of passengers are also reduced. Most of the small airlines potentially affected by the proposal are in the small certificated/commuter airline group. These airlines average about 16 passengers per flight under Option 2 (see Table 5-1). The logistics of handling information collection for about 16 passengers per flight is not the same as the logistics of handling information collection for hundreds of passengers per flight.

5.4.3 Quantitative Impacts on Small Businesses

The approach used for quantifying the impacts in this small business analysis is a revenue test, which compares the annualized costs of compliance with revenues in percentage terms. Regulatory agencies have often used revenue tests in defining small business impacts, because revenues can be more easily estimated or may be more readily available from nonpublic firms than more sensitive business data such as earnings or net income. Chapter 4 presents the estimated costs and impacts for the airlines and cruise lines of all sizes.

For the POS scenario, under any option examined, costs are less than 1 percent of revenues for all airlines and cruise lines.[9] Among all travel agencies and the small GDSs, ERG assumed that a one-time reprogramming cost of about $1,000 would be incurred to change Web sites or data entry systems to accommodate additional data fields. In addition, approximately 30 percent of passengers will book through travel agents and agents will need 45 seconds to record the new data needed by CDC. We expect that much of the information collection can be automated from the passenger's profile after the first contact. Thus, ERG estimates the annual cost to travel agencies and small GDSs will be less than $800 under the most costly option (Option 3). This is less than one-half of one percent of small travel agencies' average revenues.

Under the POD scenario, ERG estimates that 1 small airline will experience costs that are 1 percent or more of revenues under Option 1, while 2 small airlines are expected to exceed this threshold under Option 2. Under Option 3, 4 small airlines are projected to incur costs exceeding 1 percent of revenues. No cruise lines are expected to have costs exceeding 1 percent of revenues.

5.5 REFERENCES

SBA (Small Business Administration). 2005. Table of small business size standards. <http://www.sba.gov/size/indextableofsize.html>. Accessed March 11, 2005.

U.S. Census Bureau. 2004. Travel arrangement and reservation services: 2002. Economic Census 2002, administrative and support and waste management and remediation services, industry series, EC 02-561-05. Issued September, 2004.

U.S. Department of Transportation, Bureau of Transportation Statistics (BTS). 2005a. Air Carrier Financial Reports (Form 41 Financial Data) Schedule P-11 Database. Downloaded from http://www.transtats.bts.gov/. March 14, 2005.

[9] One small airline, for which direct revenue data were unavailable, showed impacts exceeding 1 percent of revenues when revenues were extrapolated from passengers carried. However, the airline carried so few passengers that ERG believes the extrapolation method results in an unreliable estimate of revenues in this case.

U.S. Department of Transportation, Bureau of Transportation Statistics (BTS). 2005b. Air Carrier Financial Reports (Form 41 Financial Data) Schedule P-12 Database. Downloaded from http://www.transtats.bts.gov/. March 14, 2005.

SECTION 6. BENEFITS ANALYSIS

Implementation of electronic manifest and passenger information transmission through the CDC rule changes should help CDC effectively trace contacts of infectious persons. The rule should facilitate faster and more complete implementation of quarantine and isolation programs. During the SARS epidemic, CDC found that current mechanisms were inadequate to locate and contact potentially infected persons in a timely manner (CDC-Mitre, 2004). Rapid intervention can reduce the economic disruption from an epidemic by quickly restoring public confidence and limiting the spread of disease. However, measuring the opportunity costs of economic disruption is problematic; ERG identifies the reduction in these costs as a large but unquantified benefit of the proposed rule (see Section 6.1). Section 6.2 identifies two other sources of unquantified benefits—improved response to in-flight exposures to common contagious diseases and reduced public anxiety. The benefits of the rule can also be measured in terms of the number of deaths and illnesses that the rapid intervention prevents. This is a more tractable problem in epidemiological and economic modeling, which is discussed in Section 6.3. Section 6.4 presents the benefit estimates. The parameters of the model are validated with a sensitivity analysis in Section 6.5. Both the POS and POD scenarios provide the same information for CDC intervention so the benefits are the same under the two scenarios.

6.1 BENEFITS OF REDUCED ECONOMIC DISRUPTION

For benefit-cost analysis, as required by Executive Order 12866, it is important to distinguish economic impacts from benefits. The key concept for valuing both benefits and costs is opportunity cost. The outbreak of a disease can cause large dislocations in regional economies. During the SARS outbreak in Hong Kong, 50 percent of flights to and from the city were cancelled (OAG, 2003). In Beijing, hotel occupancy rates fell to 20 percent and foreign investment in China was also curtailed (The Economist, 2003). Overall, the SARS outbreak is estimated to have reduced incomes in east and southeast Asia by $12.3 billion to $28.4 billion (Fan, 2003). Such regional impact measurements overstate the global impact of disease outbreaks because they generally do not take into account the redirection of investment, travel, and purchasing from affected areas to unaffected areas. The global impact would be the net loss of consumer and producer surpluses (e.g., how much travelers might have preferred to travel to China instead of other destinations) due to the outbreak-caused adjustments in economic activity. Nevertheless, the affected nation does experience a loss. For example, if an outbreak of disease in the U.S. similar to the SARS outbreak in Toronto occurred, it could have a large negative effect on the U.S. economy through impacts such as those on the travel and tourism industries, even though the net impact, measured globally, might not be significant. Because forecasting such impacts for the U.S. economy is so speculative and unique to specific outbreaks, these types of benefits from net reductions in economic impacts are not estimated.

One element of a disease outbreak is extra stress on the health care system. Emergency rooms and hospitals may see more and sicker patients than usual. The need to isolate infectious patients and take measures to reduce transmission of the disease can strain resources and slow patient care. If hospital capacity is exceeded, more costly provisional accommodations must be made. Like other forms of economic disruption, the health care-related benefit of avoiding an outbreak is the opportunity cost saved by preventing or reducing its effect. The patient's bill reflects the standard costs of hospital care but does not reflect the opportunity cost. The hospital would still have paid the capital costs of providing the building and equipment, heat and light, and staffing even if the bed had been empty. It would be quite difficult to isolate the opportunity costs of an outbreak even after the fact. ERG did not attempt to quantify the opportunity cost savings in the health care sector of avoiding a future outbreak.

It is difficult to measure what did not happen because of an outbreak. For example, the impacts of SARS were confounded with the tensions before the Iraq War, so determining the effect of SARS alone on airline bookings is problematic (OAG, 2003). Taking the analysis another step to measure benefits in terms of the opportunity costs of those changes would not produce meaningful estimates. The SARS case shows that the public and the business community respond quickly to information about infectious diseases and that these responses have significant economic impacts. Faster recognition and suppression of disease outbreaks would certainly reduce these impacts and generate benefits (Meltzer et al., 1999).

6.2 OTHER NON-QUANTIFIED BENEFITS

6.2.1 Improved Response to In-Flight Disease Exposure

The close quarters and air recirculation in modern aircraft raise the possibility of disease transmission while in flight (Kenyon, et al., 1996). One anticipated use of the improved passenger information system is to inform those who might have been exposed to common contagious diseases so that they can take steps to avoid becoming ill or be aware of the symptoms to watch for. An evaluation of an effort to contact passengers on a seven hour flight to Hawaii with a passenger with measles showed that 75 percent of passengers could be contacted within the 72 hour period after exposure for effective vaccination (Lasher, et al., 2004). However, the authors attributed much of this success to the fact that many passengers were members of tour groups and stayed in hotels. Time-to-contact was significantly longer for those who did not stay in hotels. The electronic passenger information system is expected to be used 10-12 times per month for this type of contact tracing.

Avoidance of potentially serious illness benefits passengers exposed during air travel. There is little research, however, to quantify the probability of exposure to and of contracting the panoply of contagious diseases that may be involved. For the exposed individual, the benefit of not contracting tuberculosis, measles, mumps, or rubella could be significant. ERG could not estimate the possibly substantial benefits of this use of the enhanced personal information system.

6.2.2 Reduced Anxiety

The analysis additionally does not capture the unaffected public's willingness to pay to avoid the widespread fear that can arise during an outbreak. During the SARS outbreak, people who were never exposed, nor ever in any danger of being exposed, were fearful that SARS would become an epidemic in the U.S. Much of the economic disruption from an outbreak is caused by changes in decisions that are driven by fear. There may be a substantial benefit associated with avoiding that fear if the public's confidence is bolstered by quick and effective disease outbreak control.

6.3 BENEFITS OF IMPROVED HEALTH OUTCOMES

The most direct effect of the CDC rule changes is improved contact tracing. This should facilitate faster and more complete implementation of quarantine and isolation programs. In epidemiological models, the speed of response is often more important than the specific action taken (Barrett et al., 2005; Lipsitch, 2003). Whether the chosen action is vaccination, quarantine, and/or isolation, doing it earlier in the course of the outbreak lowers the illness and death toll. This pattern suggests that one way to quantify benefits is to compare a base case in which intervention is delayed with alternatives in which intervention can proceed rapidly. (The more rapid intervention is made possible because manifests with contact information are readily available.) The benefits of the alternative are measured as the number of prevented deaths and illnesses. This change will be monetized by the public's willingness to pay (WTP) to avoid death and illness.

6.3.1 Epidemiological Model

To estimate the effect of faster contact tracing, ERG developed a Susceptible-Exposed-Infectious-Recovered (SEIR) epidemiological model that includes the effects of vaccination, quarantine, isolation, and asymptomatic carriers similar to Lipsitch et al. (2003). The model is based on a fixed course of illness with fixed outcome probabilities at each stage.

- Individuals who become ill experience:
  - a latent period, when they feel no effects and are not contagious, and
  - an infectious period during which they spread the disease but may or may not show symptoms of it.

- At the end of the infectious period, patients either:
  - recover and are immune or
  - die.

- Patients who show symptoms and recover also go through a recovery period during which they cannot work but are not infectious.

- Interventions may start on any day of the simulation.

- A quarantine program removes persons who were contacted by infectious individuals from the susceptible population. Its effectiveness is gauged by the percent of contacts who are removed. Persons who show symptoms at the end of the latent period are isolated; persons who do not show symptoms rejoin the susceptible population.

- An isolation program removes symptomatic individuals from the infectious population. Like quarantine, the isolation program can be more or less effective depending on the percentage of new symptomatic individuals that it includes.

- The rate of vaccination in the population and proportion of asymptomatic individuals are set as starting conditions and cannot be affected by policy actions in the course of the epidemic.

- Asymptomatic individuals are infectious, albeit at a lower rate than symptomatic individuals, and gain immunity when they recover.

- The growth of the recovered immune group in the course of the epidemic puts a natural limitation on the extent of the epidemic.

The epidemiological model can be adjusted to mimic many types of infectious diseases. ERG calibrated the model to yield the same results as the SARS outbreak in Hong Kong. Lipsitch et al. (2003) reported that there were 425 cases on the 22nd day of the outbreak and 1,358 on the 63rd day. They also estimated the basic reproductive number for SARS, R_0 , as 2.2 to 3.6 for serial intervals of 8 days to 12 days. The survival rate for SARS has been reported as 89 percent (Gupta et al., 2004). By adjusting the number of contacts and rate of infection, the model with these parameters can be calibrated to show the observed course of the disease and the number of deaths experienced. For this analysis, the model is limited to a 200-day time span. By 200 days, the outbreak with the base case parameters is no longer growing and the outbreak in the alternative cases has been extinguished. Running the model longer would inflate the benefits of the rule and make the model more sensitive to population size. See Appendix A for a complete exposition of the model.

6.3.2 Valuing Health Outcomes

The epidemiological model sums the number of deaths and number of days of illness, quarantine, isolation, and recovery. ERG developed WTP estimates for each health outcome in order to monetize the total benefit of faster contact tracing.

6.3.2.1 Value of a Statistical Life

The WTP to avoid an increased risk of death is termed the value of a statistical life (VSL). Although we are using a deterministic model to show the effects of the rule, its actual effect will be in terms of reducing the risk of any individual dying in an infectious disease outbreak (Viscusi and Aldy, 2003). This makes VSL an appropriate measure to apply to the number of deaths avoided. For a value measured in one study to be transferable to another policy situation, the populations and types of risks should be similar. Our population of interest is the U.S. general population. The risk from infectious disease is involuntary, pervasive, and random, as are risks from environmental hazards. EPA adopted a VSL for the general population of $4.8 million (1990 dollars) in its evaluation of the costs and benefits of the Clean Air Act (EPA, 1999; Kochi, et al., 2003). ERG updated this estimate to 2004 dollars using the Consumer Price Index and adopted $6.9 million as the value of an avoided death.

The Department of Transportation recommends the use of $3 million as the value of a statistical life (Van Tine and Lawson, 2002). This is at the low end of the range found in the literature by Viscusi and Aldy (2003). Transportation risks may be evaluated differently than health risks. Transportation deaths, for example, are generally expected to be quick and may also have an element of personal control. Persons who drive safely can personally reduce their risks of dying in a crash. Most health risks, on the other hand, entail lingering uncertain deaths and unpleasant treatment. Epidemic health risks may be perceived as random and difficult to avoid, taking away the element of personal control. Thus, people may be willing to pay more to avoid a health risk than a transportation risk. For this analysis, a VSL derived from a health risk is more appropriate.

6.3.2.2 Willingness to Pay to Avoid Illness

There are few empirical studies of the WTP to avoid illness. Johnson et al. (1997) used five studies to develop an index-based approach to valuing avoided illness. Their synthesis predicts a WTP of $43 to avoid a day of severe cough (1993 dollars) and $38 to avoid a day of severe headache. (As these studies are related to the costs of air pollution, they tend to focus on respiratory ailments.) ERG adopted the $43 estimate and updated it to 2004 dollars, $56, to represent the WTP to avoid illness.

6.3.2.3 Willingness to Pay to Avoid Idleness

Quarantine and recovery periods restrict the activities of healthy people. With widespread availability of sick leave, time away from work may not result in a loss of wages to the individual. However, the lost work time is an opportunity cost to the employer. With efficient labor markets, daily earnings should reflect the marginal product of a day of work to the employer. Presumably work provides additional rewards to the employee, such as job satisfaction and social interaction, so wages may not be a complete measure of the opportunity cost of not working. Median usual weekly earnings of full-time wage and salary workers in the United States are $638 (2004 dollars; BLS, 2005). Thus, daily earnings are $128. ERG adopted this estimate to represent the opportunity cost of days idled.

The appropriate measure of value for benefit-cost analysis is consumer surplus or WTP. ERG summed the stated WTP to avoid illness and the employer's opportunity cost of a day of lost work to

value a day of illness. If sick time is not compensated, the loss of time or income should be a component of an individual's WTP to avoid illness. Health-oriented WTP questions are rarely clear about the assumptions about lost work time, and the availability of compensated sick days further distorts published WTP results. Intuitively, $56 seems like a very low WTP to avoid serious illness and seems unlikely to have included consideration of lost wages. Thus the two are combined to give a more realistic indication of both the lost time resource and the value of the discomfort of being ill. Ultimately, the lost time and illness days component is less than one percent of the calculated benefits for the outbreak modeled.

6.3.3 Base Case and Alternatives

The characteristics of the diseases that may be addressed using the electronic information generated as a result of this rule cannot be known in advance. The latent period, symptoms, means of spread, and course of the illness influence the strategies CDC will use to address an outbreak. Any assumed base case and intervention parameters for the model are therefore arbitrary. However, SARS provides a recent and well-studied example of the types of infectious agents that may be encountered and addressed by contact tracing. ERG characterized the infectious agent using the observed serial interval (8 to 12 days), survival rate (89 percent), R_0 (2.2 to 3.6), and apparent asymptomatic population (10 percent) from SARS (Lipsitch et al., 2003). Because it is a non-linear geometric growth model, the results are highly sensitive to the starting parameters. Table 6-1 shows parameter values for the base case and the intervention that is possible with basic itinerary information. Values for number of contacts, probability of transmission, and interventions were selected so that the impact of the base case was within a plausible range. The levels of quarantine and isolation in the base case represent the current abilities of authorities to contain the spread of illness along with the natural withdrawal of an ill person to his or her home in the face of an infectious threat and illness (Barrett et al., 2005). CDC experience with SARS indicated that although the agency had the authority to isolate and quarantine, it did not have sufficient information to make this authority effective.

When basic itinerary information is collected, quarantine and isolation programs become effective a week earlier than in the base case and are 30 percent more effective. Volpe's (2004, p.4) evaluation of CDC response to SARS indicated that the "time required to [manually] track passengers could be longer than the incubation period of the SARS virus," 8-12 days, and many people were never traced. Automated passenger information systems eliminate the time needed for airlines to gather information from paper records and allow them to provide more complete information. An automated system greatly reduces the time needed to transfer information from airlines to CDC and to organize it to contact individuals. The parameters for the basic itinerary option reflect the effect of earlier, more efficient intervention even if the intervention is still not completely effective.

Table 6-1. Epidemiological Model Parameters

Parameter	Base Values	Basic Itinerary Values	Units
Number of contacts by infectious individuals per unit time	5	5	contacts
Probability of transmission per contact	10%	10%	percent
Mean duration of infectiousness	5	5	days
Mean duration of infectiousness with interventions	4.2	4.2	days
Latent period	5	5	days
Proportion of the population susceptible (not vaccinated)	100%	100%	percent
Proportion of asymptomatic cases	10%	10%	percent
Probability of transmission per contact for asymptomatics	2%	2%	percent
Day quarantine program starts	42	35	date t
Proportion of contacts quarantined	30%	60%	percent

Parameter	Base Values	Basic Itinerary Values	Units
Day isolation program starts	42	35	date t
Proportion of infectious population isolated	40%	70%	percent
Population	10,000,000	10,000,000	persons
Recovery period	4	4	days
Survival rate	89%	89%	percent

6.3.4 Discounting and Annualization

The epidemiological model shows the benefits the rule would achieve in a single outbreak in one city. However, the rule will presumably be in place for many years and be effective in many situations. In order to show the long run benefits of the rule, one must forecast or make assumptions about the frequency and scale of epidemic events.

ERG assumed that epidemics on the scale of the modeled outbreak will occur every five years during the 10-year planning period, i.e. two outbreaks. This timing reflects the experience of the last 30 years, which have seen the emergence of AIDS, Legionnaires' disease, multi-drug-resistant tuberculosis, West Nile virus, SARS, and Avian influenza.

OMB guidance requires that costs and benefits be stated in terms of annualized discounted values in order to facilitate comparison. ERG assumed epidemics in future years 2 and 7 to generate a moderate discounted value. OMB guidance requires presentation of results using both a 3 percent and a 7 percent discount rate.

6.3.5 Application to International and Domestic Flights

In order to attribute benefits specifically to international and domestic flights, ERG sought a measure of the risk of introduction of new diseases. Many factors influence where emerging diseases appear. Rural-urban migration, environmental manipulation, altered agricultural practices, changing weather patterns, and misuse of medicines can all play a role in initiating infectious diseases (WHO, 2003). Among the key influences is human population. We use population as an indicator to differentiate between the effects of collecting manifest and other passenger information from international and domestic flights.

Table 6-2 shows the population of each continent. Because 95.4 percent of the world's population does not reside in the U.S., there is a high probability that future outbreaks will begin in other countries. Thus, collecting passenger information from arriving international passengers will intercept most of the likely carriers of an initial introduction of infectious diseases into the United States. However, 25 percent of international travelers to the U.S. take a domestic flight while they are here (DOC, 2005). Twelve percent of international visitors do not list their port of entry as one of their destinations in the Survey of International Air Travelers. This implies that 12 percent of international visitors travel onward to a further destination almost immediately. If domestic flight information is not collected, CDC will not be able to trace these individuals efficiently. This reduces the effectiveness of collecting inbound traveler information by 12 percent, from 95.4 percent to 83.9 percent.

Table 6-2. World Population by Continent and United States, 2005

Continent	Population (Millions)	Proportion of World Population
Africa	906	14.0%
Asia	3,905	60.4%
Europe	728	11.3%
Latin America/Caribbean	561	8.7%
Northern America, not US	33	0.5%
United States	298	4.6%
Oceania	33	0.5%
	6,464	100.0%

Source: UN, 2005

The option that adds passenger information for all domestic travelers would ensure that information was available for all of the remaining 16.1 percent of risk. It is reasonable to expect benefits to accrue in proportion to the number of passengers included in each option. Table 6-3 summarizes the number of passengers included under each option. A small proportion of international travelers, 3.3 percent, arrives at small airports. Thus, Option 2 (International plus Large and Medium Hubs) captures an additional 11.1 percent of the initial risk posed by international travelers, i.e. 96.7 percent of the missing 12 percent. Option 2 also captures 88.4 percent of the 4.6 percent of the initial risk posed by domestic passengers, 4.1 percent, i.e. 88.4 percent of the U.S. 4.6 percent in Table 6-2. Thus, Option 2 captures 99.1 percent of the total benefits estimated if all passengers could be contacted.

6.4 ESTIMATED BENEFITS

6.4.1 Basic Results

Table 6-4 shows the results when all flights are subject to the basic reporting rules. The number of deaths clearly dominates the benefit estimates. In the base case, 900 deaths are predicted with quarantines and isolation that are less than 50 percent effective starting six weeks after the introduction of the disease. Starting more effective interventions a week earlier reduces the number of deaths to 37. As the VSL is $6.9 million, the reduction in death toll represents $5.96 billion in benefits. The reduction in numbers of impaired days is valued at $24.8 million, although there are notably fewer quarantine and isolation days with earlier intervention because the spread of disease is caught sooner.

Table 6-3. Numbers of U.S. Passengers

Option	Flights	Cumulative Proportion of International Passengers Final Destinations	Cumulative Proportion Of Domestic Passengers Included	Cumulative Proportion of All Risk
1	International Only	88.0%	-	83.9%
2	Int'l plus Large and Medium Hubs	96.7%	88.4%	99.1%
3	Int'l plus All Domestic	100.0%	100.0%	100.0%

Note: As shown in Table 6-2, 95.4% of risk of an emerging illness comes from outside the U.S., 4.6% of the risk originates within the U.S.

Table 6-4. Estimated Health Outcomes and Benefits

Parameter	Base Values	Option 3 Values	Difference
Outcomes			
Deaths	900	37	863
Illness days	18,075	670	17,405
Isolation days	23,753	1,000	22,753
Recovery days	14,460	536	13,924
Quarantine days	127,967	5,013	122,954
Benefits per Incident, Difference from Base ($ millions)			
Deaths	—	—	$5,956.1
Illness days	—	—	3.2
Isolation days	—	—	4.2
Recovery days	—	—	1.7
Quarantine days	—	—	15.7
Total	—	—	$5,980.9

6.4.2 Discounting and Annualization

The total present value of Option 3, when two outbreaks occur in 10 years, is $8.9 billion when discounted at 7 percent and $10.5 billion when discounted at 3 percent. The other options are valued in proportion to the cumulative proportion of risk of infection (the last column of Table 6-3). Annualized values range from $1.3 billion to $1.5 billion when discounted at 7 percent.

Table 6-5. Value of Improved Contact Tracing over the 10-Year Planning Period ($millions, 2004)

Option	Flights	Benefit for a Single Outbreak	Present Value over 10 Years	Annualized Value
At 7 percent discount rate				
1	International Only	$5,021	$7,512	$1,070
2	Int'l. plus Large and Medium Hubs	$5,927	$8,867	$1,263
3	Int'l plus All Domestic	$5,981	$8,949	$1,274
At 3 percent discount rate				
1	International Only	$5,021	$8,815	$1,033
2	Int'l. plus Large and Medium Hubs	$5,927	$10,405	$1,220
3	Int'l plus All Domestic	$5,981	$10,501	$1,231

6.4.3 Apportionment to International and Domestic Flights

The totals are apportioned to international and domestic flights based on the ability to trace the first introduction of the disease into the United States. The lack of information on domestic flights as covered under the International Only Option limits CDC's ability to follow travelers after their first point of entry into the country. Contact tracing would be considerably less effective without information about travel within the U.S. wherever the disease originated. Adding some domestic information improves the outcome in many more situations. While most of the benefits of the proposal are captured if data collections apply only to international arrivals, adding all domestic flights adds $1.4 billion to $1.7 billion in benefits over the 10-year planning period. To the extent, however, that passengers continuing on from foreign-based flights might pose a greater risk of contagion than the average domestic-only passenger, these incremental benefits of covering some or all domestic flights might be underestimated.

6.4.4 Model Strengths and Limitations

The SEIR epidemiological model has some limitations, but overall, these limitations are not considered major shortcomings. One limitation is that the model has no parameters for the transmission of disease in-flight so it cannot explicitly model the difference between a 1-hour and 9-hour flight. The focus in this study has been on the transmission of disease once it is present in a new population rather than in the close quarters of an aircraft. The geometric growth of cases once the pathogen is present in the population would far outweigh the in-flight transmission effects if they were modeled separately.

A strength of this approach is that this allocation of benefits is based on an index that is verifiable and relates to the emergence of epidemic disease, i.e., population. Manipulating the epidemiological model would have required greater speculation about parameter values.

The approach also allows easy revision of benefit measures if options change. Apportioning the benefits from our original presentation avoids making major changes to the epidemiological model. Any alternative selection of flights subject to the rule can be easily accommodated.

6.5 SENSITIVITY ANALYSIS

Three sets of parameters dictate the outcome of the SEIR model – the characteristics of the illness, the behavioral assumptions of the base case, and the timing and success of the intervention. ERG conducted a Monte Carlo sensitivity analysis varying all of the parameters of the illness or intervention while holding the other parameters at their base case values. The model was run 500 times using random selections of each parameter from the ranges in Table 6-6. For each simulation, software randomly drew sets of parameters from the uniform distribution and recorded the results. No interrelationships among the parameters were imposed on the parameter selection.

Table 6-6. Parameter Ranges for the Benefits Sensitivity Analysis

Parameters	Selected Value	Range for Sensitivity Analysis
Characteristics of the Illness		
Number of contacts by infectious individuals per unit time	**5**	**1 – 12 contacts**
Probability of transmission per contact	**10%**	**1% - 20%**
Mean duration of infectiousness	**5**	**2 – 21 days**
Latent period	**5**	**2 – 21 days**
Proportion of the population susceptible (not vaccinated)	**100%**	**75% - 100%**
Survival Rate	**89%**	**75% - 100%**
Effectiveness of Intervention		
Day quarantine/isolation program starts	**35**	**28 - 40**
Proportion of contacts quarantined	**60%**	**40% - 80%**
Proportion of infectious cases isolated	**70%**	**50% - 90%**

6.5.1 Characteristics of the Illness

The epidemiological model is highly sensitive to the characteristics of the illness being modeled. Even small changes in the parameters that control the rate of transmission by symptomatic individuals can change the number of fatalities and damage avoided by orders of magnitude. Based on the epidemiology literature, ERG judges that none of the parameter values shown in Table 6-6 would be considered outliers.

For example, 10 contacts per day would not be an unusual assumption for this type of epidemiological model. The sensitivity of the model is attributable to the geometric growth inherent in the model. Systems with geometric growth often exhibit rapid growth phases that are highly sensitive to starting conditions.

Table 6-7 summarizes the distribution of the annualized benefits when all flights are included in the regulation, Option 3. The median annualized benefits from the simulation are $7.5 billion and the mean is $298 billion. The annualized benefit estimate computed above (e.g., $1,274.1 million for Option 3 using a 7 percent discount rate) appears in this distribution at the 43rd percentile. Thus, ERG's estimate is reasonably consistent with the mid-range of the distribution of simulated outcomes. The distribution of outcomes includes a small probability of very high cost events that might be avoided by better contact tracing.

6.5.2 Effectiveness of Interventions

The model is remarkably insensitive to nature or effectiveness of the intervention. The last column of Table 6-7 varies by less than $100 million over ranges of intervention parameters similar to the ranges that caused results to vary by several orders of magnitude for the base case.

Experience suggests that early epidemiological intervention can be remarkably effective. Consider how many cholera deaths were avoided by removing the handle of the Broad Street pump in the classic John Snow case study (University of Alabama School of Public Health, 2002). Or, compare the number of SARS deaths in Canada where preparations were made and there were effective isolation and quarantine interventions, 43, with the 299 SARS deaths in Hong Kong where intervention only occurred later in the course of the outbreak (WHO, 2004). The nature of exponential growth models is that populations grow at an accelerating rate so *when* intervention occurs is vitally important.

The sensitivity analysis demonstrates that while some alternative assumptions could result in considerably smaller benefits estimates, many other alternative assumptions could result in disproportionately larger estimates. Although we cannot know the appropriate assumptions to model the epidemics that will be encountered in the future, it is not difficult to imagine outbreaks whose control would produce benefits exceeding the level of benefits estimated here.

Table 6-7. Distribution of Annualized Benefits from 500 Simulations ($ million, 2004; 7% discount rate)

Percentile	Characteristics of Illness	Effectiveness of Intervention
10%	$0.2	$1,243.9
15%	$1.0	$1,251.3
20%	$4.5	$1,257.0
25%	$14.4	$1,263.0
30%	$40.7	$1,266.7
35%	$198.8	$1,270.6
40%	$506.9	$1,274.6
43%	**$1,274.1**	---
45%	$1,967.7	$1,276.8
50%	$7,505.0	$1,280.4
55%	$27,363.4	$1,283.9
60%	$59,648.4	$1,288.0
65%	$131,314.8	$1,289.9
70%	$239,574.8	$1,292.7
75%	$390,243.1	$1,294.9
80%	$599,753.2	$1,296.8
85%	$741,041.9	$1,299.5
90%	$1,094,697.5	$1,302.2
95%	$1,519,275.1	$1,304.1

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SECTION 7. COMPARISON OF COSTS AND BENEFITS

7.1 BENEFIT-COST ANALYSIS

Executive Order 12866 requires that agencies "propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs." Recognizing that benefits may be more difficult to quantify than costs, the Executive Order does not impose a pure comparison of benefits and costs. Nevertheless, it is important to place benefits and costs in the same terms and compare them side by side.

As discussed in Section 6, opportunity costs are an important aspect of that comparison. Both benefits and costs must be stated in terms of changes in social welfare to be comparable and accurate. It is important to consider the alternative uses of the resources. Costs are only damaging to social welfare if they draw resources being used in some other way to being used for regulatory compliance. If compliance could be achieved using only idle resources, it would have no social cost. Since it is almost impossible to inquire into the alternative use of resources, we assume that all resources were fully utilized in an alternative use. Thus, any action required to comply with the regulation represents a social cost. With this assumption, cost estimates are on the same welfare terms as the benefit estimates.

The period of the analysis should be long enough to encompass all of the important costs and benefits of the proposed rule. The costs to industry, because of the rapid obsolescence associated with software design, have been calculated over a 10-year time frame. The time frame of the benefits is thus calculated over the same time frame for comparison purposes. ERG judges that some potential for actual outbreaks are likely over a 10-year horizon. Thus, a 10-year planning period seems adequate for analysis of this rule.

For several reasons, OMB guidance requires that costs and benefits in past or future periods be discounted to represent present values (OMB, 2003). The appropriate discount rate for purely social welfare changes is empirically measured to be 3 percent, the real social discount rate. However, many aspects of rule-making displace private investment and so should be discounted at the real private rate of return, which OMB estimates is 7 percent.

Three different methods of comparing costs and benefits are used. Section 7.2 presents a direct comparison of costs and benefits under both a 7 percent discount rate and 3 percent discount rate. Section 7.3 provides a cost-effectiveness analysis, comparing the incremental costs to incremental benefits measured as quality adjusted life years (QALYs), and Section 7.4 discusses a breakeven analysis, or the number of breakouts that would need to be avoided over the 10-year time frame in order for costs to equal benefits.

7.2 DIRECT BENEFIT-COST COMPARISON

Table 7-1summarizes the annualized, quantified cost and benefit results from earlier chapters in discounted 2004 dollars for each option under the POS scenario, discounted at both 7 percent and 3 percent. Table 7-2 presents the same information for the POD scenario, and Table 7-3 presents the midpoint of the costs between the POS and POD scenarios compared to the benefits. The size of costs under the various combinations of options and scenarios indicates that the proposed rule would be above the $100 million criterion for a significant rule under the Regulatory Flexibility Act, Executive Order 12866, and the Congressional Review Act (Subpart E of SBREFA). However, the preferred measures of costs and benefits indicate that quantified benefits exceed quantified costs under all options and under

either scenario. Options 2 and 3 are about three times as costly as Option 1 under either scenario but might still be justifiable given that benefits still outweigh costs by a wide margin.

Tables 7-1 and 7-2 also present the incremental net benefit of each option. The net benefit is calculated as the midpoint of the cost range subtracted from the estimated benefit for each option. The incremental net benefit is the difference between the net benefit of going from Option 1 to Option 2 and from Option 2 to Option 3. As the tables show, some decline in incremental net benefit occurs going from Option 1 to Option 2 to Option 3 under either scenario, regardless of discount rate.

Table 7-1. Annualized Discounted Value of Costs and Benefits of the POS Scenario over a 10-Year Planning Period

Parameter	Option 1 International Only		Option 2 International plus Medium and Large Hubs		Option 3 International plus All Domestic	
	Total Cost and Benefit	Incremental Net Benefit	Total Cost and Benefit	Incremental Net Benefit	Total Cost and Benefit	Incremental Net Benefit
At 7 percent discount rate						
Costs	$185.5		$495.0		$535.3	
Benefits	$1,070		$1,263		$1,274	
Net Benefit	$884.5	--	$768.0	($116.5)	$738.7	($29.3)
At 3 percent discount rate						
Costs	$165.7		$475.0		$515.3	
Benefits	$1,033		$1,220		$1,231	
Net Benefit	$867.3	--	$745.0	($122.3)	$715.7	($29.3)

Table 7-2. Annualized Discounted Value of Costs and Benefits of the POD Scenario over a 10-Year Planning Period

Parameter	Option 1 International Only		Option 2 International plus Medium and Large Hubs		Option 3 International plus All Domestic	
	Total Cost and Benefit	Incremental Net Benefit	Total Cost and Benefit	Incremental Net Benefit	Total Cost and Benefit	Incremental Net Benefit
At 7 percent discount rate						
Costs	$262.9		$793.8		$865.2	
Benefits	$1,070		$1,263		$1,274	
Net Benefit	$807.1	--	$469.2	($337.9)	$408.8	($60.4)
At 3 percent discount rate						
Costs	$244.1		$774.7		$846.1	
Benefits	$1,033		$1,220		$1,231	
Net Benefit	$788.9	--	$445.3	($343.6)	$384.9	($60.4)

Table 7-3. Annualized Discounted Value of Costs and Benefits of the Midpoint between the POS and POD Scenarios over a 10-Year Planning Period

Parameter	Option 1 International Only		Option 2 International plus Medium and Large Hubs		Option 3 International plus All Domestic	
	Total Cost and Benefit	Incremental Net Benefit	Total Cost and Benefit	Incremental Net Benefit	Total Cost and Benefit	Incremental Net Benefit
At 7 percent discount rate						
Costs	$224.2		$644.4		$700.3	
Benefits	$1,070		$1,263		$1,274	
Net Benefit	$845.8	--	$618.6	($227.2)	$573.7	($44.9)
At 3 percent discount rate						
Costs	$204.9		$624.9		$680.7	
Benefits	$1,033		$1,220		$1,231	
Net Benefit	$828.1	--	$595.1	($233.0)	$550.3	($44.8)

7.3 COST-EFFECTIVENESS ANALYSIS

Another way to compare costs and benefits is to conduct a cost-effectiveness analysis. OMB guidelines, for a major rulemaking, require a cost-effectiveness analysis that restates costs in terms of a measure of the goals accomplished by the proposed regulation. This rule is expected to improve health outcomes in the event of an outbreak by facilitating contact tracing. The benefit assessment estimated the number of deaths, illness days, and quarantine days avoided by earlier intervention in an outbreak. In order to include both mortality and morbidity effects in a single metric for cost effectiveness analysis, these measures were converted to QALYs. Preference scores indicate the relative quality of life for different health states where 1 indicates perfect health and 0 indicates death. Given the prevalence of minor illness in the population, it has become standard practice to assume the population normally lives with a preference score of less than 1 (Hubbell, 2003). We assume the population level is 0.95. We considered hospitalization with non-fatal tuberculosis to be similar to the state of health for persons ill or isolated in the infectious stage of the outbreak in our model. This condition has a preference score of 0.50 (Harvard Center for Risk Analysis, 2005). Persons recovering from the illness or in quarantine may not be very ill so we assign them a preference score of 0.93 (Harvard Center for Risk Analysis, 2005).

Another important issue is the number of years of life lost by premature death. Frequently, deaths from influenza and similar infectious diseases occur in children, the elderly, and immunodeficient individuals. The death of a child results in more lost years because they have a longer life expectancy. Ideally, the susceptibility of each population would be assessed to arrive at an appropriate average number of years lost, but as we do not know any characteristics of the disease, we simply assume that 20 years will be lost with each death. Individuals have a preference for the near term. Living well next year is preferred to living well 20 years from now. To capture this preference, future years are discounted at 3 percent, with a preference score of 0.95, so that each death represents 14.56 QALYs lost.

The QALY losses avoided by implementation of the proposed rule annualized at 7 percent are presented in Tables 7-4, 7-5, and 7-6. As with the dollar denominated benefit estimates, the number of deaths avoided is the largest component of benefits. Costs per QALY for Options 1 and 2 are less than $300,000 under the higher-cost POD scenario.

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

As Tables 7-4 , 7-5, and 7-6 show, after Option 1 (international flights and cruise lines only) under either scenario and under the midpoint of costs between the two scenarios, respectively, costs rise quickly. Option 2 (international plus large and medium hubs) is associated with a slightly lower average cost effectiveness value compared to Option 3 (international plus all domestic), but a significantly lower incremental cost effectiveness value compared to Option 3 under either scenario or under the midpoint between the POS and POD scenarios.

Table 7-4. Average and Incremental Cost Effectiveness of the Options under the POS Scenario (ranked by number of QALYs) (7 percent discount rate)

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

Table 7-5. Average and Incremental Cost Effectiveness of the Options under the POD Scenario (ranked by number of QALYs) (7 percent discount rate)

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

Table 7-6. Average and Incremental Cost Effectiveness of the Options under the Midpoint between the POS and POD Scenarios (ranked by number of QALYs) (7 percent discount rate)

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

7.4 BREAKEVEN ANALYSIS

As another alternative measure of the relationship between costs and benefits, ERG also calculated the number of years between outbreaks that would need to occur for benefits to equal costs. The benefits of one outbreak were discounted as if the outbreak would occur five years in the future and annualized to be comparable to annualized costs. Dividing annualized costs by annualized benefits indicates the number of outbreaks that would need to occur during the planning period for benefits to equal costs. Dividing the planning period, 10 years, by this number shows the expected period of time between outbreaks. If this period is longer than the expected recurrence of serious outbreaks, then the expected benefits outweigh the expected costs.

Table 7-7 shows these results for the three options considered under the POS and POD scenarios, as well as under a midpoint cost assumption. Whether or not one believes that there will be two outbreaks of this magnitude in the next 10 years, it may be reasonable to expect that there may be one such outbreak in 9 to 27 years, as represented for the midpoint cost assumption.

Table 7-7. Costs in Terms of the Number and Frequency of Outbreaks.

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

7.5 REFERENCES

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SECTION 8. UNFUNDED MANDATES REFORM ACT AND CIVIL JUSTICE REFORM ANALYSES

8.1 UNFUNDED MANDATES REFORM ACT ANALYSIS

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA; Public Law 104-4) establishes requirements for Federal agencies to assess the effects of their regulatory actions on state, local, and tribal governments as well as the private sector. Under Section 202(a)(1) of UMRA, an agency must generally prepare a written statement, including a cost-benefit analysis, for proposed and final regulations that "includes any Federal mandate that may result in the expenditure by state, local, and tribal governments, in the aggregate or by the private sector" of annual costs in excess of $100 million.[1] As a general matter, a federal mandate includes federal regulations that impose enforceable duties on state, local, and tribal governments, or on the private sector (Katzen, 1995). Significant regulatory actions require Office of Management and Budget (OMB) review and the preparation of a Regulatory Impact Assessment that compares the costs and benefits of the action.

The proposed CDC regulations are not an unfunded mandate on state, local, or tribal governments because industry bears the cost of the regulation. The costs estimated for industry exceed $100 million/year under some options, although the actual cost might be far lower if CDC can access data already collected by other agencies. CDC is responsive to all required provisions of UMRA. In particular, this Regulatory Impact Analysis addresses:

- Section 202(a)(1)—authorizing legislation (see Section 1 and the preamble to the rule).
- Section 202(a)(2)—a qualitative and quantitative assessment of the anticipated costs and benefits of the regulation, including administration costs (see Sections 3 and 6).
- Section 202(a)(3)(A)—accurate estimates of future compliance costs (as reasonably feasible; see Section 3).
- Section 202(a)(3)(B)—disproportionate effects on particular regions or segments of the private sector, or on local communities. Because the costs for Part 70 will be distributed among passengers and carriers throughout the United States, there are no disproportionate impacts. For international arrivals, the impacts will be distributed around the border of the United States, but the impacts are not expected to cluster in any one particular region or segment of the United States. Section 5 examines whether there are significant impacts on a substantial number of small entities as a result of the rule.
- Section 202(a)(4)—estimated effects on the national economy (discussed in this section).
- Section 205(a)—least burdensome option or explanation required (discussed in this section).

The estimated annualized cost of the rule under the POS scenario ranges from $117.9 million to $168.0 million (excluding opportunity costs), depending on option, when annualized at 7 percent over 10 years. Under the POD scenario, annualized costs total $172.4 million to $425.3 million per year. These costs have "ripple effects" as they flow through the economy; input-output techniques allow an estimate

[1] The $100 million in annual costs is the same threshold that identifies a "significant regulatory action" in Executive Order 12866.

to be made of how much additional activity will be generated by spending by a particular industry. Ripple effects are classified in three phases. Direct effects result from onsite jobs, software upgrades, and sales of data-gathering equipment. Indirect effects occur as local businesses spend their new revenue to re-stock and pay their employees. Induced effects occur when employees spend their paychecks. The amount of spending in each phase is estimated using "multipliers." The U.S. Department of Commerce, Bureau of Economic Analysis (BEA) developed a Regional Input-Output Modeling System (RIMS) to estimate the multiplicative effects of projects on regional and national economics (BEA, 1992). We use the national-level final-demand multipliers for output to approximate the impact on the national economy:

- BEA industry 65.0400 (water transportation) multiplier for output: 3.0285
- BEA industry 65.0500 (air transportation) multiplier for output: 2.8937.
- BEA industry 65.0702 (arrangement of passenger transportation) multiplier for output: 3.2989

For an initial perspective on the potential impact of these costs on the national economy, we compared the annualized costs to the Gross Domestic Product (GDP). After rippling through the economy, the estimated change in national output from the annualized cost of the rule under the POS scenario ranges from $345.6 million to $510.2 million. The change in national output from the annualized cost of the rule will range from $ 345.6 million (POS, Option 1) to $1.2 billion (POD, Option 3). At the end of 2004, the preliminary GDP estimate is $12 trillion (CEA, 2005). That is, the potential change in output from the highest cost option is less than one percent of one percent of 2004 GDP.

Pursuant to Section 205(a)(1)–(2), the "least costly, most cost-effective or least burdensome alternative" would involve CDC gaining access to data already or planned to be collected by other government agencies. Because this is considered not be a viable option, CDC has estimated the cost assuming the data must be collected separately from other possible data collection by various government agencies.

8.2 CIVIL JUSTICE REFORM ANALYSIS

8.2.1 Background

Executive Order (EO) 12988, "Civil Justice Reform" provides principles to promulgate regulations that do not unduly burden the federal court system (Federal Register 61:4729–4734, February 7, 1996). Section 3(a) requires Federal agencies to (1) review the regulations to eliminate drafting errors and ambiguity, (2) write regulation so as to minimize litigation, (3) provide a clear legal standard for affected conduct rather than a general standard, and (4) promote simplification and burden reduction. Section 3(b)(2) provides a checklist of specific issues for the regulation, while Section 3(c) requires an agency to review a draft regulation to ascertain whether it meets the applicable standards in Sections 3(a) and 3(b) or explain that is it unreasonable to require the regulation to meet one or more of those standards.

Section 8.2.2 addresses the requirements of EO 12988, Section 3(a). Section 8.2.3 contains a detailed discussion of how and where each of the Section 3(b)(2) issues are addressed in the proposed regulation. Section 8.2.4 concerns Section 3(c) requirements.

8.2.2 EO 12988 Section 3(a) Requirements

The Notice of Proposed Rulemaking, Control of Communicable Diseases, 42 CFR Parts 70 and 71, are responsive to the provisions of EO 12988 Section 3(a). Specifically:

- This report is the documentation that the proposed regulation has been reviewed to eliminate drafting errors (Section 3(a)(1)).

- The proposed regulation meets EO 12988 Section 3(a)(1) requirement to eliminate ambiguity by:
  - providing additional and explicit definitions in proposed Sections 42 CFR 70.1 and 71.1;
  - specifying due process procedures to protect individual liberties in proposed Sections 42 CFR 70.11–19 and 71.11–19; and
  - specifying the data required in crew manifests and passenger information collections, required time for holding such data, response time to a CDC request for the data, and the data format (proposed Sections 42 CFR 70.3 and 71.6).

- The proposed regulation meets EO 12988 Section 3(a)(2) requirement to minimize litigation by clarifying administrative procedures and specifying elements of due process (see Section 8.2.3.3 below).

- The proposed regulation meets EO 12988 Section 3(a)(3). The preamble references 42 U.S.C. paragraph 264 for the authority and standards for a decision to detain, quarantine, or isolate persons for the purpose of protecting public health (i.e., to prevent the introduction, transmission, or spread of communicable diseases into the United States and from one State or possession to another). The proposed regulation outlines standards to be met to protect a person's right to due process during the detention, quarantine, or isolation period.

8.2.3 EO 12988 Section 3(b)(2) Requirements

EO 12988 Section 3(b)(2) lists seven requirements that the regulation must meet. Each of these "litigation checklist" issues is discussed in an individual section below.

8.2.3.1 (A) Preemptive Effect

The Notice of Proposed Rulemaking (NPRM) states that "the proposed rule preempts all State and local laws and regulations that are inconsistent with this rule." Thus, it meets the requirement to specify in clear language the preemptive effect of the regulation.

8.2.3.2 (B) Effect on Existing Federal Law or Regulation

The preamble to the rule provides three different methods to specify in clear language the effect of the proposed rule on existing Federal regulation. First, there is a section-by-section *discussion* in the preamble that describes new provisions and how existing provisions are modified or otherwise changed. Second, there is a *summary listing* specifying sections cancelled, moved, or added. Third, there is a *table* providing a section-by-section comparison between the existing regulation and the proposed regulation. These three methods are used for both 42 CFR 70 and 42 CFR 71. Thus, the NPRM meets the requirement of EO 12988, Section 3(b)(2)(B).

8.2.3.3 (C) Clear Legal Standard for Affected Conduct

In deciding to detain, quarantine, or isolate an individual, one must balance individual civil liberties against the public health. The proposed regulation includes explicit due process protections rather than a general standard. In particular, the proposed regulation provides details on:

- Reasonable and adequate notice.
- Opportunity to be heard in a reasonable time and manner.
- Access to legal counsel.
- Review by an impartial decision-maker.
- Written articulation of the rationale of the underlying the decision.

Sections 70.13(b) and 71.16(b) specify that provisional quarantine begins with the (1) service of a provisional quarantine order, (2) a verbal provisional quarantine order, or (3) actual provisional quarantine restrictions. Provisional quarantine is limited to three days based on the time needed for sample collection, transfer, and testing to ascertain whether the person is a possible carrier of disease.

A provisional quarantine order is served at the time or as soon thereafter as circumstances reasonably permit. Sections 70.14(d) and 71.17(c) specify that the provisional quarantine order must contain, among other items, the written articulation of the rationale underlying the decision notification that the person may request a hearing within the next two business days, information on how to request a hearing, and notification that the person may be represented at the hearing by legal counsel or another representative.

Sections 70.15 and 71.18 provide details about the provisional quarantine hearing. First, the hearing is held within one business day of the request for the hearing and the person must be notified that the hearing has been scheduled. Sections 70.15(d) and 71.18(d) specify the designation of a hearing officer or authorized representative. The person also may request a hearing to reconsider a quarantine order upon request, provided that a hearing into that person's provisional quarantine has not already occurred (Sections 70.19(a) and 71.19(f)). The preamble clarifies that that the hearing officer or authorized representative is not the person who ordered the provisional quarantine.

Pertaining to a person's right to be heard, the person (or legal counsel or representative) can submit evidence concerning whether the person is in the qualifying stage of a quarantinable disease; see Sections 70.15(e) and 71.18(e). The text of the regulation details the measures that the Director might reasonably take to allow a person in provisional quarantine access to his or her legal council or representative; see Sections 70.15(f) and 71.18(f).

The Director has one business day in which to release or quarantine a person once the hearing officer has presented findings and a written recommendation; see Sections 70.15(h) and 71.18(i).

Similar protections for individual rights are in place for quarantine (Sections 70.16–17 and 71.19–20). The quarantine order must be written and a copy served to the person as soon as the quarantine commences or as soon thereafter as circumstances permit. The order must explain its basis and list the date and time at which quarantine begins and ends, as well as the location where the quarantine will take

place. The person is to be notified of his or her right to a hearing (except where a previous hearing into the provisional quarantine has already occurred) and right to refuse examination, medical monitoring, treatment, vaccination, or prophylaxis. Sections 70.23 and 71.26 provide for an administrative record to be kept which provides a record for a court to review.

In sum, the proposed rulemaking meets the requirement for clear legal standards for affected conduct with regard to due process.

The legal standard and authority to collect manifest data for the purposes of preventing the introduction, transmission, or spread of communicable diseases from foreign countries into the United States and from one state or possession into another is based on the Public Health Services Act Section 301(42 U.S.C.).

8.2.3.4 (D) Retroactive Effect

The NPRM states that the proposed rule "has no retroactive effect." Thus, it meets the requirement to specify in clear language the retroactive effect of the regulation.

8.2.3.5 (E) Administrative Proceedings

The proposed rule meets the EO 12988 Section 3(b)(2)(E) requirements in that it specifies "whether administrative proceedings are required before parties may file suit in court and, if so, describes those proceedings and requires the exhaustion of administrative remedies." The specification and description of the administrative hearings are summarized in Section 8.2.3.3 above. Section 70.14(f) identifies the CDC Director's quarantine order as the final agency action. The preamble to the rule establishes that, when administrative remedies are exhausted, the person can obtain a judicial review of the quarantine order through a petition for writ of habeas corpus.

8.2.3.6 (F) Definition of Key Terms

The proposed rule defines key terms in Sections 70.1 and 71.1. New key terms for Section 70.1 include "business day," "carrier," "provisional quarantine," "detention," "Director," "ill person," "Indian country," "infectious agent," "interstate traffic," "medical monitoring," "military service," "public health emergency," "qualifying stage," "quarantine," "quarantinable disease," "sanitary measure," "Secretary," and "vector." Section 70.12(c)(1) clarifies the definition of "qualifying stage" by providing examples of the basis for the belief that the person is in a qualifying stage, such as travel history, clinical manifestations, or any other evidence of infection or exposure. Key terms modified in Section 70.1 include "possession" and "state." The preamble explains that the terms have been added or modified to be consistent with modern quarantine concepts and current medical principles and practice.

Similarly, Section 71.1 adds and defines the key terms "business day," "bill of health," "provisional quarantine," "infectious agent," "medical monitoring," "possession," "quarantine," "quarantinable disease," and "state." Section 71.1 modifies the key terms "ship sanitation control certificate," "ship sanitation control exemption certificate," "detention," "Director;" "ill person," "International Health Regulations," "military services," "sanitary measures," and "United States." Again, the purpose of the additions and changes is to be consistent with modern quarantine concepts and current medical principles and practice. The preamble text explains the absence of the terms "public health emergency" and "qualifying stage" from Section 71. The intent is to remove ambiguity and add clarity to the regulation.

The regulation also provides definitions by reference to other regulations and statutes that explicitly define terms. The definition of "quarantinable disease" is linked to Executive Order 13295, Section 70.1(b)(18) and Section 71.1(b)(21).

Thus, the NPRM meets the requirement of EO 12988 Section 3(b)(2)(F) by defining key terms.

8.2.3.7 (G) Concurrence on Clarity and General Draftsmanship

EO 12988 Section 3(b)(2)(G) "addresses other important issues affecting clarity and general draftsmanship of regulations set forth by the Attorney General, with the concurrence of the Director of OMB after consultation with affected agencies . . ." By participating in the OMB review process as part of EO 12866, CDC also meets the EO 12988 requirement for concurrence.

8.2.4 Agency Review

EO 12988 Section 3(c) requires an agency to review draft regulations to determine that either a draft regulation meets the applicable standards in Sections 3(a) and 3(b) or that it is unreasonable for the regulation to meet one or more requirements. This report documents the CDC review and the determination that the proposed regulation meets the applicable standards in Sections 3(a) and 3(b).

8.3 REFERENCES

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APPENDIX A

EPIDEMIOLOGICAL MODEL DETAIL

The model is a simplified version of the standard Susceptible-Exposed-Infectious-Recovered (SEIR) structure modified to include the effects of asymptomatic carriers, quarantine, and isolation (Lipsitch, et al., 2003; Anderson and May, 1991). The model is deterministic. It is based on a fixed course of illness with fixed probabilities of outcomes at each stage. Individuals who become ill experience a latent period, when they feel no effects and are not contagious, and an infectious period during which they spread the disease but may or may not show symptoms of it.

Individuals are exposed to the illness from either symptomatic or asymptomatic carriers of the disease and contract it according to a fixed probability for each source of contact. If there is a quarantine program in place, individuals exposed by symptomatic carriers may be quarantined with probability *Q*. The quarantine is effective as soon as the individual is exposed, so any failure of quarantine or inability to identify contacts is reflected in *Q*. At the end of the latent period, individuals either show symptoms or do not. If there is an isolation program, those who show symptoms may be isolated. Persons in quarantine who show symptoms are always isolated. Asymptomatic individuals become carriers in the population for the duration of the infectious period. At the end of the infectious period, patients with symptoms either die or enter a recovery period. Asymptomatic individuals do not die from the illness. Both symptomatic and asymptomatic individuals acquire immunity to the illness and become part of the recovered immune group. In testing, it is the growth in the recovered immune group that limits the extent of the outbreak in a susceptible population.

Dot notation indicates change in a population variable in a time period.

Variables

N	Population
N^s	Susceptible population
G	Deaths
B	Infectious population
S	Symptomatic infectious population
A	Asymptomatic infectious population
M	Recovered immune population
I	Isolated population
Q	Quarantined population

Time Periods

L	Mean duration of latent period (days)
D	Mean duration of infectious period (days)

Parameters

k	Number of contacts by infectious individuals per day
b	Probability of transmission per contact by symptomatic patient
b_a	Probability of transmission per contact by an asymptomatic patient
x	Proportion of population at time 0 that is susceptible to illness
a	Proportion of cases that are asymptomatic
q	Proportion of contacts that are quarantined
i	Proportion of symptomatic cases that are isolated

Overall population is the population of the period before fewer deaths.

(1) $$N_t = N_{t-1} - \dot{G}_{t-1}$$

The susceptible population consists of the beginning overall population that is not immune, N_x, less deaths and those who have recovered and have immunity plus those already in quarantine or isolation.

(2) $$N_t^S = N_0 x - G_{t-1} - M_{t-1} - Q_{t-1} - I_{t-1}$$

The symptomatic population shows symptoms of the illness and is infectious to the general population. It consists of the symptomatic population from the previous period plus newly symptomatic patients, less those who are ending their period of infectiousness (that is, those who became ill in the period *D* days ago). As the symptomatic population, *S*, represents the group that spreads the disease to the general population, the group of ill individuals who have been isolated must be removed from S.

(3) $$S_t = S_{t-1} + \dot{S}_{t-1} - \dot{S}_{t-D} - \dot{I}_{t-1} + \dot{I}_{t-D}$$

The asymptomatic, infectious population is defined similarly but as asymptomatic individuals cannot be isolated, there is no adjustment for isolation.

(4) $$A_t = A_{t-1} + \dot{A}_{t-1} - \dot{A}_{t-D}$$

The total infectious population is the sum of *S* and *A*.

(5) $$B_t = A_t + S_t$$

The illness spreads from this population in proportion to the number of contacts each individual has, *k;* the proportion of the susceptible population to the general population; and the degree of infectiousness of symptomatic *(b)* and asymptomatic *(b_a)* individuals. Since B_t indicates infectiousness, the relevant populations are those now leaving their latent period, i.e., those from *L* periods prior. In addition, those individuals who were quarantined at time *t–L* were counted in the infectious population at that time. At time *t,* those who became ill while quarantined would be isolated and so should not be counted as part of the infectious population. They are subtracted out.

(6) $$\dot{B}_t = k\left(\frac{N_t^S}{N_t}\right)\left(S_{t-L}b + A_{t-L}b_a\right) - \dot{I}_t^Q$$

The new group of future symptomatic patients that enters its latent period in time *t* is defined as:

(7) $$\dot{S}_t = \dot{B}_t(1-a)$$

The new group of asymptomatic patients also includes those who were quarantined but did not show symptoms and so were released.

(8) $$\dot{A}_t = \dot{B}_t a + \dot{Q}_{t-L}b_a$$

If there is an isolation program, the number of individuals being isolated depends on its effectiveness, *i,* and the symptomatic population. Patients may also enter the isolated group if they become ill while quarantined.

(9) $$\dot{I}_t = i\dot{S}_t$$

(10) $$\dot{I}_t^Q = \dot{Q}_{t-L}b$$

The isolated population at any time, *t,* is:

(11) $$I_t = I_{t-1} + \dot{I}_t + \dot{I}_t^Q - \dot{I}_{t-D} - \dot{I}_{t-D}^Q$$

The quarantined population depends on the effectiveness of the quarantine program, *q,* and the symptomatic population adjusted for susceptibility and number of contacts.

(12) $$\dot{Q}_t = k\left(\frac{N_t^S}{N_t}\right)S_t\, q$$

The quarantined population at any time is:

(13) $$Q_t = Q_{t-1} + \dot{Q}_t - \dot{Q}_{t-L}$$

Deaths occur among patients isolated from quarantine and those infected in the general population at 1 minus the survival rate, *SR*.

(14) $$\dot{G}_t = (\dot{I}^Q_{t-D} + \dot{S}_{t-D})(1 - SR)$$

The number of recovered immune individuals also grows each period.

(15) $$\dot{M}_t = \dot{A}_{t-D} + \left(\dot{I}^Q_{t-D} + \dot{S}_{t-D}\right)SR$$

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