

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

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

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

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

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

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

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

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

#### **A. Objectives and Basis for the Proposed Regulation**

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

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

Stopping an outbreak—whether it is naturally occurring or caused intentionally—requires the use of the most rapid and effective public health tools available. One of those tools is quarantine—restricting the movement of persons exposed to infection to prevent them from infecting others, including family members, friends, and neighbors.

Quarantine of exposed persons may be the best initial way to prevent the uncontrolled spread of highly dangerous biologic agents such as smallpox, plague, and Ebola fever—especially when combined with other health strategies such as vaccination, prophylactic drug treatment, patient isolation, and other appropriate infection control measures.

### **B. The Nature of the Impacts**

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

comment from the airlines and their passengers concerning the most efficient means of data collection.

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

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

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

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

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

Second, the economic impact of a sanitation order may differ significantly depending on the circumstances. Experience shows that, in some cases, public health

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

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

### **C. Need for the Rule**

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

## **D. Baseline**

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

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

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

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

## **E. Alternatives**

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

Overall, the proposed rule seeks to:

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

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

The major cost component of the proposed regulation is creation and maintenance of a passenger information database including home address, emergency contact, and itinerary information. Under current regulations, the airlines do not typically collect this information in an easily accessible format, nor do they maintain it for the proposed 60-day period. Airlines, Global Distribution Systems (GDSs), and travel agencies may already collect some of it, however. If the information can be shared, then this data collection may be relatively invisible to the traveler and primarily a programming problem for the airlines, although passengers will incur some opportunity costs of their

time to provide information and travel agencies and similar entities will incur some costs to collect the data. This scenario is CDC's "Point of Sale" (POS) scenario. However, CDC also examined the situation where a wholly separate information collection must be undertaken at departure; this process could add to check-in times and entail gathering information that is already gathered by many travel agencies, generating additional real and opportunity costs for carriers and passengers. This is the "Point of Departure" (POD) scenario.

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

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

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

## **F. Cost Analysis of Proposed Option and Alternatives**

### **F.1 Profile of Airline and Cruise Ship Industries**

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

#### ***Airline Industry***

Commercial air carriers are classified according to the size of the aircraft and type of service provided. Airlines operating aircraft with more than 60 seats are classified as large certificated carriers, and further distinguished as major, national, and regional according to annual revenues. Carriers operating aircraft with 60 seats or fewer may be classified as small certificated carriers and commuter airlines. Some commercial air carriers operate under code-sharing partnerships with other, typically major, airlines. Generally, reservations are made with, and flight manifests are generated by, the parent

airline, not the codeshare airline (Franz, 2005). We estimate that 23 codeshare airlines fly exclusively under other airlines' codes (RAA, 2005).

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

**Table VI.F-1. Flights and Passengers Carried by Airlines on Routes Affected by Rule, Revenue and Net Income July 1, 2003 - June 30, 2004 (all potentially affected international and domestic flights).**

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

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

### *Cruise Ship Industry*

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

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

Most of the largest cruise lines are members of the International Council of Cruise Lines (ICCL); of the 16 cruise lines in this category, two are U.S.-owned. The second tier consists of 16 cruise or ferry lines that are not members of ICCL, but are considered large operations under the terms of the small business analysis. One cruise line in this group is

U.S.-owned. Small cruise lines and international ferry lines number 25; all of these appear to be U.S.-owned. Table VI.F-2 summarizes relevant data for the cruise line industry and presents limited financial data for U.S.-owned cruise and ferry lines.

**Table VI.F-2. Available Data for U.S. Cruise Lines**

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

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

## **F.2 Incremental Costs to Industry of Data Collection**

### *Data Collection Costs*

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

passengers must devote time to providing additional information when they make reservations (discussed later in this section).

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

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

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

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

### ***Reprogramming Costs***

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

substantially lower (Airline Web Sites, 2005; Delta, 2005; FR, 2003; Pace, 2005; Sun Country, 2005).

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

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

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

#### *Archiving and Other Administrative Costs*

Major airlines tend to keep flight manifests in electronic format for only a few days because their intensive flight operations would otherwise result in massive storage requirements (United, 2005; Volpe, 2004). Incremental costs will be incurred for archiving manifest and passenger information in electronic format up to 60 days, as well as administrative costs for submitting data each time CDC requests data and for documenting how they will collect data and submit it to CDC. This includes time to provide passenger lists and data for the 10-12 times per month CDC expects to routinely request this information. It is assumed that, with the software modifications in place, such routine requests will require only a small amount of time to process and submit data. CDC assumed major, national, and foreign airlines would require 5 percent of a full-time-equivalent airline database manager to handle these tasks, declining to 1 percent for small

certificated/commuter airlines. For cruise lines, ICCL members are assigned 5 percent, other large lines are assigned 3 percent, and small lines and ferries are assigned 1 percent. The average wage for this occupation is taken to be \$44.00 per hour fully loaded (BLS, 2005). CDC assumed archiving will occur on 50-gigabyte tapes, and airlines will need a maximum of 12 tapes over a 3-month period. Because these tapes can be recycled and reused for a number of years, annualized costs of tapes are assumed minimal. Storage space requirements are also considered negligible. CDC estimated annual archiving and administrative tasks (under either scenario) would cost \$676,000 to \$710,000 for airlines, depending on option, and \$140,000 for cruise lines across all options, for a total of \$816,000 to \$855,000 depending on option. GDSs and travel agencies would not have an equivalent responsibility to provide data to CDC, so no archiving or administrative costs are assumed for these entities.

#### ***Opportunity Costs to Passengers***

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

average of 1.5 minutes for passengers to provide the required additional information to airlines/cruise lines.

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

### **F.3 Projected National Costs of the Proposed Rule**

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

Under the POD scenario, airlines and cruise ship industries incur all compliance costs as they are collecting and compiling all required passenger information.

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

**Table VI.F-3a. Estimated Annualized National Costs for the Point of Sale Scenario (\$millions, 2004)**

<b>Affected Entity</b>	<b>Option 1 International Only</b>	<b>Option 2 International plus Large and Medium Hubs</b>	<b>Option 3 International plus All Domestic</b>
Airlines	\$106.6	\$108.2	\$108.2
Cruise lines	\$0.8	\$0.8	\$0.8
Travel agencies	\$7.6	\$50.5	\$56.1
GDSs	\$3.0	\$3.0	\$3.0
<b>Total Industry Cost</b>	<b>\$117.9</b>	<b>\$162.4</b>	<b>\$168.0</b>
Opportunity cost to passengers	\$67.6	\$332.6	\$367.3
<b>Total with Opportunity Cost</b>	<b>\$185.5</b>	<b>\$495.0</b>	<b>\$535.3</b>

**Table VI.F-3b. Estimated Annualized National Costs for the Point of Departure Scenario (\$millions, 2004)**

<b>Affected Entity</b>	<b>Option 1 International Only</b>	<b>Option 2 International plus Large and Medium Hubs</b>	<b>Option 3 International plus All Domestic</b>
Airlines	\$133.4	\$356.4	\$386.3
Cruise lines	\$39.0	\$39.0	\$39.0
Travel agencies	\$0	\$0	\$0
GDSs	\$0	\$0	\$0
<b>Total Industry Cost</b>	<b>\$172.4</b>	<b>\$395.4</b>	<b>\$425.3</b>
Opportunity cost to passengers	\$90.5	\$398.4	\$439.9
<b>Total with Opportunity Cost</b>	<b>\$262.9</b>	<b>\$793.8</b>	<b>\$865.2</b>

### **G. Impacts on Industry**

Impacts on industry, including airlines, cruise lines, travel agencies, and GDSs, were measured using a comparison of annualized costs per firm to each firm's revenues, if available. Impacts were identified where the annualized costs exceeded 1 percent of revenues and/or where the annualized costs exceeded the net income of a firm (airlines

only). For airlines, we used a second test, comparing annualized costs to net income (similar baseline net income figures are not available for the other entities). Impacts were identified where annualized compliance costs exceeded net income, where net income was currently positive.

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

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

## **H. Benefits**

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

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

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

The most direct effect of the CDC rule changes is improved contact tracing leading to better health outcomes when an outbreak threatens. In epidemiological models,

the speed of response is often more important than the specific action taken (Barrett et al., 2005; Lipsitch, 2003). Whether the chosen action is vaccination, quarantine, and/or isolation, early implementation lowers the illness and death toll. Thus one way to quantify benefits is to compare a base case in which intervention proceeds using existing tools with alternatives in which intervention can proceed more rapidly. (The more rapid intervention is made possible because passenger information that includes contact information is readily available.) The benefits of the alternative are measured in terms of the number of prevented deaths and illnesses.

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

The risks of illness and death from an infectious disease are similar to risks from some environmental hazards in that they are involuntary, pervasive, and random. Thus, we updated values from the Environmental Protection Agency's evaluation of the benefits of the Clean Air Act (Kochi, et al., 2003) to 2004 dollars as a measure of WTP for changes in the risk of death or value of a statistical life (VSL). We applied this \$6.9 million to the number of deaths the SEIR model forecast would be avoided by faster government action. Johnson et al. (1997) found a WTP to avoid a day of severe cough was \$56 (updated to 2004 with CPI). In addition, the WTP for workdays lost to illness and recovery is measured as wages lost. CDC valued these losses using the median usual

weekly earnings of full-time wage and salary workers, \$128 per day (BLS, 2005). Lost earnings are an element of WTP that was not captured by Johnson et al. (1997) so it is appropriate to add the two components together.

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

**Table VI.H-1. Outcomes in Base Case and Early Intervention**

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

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

the WTP in current dollars as well as the 10-year annualized discounted values at three and seven percent.

**Table VI.H-2. Estimated Willingness to Pay for Change in Outcomes (Million, 2004 dollars)**

<b>Outcome</b>	<b>Option 1 International Only</b>	<b>Option 2 International plus Medium and Large Hubs</b>	<b>Option 3 International plus All Domestic</b>
Deaths Avoided	\$4,999.7	\$5,901.9	\$5,956.1
<b>Other Outcomes Avoided:</b>			
Illness days	\$2.7	\$3.2	\$3.2
Isolation days	\$3.5	\$4.2	\$4.2
Recovery days	\$1.4	\$1.7	\$1.7
Quarantine days	\$13.2	\$15.6	\$15.7
Total	\$5,020.6	\$5,926.5	\$5,980.9
<b>Annualized Benefits</b>			
7 percent discount rate	\$1,069.5	\$1,262.5	\$1,274.1
3 percent discount rate	\$1,033.3	\$1,219.8	\$1,231.0

The effect of the earlier intervention reducing the number of deaths from 900 to 37 is remarkable but not inconceivable; compare the 43 SARS deaths in Canada where preparations were made and there were effective public health measures with the 299 SARS deaths in Hong Kong. A Monte Carlo simulation demonstrated that the set of parameters used in the analysis yielded a benefit estimate at the 42<sup>nd</sup> percentile of a range of possible parameter choices. While some alternative assumptions could result in considerably smaller benefits estimates, many other alternative assumptions could result in much larger estimates. Although we cannot know the appropriate assumptions to

model the epidemics that will be encountered in the future, it is not difficult to imagine outbreaks whose control would exceed this level of benefits. We invite comments on the benefits model, which is described in detail in the RIA (CDC, 2005).

### **I. Comparison of Costs and Benefits**

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

Tables VI.I-1a and VI.I-1b summarize the estimated annualized costs and benefits associated with the proposed rule under the POS and POD scenarios, respectively. Table VI.I-1c presents these same results assuming the actual costs are at the midpoint between the two bounding scenarios. The benefits of the rule are measured in terms of the number

of deaths and illnesses prevented by rapid intervention. The costs and benefits of the rule are considered over a 10-year period. As the table shows, under all options, the benefits substantially outweigh the costs under either scenario and assuming actual costs are the midpoint of costs under the two scenarios.

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

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

**Table VI.I-1b. Annualized Discounted Value of Costs and Benefits of the POD Scenario over a 10-Year Planning Period**

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

**Table VI.I-1c. Annualized Discounted Value of Costs and Benefits of the Midpoint between the POS and POD Scenario over a 10-Year Planning Period**

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

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

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

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

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

**Table VI.I-2a. Average and Incremental Cost Effectiveness of the Options under the POS Scenario (ranked by number of QALYs) (7 percent discount rate)**

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

**Table VI.I-2b. Average and Incremental Cost Effectiveness of the Options under the POD Scenario (ranked by number of QALYs) (7 percent discount rate)**

Option	Annualized Cost (\$millions)	QALYs	Incremental Cost	Incremental QALYs	Average Cost Effectiveness	Incremental Cost Effectiveness
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			(\$millions)		ness (\$/QALY)	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 VI.I-2b. Average and Incremental Cost Effectiveness of the Options at the Midpoint of Costs between the POS and POD Scenario (ranked by number of QALYs) (7 percent discount rate)**

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

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

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

**Table VI.I-3. Costs in Terms of the Number and Frequency of Outbreaks.**

	Annualized Costs (\$ millions,	Number of Outbreaks in 10 Years for Benefits to Equal	Frequency of Outbreaks to Equal Costs

	<b>2004)</b>	<b>Costs</b>	<b>(Years)</b>
<b>POS Scenario</b>			
<b>Option 1</b>	\$185.5	0.31	32.7
<b>Option 2</b>	\$495.0	0.82	12.3
<b>Option 3</b>	\$535.3	0.88	11.3
<b>Mid-Point</b>			
<b>Option 1</b>	\$224.2	0.37	27.1
<b>Option 2</b>	\$644.4	1.06	9.4
<b>Option 3</b>	\$700.3	1.15	8.7
<b>POD Scenario</b>			
<b>Option 1</b>	\$262.9	0.43	23.1
<b>Option 2</b>	\$793.8	1.35	7.7
<b>Option 3</b>	\$865.2	1.43	7.1

## **J. Regulatory Flexibility Analysis**

CDC considered the proposed regulation's effects on small entities, as required by the Regulatory Flexibility Act (RFA; 5 U.S.C. et seq.; Public Law 96-354) as 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 agency has prepared an Initial Regulatory Flexibility Analysis (IRFA). This analysis suggests that that this rule will not have a significant effect on a substantial number of small businesses, small organizations, or small governmental jurisdictions. However, CDC is asking for comment on the costs and impacts of the rule on small entities. As required by the RFA, in the final rule, CDC will provide the public comments it received in response to the proposal, prepare a Final Regulatory Flexibility Analysis (FRFA) and make a determination whether a certification of no significant impact on a substantial number of small entities is appropriate.

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

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

CDC, as discussed earlier, considered three options under two scenarios. The first option requires information to be collected from passengers only for those arriving on international flights and cruise lines with international to domestic itineraries. Option 2 adds domestic flights from medium and large airports to Option 1, and Option 3 adds all domestic flights to Option 1. The two scenarios are the Point of Sale scenario, under which CDC assumes that the airlines will be able to gain access to data collected by

travel agencies and GDSs and will not have to collect data from passengers at the point of departure. In the second scenario, CDC assumes that the logistical and legal barriers to this information sharing are such that all information would need to be collected by the airlines at the point of departure (the Point of Departure scenario).

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

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

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

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