

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Control of Communicable Diseases

Final Rule

RIN 0920-AA63

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Supplemental Analyses for the Regulatory Impact Analysis

HHS/CDC examined the impacts of the final rule under Executive Order 12866, Regulatory Planning and Review (58 FR 51735, October 4, 1993)¹ and Executive Order 13563, Improving Regulation and Regulatory Review, (76 FR 3821, January 21, 2011).² Both Executive Orders direct agencies to evaluate any rule prior to promulgation to determine the regulatory impact in terms of costs and benefits to United States populations and businesses. Further, together, the two Executive Orders set the following requirements: quantify costs and benefits where the new regulation creates a change in current practice; define qualitative costs and benefits; choose approaches that maximize net benefits including potential economic, environmental, public health and safety, and other advantages; support regulations that protect public health and safety; and minimize the adverse impact of regulation. Relative to a status quo baseline, the monetized annual benefits and costs of the final rule are less than \$1 million and therefore the final rule is not economically significant.

¹ Executive Order 12866 of September 30, 1993: Regulatory Planning and Review. Federal Register. Monday, October 4, 1993;58(190). <http://www.archives.gov/federal-register/executive-orders/pdf/12866.pdf>. Accessed January 2016.

² Executive Order 13563 of January 18, 2011: Improving Regulation and Regulatory Review. Federal Register. Friday, January 21, 2011; 76(14). <http://www.gpo.gov/fdsys/pkg/FR-2011-01-21/pdf/2011-1385.pdf>. Accessed January 2016.

However, there is some uncertainty about the appropriate analytic baseline, and relative to some possible baselines, the effects of the rule are non-negligible. For example, if in the absence of this rule, some aspects of future HHS/CDC screening or risk assessment activities are found to be legally impermissible, then the status quo baseline would not represent a reasonable approximation of the state of the world without the rule. Relative to a non-status quo baseline, the rule would lead to activities (e.g., the 2014-16 Ebola risk assessment and management program) that have both substantial costs and substantial benefits.

Where quantification is not possible (as is largely the case with the non-status quo baseline), a semi-quantitative/qualitative discussion is provided in this appendix of the costs and/or benefits that HHS/CDC anticipates from issuing these regulations.

The semi-quantitative and qualitative economic impact analysis of past activities is subdivided into three sections:

1. The costs and benefits associated with the 2014-2016 Ebola enhanced risk assessment and management program are used to illustrate the costs and benefits of implementation of some of these authorities, and are

especially relevant when analyzing the effects of the rule relative to a non-status quo baseline.

2. An analysis of the revisions to 42 CFR 70.13/71.30:

Payment for care and treatment, which are not expected to lead to a change in HHS/CDC policy under which HHS/CDC may act as the payer of last resort for individuals subject to medical examination, quarantine, isolation, and conditional release under Federal orders. The primary benefit of codification is increased transparency around HHS/CDC policies to assist in paying for treatment or transportation for individuals under Federal orders. The analysis for these provisions is an examination in potential transfer payments between HHS/CDC and healthcare facilities that provide treatment to individuals under Federal orders or to other payers.

3. An analysis of 42 CFR 71.63: Suspension of entry of animals, articles, or things from designated foreign countries and places into the United States. In this final rule, HHS/CDC is explaining its existing regulatory authority. HHS/CDC cannot predict how often such authority may be used in the future or for what purpose. HHS/CDC previously exercised this authority on June 11, 2003, when under 42 CFR 71.32(b), HHS/CDC

implemented an immediate embargo on the importation of all rodents from Africa (order Rodentia).³ A simple economic impact analysis of this embargo is performed to demonstrate the costs and benefits of one example, but HHS/CDC does not anticipate an increase in frequency of such actions based on the provisions included in this final rule. The primary purpose of the analysis is to demonstrate potential costs and benefits using a realistic example.

1. The 2014-2016 Ebola Outbreak

The costs and benefits from the 2014-2016 Ebola enhanced entry risk assessment and management program are used to demonstrate the costs and benefits of implementation of its regulatory authorities, and are especially relevant when analyzing the effects of the rule relative to a non-status quo baseline. Although most of the costs incurred by HHS/CDC, DHS/CBP, and travelers can be quantified, the benefits are more difficult to quantify. HHS/CDC did not issue any Ebola-related Federal orders during the 2014-2016 Ebola epidemic, although it did

³ Federal Register 62353 Vol. 68, No. 213 Tuesday, November 4, 2003. P. 62353-69.

establish a port of entry risk assessment program. This program is chosen because of its significant economic impacts. For this outbreak analysis, a less restrictive alternative would be for HHS/CDC not to execute its existing regulatory authorities to implement the Ebola enhanced entry risk assessment and management program. The more restrictive alternative would be a suspension of entry for persons from countries with widespread transmission for a period of 21 days (equivalent to the maximum expected incubation period for Ebola disease).

The quantified cost of the Ebola enhanced entry risk assessment and management program (\$109 million) outweighs what HHS/CDC estimates as directly associated-benefits (\$7.7 million), but there are multiple benefits that HHS/CDC could not estimate. Around the time the program was implemented, public opinion surveys ranked Ebola as the third highest health care concern among a list of issues facing the country, only health care costs and access to care ranked higher. The same poll found that about 45% were either somewhat worried or very worried that they or someone in their family could become sick with Ebola. The Ebola enhanced entry risk assessment and management program in combination with a number of other Federally-funded initiatives helped reduce the potential risk for Ebola

exposure in the United States from travelers from the affected countries to almost zero.⁴ The average cost per U.S. citizen for these programs was approximately \$17. Thus, if willingness to pay for such a risk reduction was greater than \$17 per person on average, the programs would pass a cost-benefit test. HHS/CDC emphasizes that this \$17 per person amount represents all Federal spending on Ebola, both domestic and international. HHS/CDC was not able to conduct a survey to estimate such willingness to pay from the American public. HHS/CDC solicited public comment on willingness to pay when it published the NPRM preceding this final rule. A small number of individuals and one non-profit research organization for health security provided public comments during the comment period for the NPRM indicating that the risk of infection for an individual U.S. citizen would have been very small even if HHS/CDC and local health departments had not attempted to identify all travelers arriving from countries with widespread Ebola transmission and monitor such travelers for 21 days. Because of this very low risk, the commenters indicated that willingness to pay should be low. Finally HHS/CDC examined the economic impact of the recent MERS outbreak in

⁴ SteelFisher GK, Blendon RJ, Lasala-Blanco N. Ebola in the United States – Public Reactions and Implications. N Eng J Med. 2015;373:789-91.

South Korea and asks the question, what would be the cost to the United States if an outbreak of similar magnitude occurred. HHS/CDC estimates the cost of such an outbreak could be as much as \$41 billion indicating the potential costs associated with unexpected outbreaks of quarantinable communicable diseases. This large estimate demonstrates the significant cost of outbreaks of quarantinable communicable diseases such as Ebola and MERS even when the number of cases and deaths are relatively small.

In late 2014, two imported cases of Ebola were identified in the United States, one of which resulted in two additional domestic cases and extensive contact investigations in the community and for travelers on two domestic flights.^{5,6,7,8}

Around the same time, some political leaders and members of the public demanded increasing the domestic response, including banning air travel between the United

⁵ Chevalier MS, Chung W, Smith J, et al. Ebola virus disease cluster in the United States—Dallas County, Texas, 2014. MMWR Morb Mortal Wkly Rep 2014;63:1087-8.

⁶ McCarty CL, Basler C, Karwowski M, et al. Response to importation of a case of Ebola virus disease—Ohio, October 2014. MMWR Morb Mortal Wkly Rep 2014;63:1089-91.

⁷ Regan JJ, Jungerman R, Montiel SH, et al. Public health response to commercial airline travel of a person with Ebola virus infection—United States, 2014. MMWR Morb Mortal Wkly Rep 2015;64:63-6.

⁸ Yacisin K, Balter S, Fine A, et al. Ebola virus disease in a humanitarian aid worker—New York City, October 2014. MMWR Morb Mortal Wkly Rep 2015;64:321-3.

States and the three countries with widespread transmission.⁹ Many public health professionals cautioned that such a ban would cause greater harm than good to the public health response by hampering travel of responders and delivery of supplies into the region and paradoxically could increase the risk for spread via covert and circuitous travel routes.^{10,11} The paradox results because travel restrictions cannot stop people from moving across borders and spreading disease to new countries, especially because such travel is often more difficult to track than if travel is not restricted entirely.¹²

To reduce the risk of importation of Ebola to the United States, HHS/CDC supported the implementation of exit screening at international airports in countries with widespread Ebola transmission. After Ebola spread from

⁹ McAuliff M. Lawmakers ignore experts, push for Ebola travel ban. The Huffington Post. October 16, 2014.

http://www.huffingtonpost.com/2014/10/16/congress-ebola_n_5997214.html
⁹. Nuzzo JB, Cicero AJ, Waldhorn R, Inglesby TV. Travel bans will increase the damage wrought by Ebola. Biosecur Bioterror 2014;12:306-9. <http://dx.doi.org/10.1089/bsp.2014.1030>

¹⁰ Nuzzo JB, Cicero AJ, Waldhorn R, Inglesby TV. Travel bans will increase the damage wrought by Ebola. Biosecur Bioterror 2014;12:306-9. <http://dx.doi.org/10.1089/bsp.2014.1030>

¹¹ Poletto C, Gomes MF, Pastore y Piontti A, et al. Assessing the impact of travel restrictions on international spread of the 2014 West African Ebola epidemic. Euro Surveill 2014;19:pii 20936. <http://dx.doi.org/10.2807/1560-7917.ES2014.19.42.20936>

¹² Frieden T. CDC Chief: Why I don't support a travel ban to combat Ebola outbreak (2014) <http://www.foxnews.com/opinion/2014/10/09/cdc-chief-why-dont-support-travel-ban-to-combat-ebola-outbreak.html>
Accessed 6/9/2015

Liberia to Nigeria by air travel, concerned airlines canceled flights to Guinea, Liberia, and Sierra Leone, and multiple countries closed their borders to travelers from these countries;¹³ the shortage of commercial flights caused delays to the provision of humanitarian aid, resulting in shortages of medical supplies, personal protective equipment, and food.¹⁴ The few airlines that continued to fly to the countries with Ebola outbreaks insisted that departing travelers be screened before boarding.¹⁵ HHS/CDC Border Health teams in Guinea, Liberia, Nigeria, and Sierra Leone, and later Mali and Senegal, helped airport and health authorities implement airport exit screening measures that included administering an exposure-and-symptom questionnaire and at least one temperature check with a handheld noncontact thermometer to all departing passengers. Health screeners were trained to conduct secondary assessments of travelers who reported possible exposures or who had symptoms compatible with Ebola.

¹³ Anderson M. Ebola: airlines cancel more flights to affected countries. The Guardian. August 22, 2014. <http://www.theguardian.com/society/2014/aug/22/ebola-airlines-cancel-flights-guinea-liberia-sierra-leone>. Accessed 6/9/2016

¹⁴ Balen B. Ebola supplies sit as airlines cancel flights to countries with infection. The Guardian. September 8, 2014. <http://guardianlv.com/2014/09/ebola-supplies-sit-as-airlines-cancel-flights-to-countries-with-infection/>. Accessed 6/9/3026

¹⁵ Anderson M. Ebola: airlines cancel more flights to affected countries. The Guardian. August 22, 2014. <http://www.theguardian.com/society/2014/aug/22/ebola-airlines-cancel-flights-guinea-liberia-sierra-leone>. Accessed 6/9/2016.

Symptomatic or exposed travelers were denied boarding and referred for further medical and public health assessment. As national databases of known contacts became more robust, they were matched against passenger manifests for departing flights. These measures helped countries with Ebola outbreaks meet WHO recommendations and ensured that some commercial air carriers continued to fly to these countries, serving as vital conduits for supplies and response personnel.

During August 2014–January 2016, approximately 300,000 travelers were screened in Guinea, Liberia, and Sierra Leone. Only four cases of Ebola were exported through air travel to other countries (United States [two cases], United Kingdom [one case], Italy [one case]) after exit screening was implemented; none of the infected travelers were overtly symptomatic at the time of travel.^{16,17,18,19} No Ebola cases were reported to have been detected during exit screening.

¹⁶ Chevalier MS, Chung W, Smith J, et al. Ebola virus disease cluster in the United States–Dallas County, Texas, 2014. *MMWR Morb Mortal Wkly Rep* 2014;63:1087–8.

¹⁷ Yacisin K, Balter S, Fine A, et al. Ebola virus disease in a humanitarian aid worker–New York City, October 2014. *MMWR Morb Mortal Wkly Rep* 2015;64:321–3

¹⁸ Gulland A. Second Ebola patient is treated in UK. *BMJ* 2014;349:g7861. <http://dx.doi.org/10.1136/bmj.g7861> PubMed

¹⁹ World Health Organization. Ebola virus disease–Italy. *Disease Outbreak News*, May 13, 2015. <http://www.who.int/csr/don/13-may-2015-ebola/en/>

To build on the exit screening already in place, HHS/CDC collaborated with the U.S. Department of Homeland Security to initiate an enhanced entry risk assessment and management program for travelers from countries with Ebola outbreaks. This unprecedented operation required coordination across multiple U.S. government agencies, as well as with airport authorities and health departments in all U.S. States and territories.²⁰

HHS/CDC issued revised interim guidance in October 2014²¹ after the first imported case of Ebola in the United States was identified (and initially diagnosed as presumed sinusitis) in Dallas, Texas;²² an infected U.S. health care worker (HCW) flew on two domestic commercial flights, causing panic among U.S. travelers and disrupting the

²⁰ Brown CM, Aranas AE, Benenson GA, et al. Airport exit and entry screening for Ebola—August–November 10, 2014. *MMWR Morb Mortal Wkly Rep* 2014;63:1163–7

²¹ CDC. Notes on the interim U.S. guidance for monitoring and movement of persons with potential Ebola virus exposure. February 19, 2016. <http://www.cdc.gov/vhf/ebola/exposure/monitoring-and-movement-of-persons-with-exposure.html>

²² Chevalier MS, Chung W, Smith J, et al. Ebola virus disease cluster in the United States—Dallas County, Texas, 2014. *MMWR Morb Mortal Wkly Rep* 2014;63:1087–8

travel industry;^{23,24,25} and an infected humanitarian aid worker was reported to have been in public areas, including the New York City subway, during the early stages of his illness.^{26,27} HHS/CDC's guidance was revised in response to assertions that self-monitoring was insufficient; growing concerns about infected HCWs in Spain, the United States, and the West African countries with widespread Ebola transmission;^{28,29,30,31} and renewed calls for travel bans.³² Demands to restrict movement of HCWs caring for patients

²³ Regan JJ, Jungerman R, Montiel SH, et al. Public health response to commercial airline travel of a person with Ebola virus infection—United States, 2014. *MMWR Morb Mortal Wkly Rep* 2015;64:63–6.

²⁴ Bever L. Chain reaction: concern about Ebola nurse's flight prompts school closings in two states. *The Washington Post*. October 16, 2014. <https://www.washingtonpost.com/news/morning-mix/wp/2014/10/16/after-concern-about-ebola-patients-flight-schools-close-in-two-cities/>

²⁵ Mejia P. Planes, automobiles and cruise ships: vehicles for Ebola panic. *Newsweek*. October 17, 2014. <http://www.newsweek.com/planes-automobiles-and-cruise-ships-vehicles-ebola-panic-278206>

²⁶ Yacisin K, Balter S, Fine A, et al. Ebola virus disease in a humanitarian aid worker—New York City, October 2014. *MMWR Morb Mortal Wkly Rep* 2015;64:321–3

²⁷ Spencer C. Having and fighting Ebola—public health lessons from a clinician turned patient. *N Engl J Med* 2015;372:1089–91. <http://dx.doi.org/10.1056/NEJMp1501355>

²⁸ Chevalier MS, Chung W, Smith J, et al. Ebola virus disease cluster in the United States—Dallas County, Texas, 2014. *MMWR Morb Mortal Wkly Rep* 2014;63:1087–8

²⁹ Yacisin K, Balter S, Fine A, et al. Ebola virus disease in a humanitarian aid worker—New York City, October 2014. *MMWR Morb Mortal Wkly Rep* 2015;64:321–3

³⁰ Forrester JD, Hunter JC, Pillai SK, et al. Cluster of Ebola cases among Liberian and U.S. health care workers in an Ebola treatment unit and adjacent hospital—Liberia, 2014. *MMWR Morb Mortal Wkly Rep* 2014;63:925–9. PubMed

³¹ Matanock A, Arwady MA, Ayscue P, et al. Ebola virus disease cases among health care workers not working in Ebola treatment units—Liberia, June–August, 2014. *MMWR Morb Mortal Wkly Rep* 2014;63:1077–81

³² McAuliff M. Lawmakers ignore experts, push for Ebola travel ban. *The Huffington Post*. October 16, 2014. http://www.huffingtonpost.com/2014/10/16/congress-ebola_n_5997214.html

with Ebola were countered by predictions that stringent restrictions would discourage HCWs from supporting the response in West Africa or taking care of patients with Ebola at designated facilities in the United States.^{33,34} The revised guidance recommended that State or local public health authorities assume responsibility for monitoring all potentially exposed persons for the duration of the 21-day incubation period (active monitoring); established a higher standard of monitoring (direct active monitoring that included daily direct observation by public health officials) for persons with greater potential risk for exposure, including HCWs; and provided guidance for possible application of movement restrictions within communities. Although HHS/CDC's guidance represented a minimum standard, States could, and in many cases did, apply more restrictive measures (e.g., temporarily quarantining HCWs returning from West Africa).³⁵ Many of

³³ Infectious Diseases Society of America. IDSA statement on involuntary quarantine of healthcare workers returning from Ebola-affected countries. http://www.idsociety.org/2014_ebola_quarantine/

³⁴ Devaney T. Fauci calls Ebola quarantines "draconian." The Hill. October 26, 2014. <http://thehill.com/policy/healthcare/221890-top-nih-officials-calls-quarantines-draconian>

³⁵ American Civil Liberties Union; Yale Global Health Justice Partnership. Fear, politics, and Ebola: how quarantines hurt the fight against Ebola and violate the Constitution. December 2015. https://www.aclu.org/sites/default/files/field_document/aclu-ebolareport.pdf

these measures were put in place before HHS/CDC issued the updated guidance.

Objectives of the Enhanced Entry Risk Assessment Process

Enhanced entry risk assessment had three main objectives:

- To identify travelers who may have been exposed to Ebola, or be sick when they arrive in the United States,
- To ensure that these travelers were directed to appropriate care and monitoring, if needed, which would also help protect the health of all Americans, and
- To educate travelers and provide tools to help them monitor themselves for symptoms, and report to the local or State health department at their domestic destination(s) for active monitoring and health care if they developed symptoms.

Beginning October 2014, all travelers from Guinea, Sierra Leone and Liberia were required to undergo risk assessment for Ebola. Enhanced entry risk assessment was discontinued for countries after widespread transmission of Ebola had been halted. The last travelers from Guinea were screened in February 2016. Enhanced entry risk assessment

at U.S. airports included processes (referred to operationally as "primary screening") to identify travelers from countries with Ebola outbreaks, either through scheduled flight itineraries or during customs and immigration inspections. CBP officers and other U.S. Department of Homeland Security staff or contractors collected contact and locating information, administered an exposure-and-symptom questionnaire, checked travelers' temperatures with noncontact thermometers, and observed travelers for signs of illness. Data were entered electronically through an online interface and transmitted securely to an HHS/CDC database and then to States. These processes were collectively referred to as "secondary screening." Travelers who were symptomatic or who reported possible exposures were referred to HHS/CDC for an in-depth public health risk assessment (referred to as "tertiary screening"). Symptomatic travelers who met predefined criteria were referred for medical evaluation to designated assessment hospitals, in consultation with the health department with jurisdiction for the airport. Travelers with certain types of higher risk exposures were not permitted to travel further by commercial transport even if they were not symptomatic.

HHS/CDC developed a new intervention called the CARE (Check and Report Ebola) Program to supplement the Ebola entry risk assessment process. Airport-located CARE 'Ambassadors' that connected with travelers were trained health educators, counselors, or social workers. Each traveler arriving from West Africa was counseled by a CARE Ambassador and received a CARE Kit that included educational materials, a digital thermometer, and a pre-paid cell phone to help with daily reporting to State or local health departments. The program was designed to reduce the burden on State and local health departments by risk stratifying travelers and providing travelers an overview of what to expect during active monitoring and a phone to communicate with health departments. The program was also designed to try to minimize traveler and industry disruptions (i.e. missed flight connections) at the five airports. As a result, the program was more expensive per traveler screened compared to some more limited programs set up in other countries to identify travelers with possible SARS infections during the 2003 SARS epidemic.³⁶

³⁶ St. John, R. K., A. King, D. de Jong, M. Bodie-Collins, S. G. Squires and T. W. S. Tam (2005). "Border Screening for SARS." *Emerging Infectious Diseases* 11(1): 6-10.

Analysis of the costs of Ebola enhanced entry risk
assessment and management program

Every public health emergency is different, but HHS/CDC is confident that had the agency been able to answer 'who, where and how,' the government expenditures on Ebola entry risk assessment program would have been lower. In the absence of such data, HHS/CDC had to implement an expensive program in part just to help identify the small number of people within the United States that had been in countries with widespread Ebola transmission within the previous 21 days.

While some HHS/CDC and CBP personnel would still undoubtedly have been assigned to airports, some costs associated with travel time, training, and airport Ebola response work may have been avoided with the availability of better traveler contact data. More specifically, some examples cutting back on the domestic response might include:

- Reduction in travel of HHS/CDC employees assigned to airports. Each reassigned employee receives airfare, hotel, and per diem for incidentals such as meals.

- Reduction in overtime. Initially, staff at airports universally worked seven days a week, 12 to 16 hours a day, for 30 days at a time. At HHS/CDC headquarters, the Emergency Operations Center had persons answering calls 24-7, and many others working seven days to make travel arrangements, provide supplies, and answer press or congressional inquiries. Middle- and upper-level managers in more than one HHS/CDC center and division, as well as the HHS/CDC Director and staff, were on call 24-7.
- Reduction in supplies. The people reporting to airports needed personal protective gear, cellphones, laptops, and phones. At different points in time during the response, some airports needed to supply special contractors to remove used protective gear.

During the past fifteen years there have been several international disease events where this type of risk assessment was either considered by HHS/CDC or suggested by other branches of Federal government, e.g., SARS, MERS, and multiple novel influenzas. However, this was the first instance in which such a program was implemented.

First this section estimates the time-costs or opportunity costs to travelers from West Africa to comply with protocols at the ports of entry. Then HHS/CDC provides estimates of the budgetary costs to HHS/CDC and CBP for standing up the Ebola entry risk assessment program.

Screened-Traveler Opportunity and Out-of-Pocket Costs

The actual number of travelers who underwent the risk assessment program at airports between October 11, 2014 and February 18, 2016 is summarized in Table 1. These numbers were tabulated using electronic records kept by HHS/CDC of the number of travelers from West Africa who were screened at U.S. airports.

Using the numbers of travelers screened, HHS/CDC estimates the opportunity costs for travelers. To represent the time involved in waiting for, and complying with, risk assessment for travelers, HHS/CDC assumes 30 minutes per traveler for secondary screening and an additional 30 minutes for travelers that had to undergo tertiary screening. Primary screening time was not included because all international travelers already interact with CBP in order to enter the United States.

Hospital evaluations would require an additional 24 hours. The cost to provide transportation to hospitals from airports and to conduct further evaluation was covered by travelers and/or their insurance providers or employers. Over the 16 month period of this program, a total of 29 travelers out of 38,344 screened (0.08%) were recommended to travel from the airport to a hospital for further testing. All travelers complied voluntarily and there was no need to issue a Federal order. HHS/CDC does not have any data to estimate the cost of transportation to and evaluation at hospitals. The cost to treat Ebola patients was reported to be about \$30,000 per day at the Nebraska Medical Center and about \$50,000 per day at the National Institutes of Health.³⁷ If the daily cost of evaluation is estimated to be similar to the cost of treating Ebola patients (i.e. \$30,000 - \$50,000 per day) and it is assumed that evaluation requires 24-48 hours, a lower bound cost estimate for evaluation would be $\$30,000/\text{day} \times 1 \text{ day} = \$30,000$ and an upper bound cost estimate can be calculated from $\$50,000/\text{day} \times 2 \text{ days} = \$100,000$. The midpoint cost estimate is \$65,000. For 29 patients at the midpoint cost

³⁷ Sun L.H. Cost to treat Ebola in the U.S.: \$1.16 million for 2 patients. Washington Post November 18, 2014 https://www.washingtonpost.com/news/post-nation/wp/2014/11/18/cost-to-treat-ebola-in-the-u-s-1-16-million-for-2-patients/?utm_term=.283370dc6c47 Accessed 6/10/2016

estimate, the total cost is 29 patients x \$65,000 per patient = \$1,885,000. HHS/CDC did not directly pay these hospitals for these evaluations. However, States received Federal assistance to establish hospitals as Ebola assessment or treatment centers during the period when risk assessments at airports identified travelers with symptoms consistent with Ebola, and travelers and others with potential exposure were being monitored in communities. Because these hospitals received direct or indirect Federal assistance to become Ebola assessment or treatment centers, it is possible that some of the marginal costs of isolating these individuals from other patients were not assessed to travelers or their insurance carriers, but rather covered by this Federal grant money.

During a one-year period from August 2013 through July 2014, approximately 90% of passengers from Liberia, Guinea, and Sierra Leone entered the United States at the five airports that CBP funneled all travelers identified as having recently traveled to, from, or through an affected country for Ebola risk assessment. Therefore, HHS/CDC assumes that 10% of travelers designated for risk assessment had to change travel plans to comply with the funneling restrictions. This re-routing likely resulted in increased time spent in transit and some unplanned out-of-

pocket expenditures for items such as rescheduled flights, layover delays or meals. In the absence of data to quantify these costs, HHS/CDC assumed that re-routing required an additional 6 hours of travel time and a \$100 increase in costs for each traveler redirected from their original destination. This would apply to 10% of 38,344 (3,834) travelers over an 18-month period.

Traveler opportunity costs are valued at \$23.23 per hour³⁸/ 60 minutes to arrive at an estimate of \$0.39 per minute using the 2015 U.S. average hourly wage reported by the Bureau of Labor Statistics. The total opportunity costs for travelers funneled to airports and participating in risk assessment is estimated to be \$744,834 and the total out-of-pocket cost is estimated at \$2.3 million (including the cost of evaluation at hospitals after referrals from airports. Thus, the total traveler cost is \$3,146,596 (Table 1).

Table 1. Traveler opportunity and out-of-pocket Cost Estimates for Ebola Risk Assessment (16 Months), 2015 USD						
	# Traveler ^a	Time per Traveler (min)	Time Cost per Traveler -hour ^b	Total opportunity cost	Traveler and hospital	Total

³⁸ Bureau of Labor Statistics May 2015 National Occupational Employment and Wage Estimates United States.
http://www.bls.gov/oes/current/oes_nat.htm Accessed 6/12/2016.

					expenditures ^c	
2nd ^d	38,344	30	\$23.23	\$445,366	\$0	\$445,366
3rd ^d	2,736	30	\$23.23	\$32,867	\$0	\$32,867
Hosp.	29	1,440	\$23.23	\$25,471	\$1,885,000	\$1,910,471
Funneled	3,834	360	\$23.23	\$374,453	\$383,440	\$757,893
Total	38,344	NA	NA	\$744,834	\$2,268,440	\$3,146,596
<p>^a All travelers identified from countries with widespread Ebola transmission</p> <p>^b Time cost is estimated by multiplying no. of minutes/60 by \$23.23 (average hourly wages according to the 2015 Occupation and Employment Survey)</p> <p>^c Assumed \$100 per travelers for 10% of travelers that are redirected (funneled) and \$65,000 per traveler evaluated at hospitals.</p> <p>^d Secondary and Tertiary Screening</p>						

Federal government spending for Ebola Entry Risk Assessment

Current and projected spending for initiation and compliance with Ebola entry risk assessment is about \$96M for HHS/CDC. All HHS/CDC funds have been either spent or are obligated in Fiscal Year (FY) 2016. CBP spending as of May 18, 2015 was \$4.9 M. If this level of spending is extrapolated to 16 months of steady State spending, CBP costs would be \$9.8 million. HHS/CDC does not have estimates of the costs to the other Federal or State

agencies or airlines for time spent working in conjunction with HHS/CDC staff to develop the domestic response to Ebola.

Although Federal government spending occurred over 16 months, the monies were allocated and obligated within a single calendar year. Thus, the spending amounts are not discounted, but rather are treated as a one-time spending event. The total cost (\$109 million) to the U.S. Federal government and to travelers is summarized in Table 2.

Table 2. U.S. Govt. and Traveler Cost Estimates for Ebola Risk Assessment (18 months), 2015 USD	
Budget/Cost Category	Event Cost
HHS/CDC Budget	\$96,026,532
CBP Budget	\$9,830,583
Passenger Opportunity and Out-of-Pocket Cost	\$3,146,596
Total 16 Months	\$109,003,711

Analysis of the Benefits of Ebola Enhanced entry risk assessment and management

The benefits of the Ebola enhanced entry risk assessment and management program are much more difficult to quantify than the costs. This program was part of more than \$5.4 billion spent on emergency Federal programs in

the United States and abroad to contain the Ebola epidemic in West Africa to minimize the risk to the U.S. public.

The potential benefits from the enhanced entry risk assessment and management program include:

- Reduced time to health care evaluation/isolation for cases
- Treatment at appropriate facilities leads to better outcomes, reduced transmission risk
- Quarantine of persons at high risk to prevent transmission
- Reduction in effort by State/local health departments to conduct active monitoring due to increased engagement/communication tools (CARE program)

For the Ebola enhanced entry risk assessment and management program to be effective, there were a number of other activities conducted in parallel. Health departments had to effectively implement active monitoring and quarantine restrictions to respond to travelers who may become ill during the 21-day period in which travelers from Ebola-affected countries could become ill. Available evidence suggests that all States conducted active monitoring at least as stringently as the guidelines circulated by HHS/CDC. In fact, analysis of publicly

available State guidelines determined that 17 States and the District of Columbia had policies that were more restrictive than HHS/CDC guidance, 35 States and territories had policies equivalent to HHS/CDC guidance, and no States or territories had guidance that was less restrictive than HHS/CDC guidance.³⁹ Travelers must comply with monitoring/quarantine and give accurate information during entry risk assessment. Treatment facilities must be able to appropriately evaluate and treat patients. Part of the Federal Ebola funding was used to identify and prepare hospitals to treat Ebola patients. Laboratory testing must be accessible, accurate, and timely to properly diagnose patients with communicable diseases not commonly seen in the United States.

The groups at greatest risk to contract Ebola, MERS, and SARS in non-endemic countries have been health care workers and patients in hospital settings.⁴⁰ This points to the importance of infection control processes at hospitals.

³⁹ Sunshine G, Pepin D, Cetron M, Penn M. State and Territorial Ebola Screening, Monitoring, and Movement Policy Statements – United States, August 31, 2015. Morbidity and Mortality Weekly Report (MMWR). 2015;64(40):1145-6.

⁴⁰ Weber DJ, William A. Rutala, William A. Fischer, Hajime Kanamori, Sickbert-Bennett EE. Emerging infectious diseases: Focus on infection control issues for novel coronaviruses (Severe Acute Respiratory Syndrome-CoV and Middle East Respiratory Syndrome-CoV), hemorrhagic fever viruses (Lassa and Ebola), and highly pathogenic avian influenza viruses, A(H5N1) and A(H7N9) American Journal of Infection Control. 2016;44(5):e91-e100.

However, the outcome from the first Ebola patient diagnosed with Ebola after arrival in the United States can be compared to the outcome of the second patient to demonstrate the utility of properly linking persons with potentially devastating communicable disease to treatment at a facility that has prepared to treat such patients. All of the other Ebola cases treated in the United States were diagnosed while the patients were in West Africa and are not included in this analysis.

The first index case of Ebola in the United States among a traveler exposed in West Africa was diagnosed in a foreign national at a hospital in Dallas, Texas. At the initial presentation, the hospital did not suspect Ebola and did not test the patient before releasing him back into the community. As the patient's health continued to deteriorate, he returned to the same hospital and was then diagnosed with Ebola. Fortunately, there was no transmission to others in the community during the time between the initial and follow-up visits. Two health care workers at the hospital contracted Ebola after caring for the index patient; one nurse flew on an interstate flight to and from Cleveland, Ohio. This single case led to 516 contacts who underwent active monitoring by health departments in six States. Among the 516 contacts, 147 were

health care workers all of whom were exposed at the first hospital. All 147 health care workers had voluntary movement restrictions and 30 underwent voluntary home quarantine.^{41,42} In addition, there were 101 persons exposed in the community and who were actively monitored in Texas and Ohio of which 41 had restricted movement and 9 underwent home quarantine.^{43,44,45} Finally, there were 274 travelers exposed during interstate travel and actively monitored in 6 States. Of these, 20 travelers had movement restrictions.⁴⁶ In Texas and Ohio, 7 schools were closed for one day, and 2 students were asked not to go to school for 21 days after being on same flight as the infected health care worker.⁴⁷

⁴¹ Chevalier MS, Chung W, Smith J, et al. Ebola virus disease cluster in the United States—Dallas County, Texas, 2014. *MMWR Morb Mortal Wkly Rep* 2014;63:1087-8.

⁴² McCarty CL, Basler C, Karwowski M, et al. Response to importation of a case of Ebola virus disease—Ohio, October 2014. *MMWR Morb Mortal Wkly Rep* 2014;63:1089-91.

⁴³ Chevalier MS, Chung W, Smith J, et al. Ebola virus disease cluster in the United States—Dallas County, Texas, 2014. *MMWR Morb Mortal Wkly Rep* 2014;63:1087-8

⁴⁴ Chung WM, Smith JC, Weil LM, Hughes SM, Joyner SN, Hall EM, et al. Active Tracing and Monitoring of Contacts Associated With the First Cluster of Ebola in the United States. *Ann Intern Med*. 2015;163:164-73.

⁴⁵ Chung WM, Smith JC, Weil LM, Hughes SM, Joyner SN, Hall EM, et al. Active Tracing and Monitoring of Contacts Associated With the First Cluster of Ebola in the United States. *Ann Intern Med*. 2015;163:164-73.

⁴⁶ Regan JJ, Jungerman R, Montiel SH, et al. Public health response to commercial airline travel of a person with Ebola virus infection—United States, 2014. *MMWR Morb Mortal Wkly Rep* 2015;64:63-6.

⁴⁷ Bever L. Chain reaction: concern about Ebola nurse's flight prompts school closings in two states. *The Washington Post*. October 16, 2014. <https://www.washingtonpost.com/news/morning-mix/wp/2014/10/16/after-concern-about-ebola-patients-flight-schools-close-in-two-cities/>

In contrast, the second incident case of Ebola among a traveler from West Africa in the United States occurred in New York City. However, the patient was a health care worker that volunteered in a treatment center in West Africa. Per HHS/CDC guidance, the patient had been self-monitoring his temperature and symptoms. The patient was quickly identified as at risk for Ebola and was transported to a hospital designated to be capable of accepting potential Ebola patients. This patient did not infect any healthcare workers and only 3 community contacts and zero health care workers had movement restrictions imposed.⁴⁸ There were no school closures in New York.

A comparison of estimated costs incurred for the first versus second incident cases of Ebola in the United States is presented in Tables 3 and 4. The opportunity costs for health care workers placed under movement restrictions are estimated based on average health care worker salary reported in the 2015 Occupational and Employment Statistics Survey (\$37.40 per hour, code 29-0000) assuming that each employee is unable to work for a period of 3 weeks (15 work days). The costs to public health departments are estimated based on the average salary of epidemiologists (\$36.97 per

⁴⁸ Yacisin K, Balter S, Fine A, et al. Ebola virus disease in a humanitarian aid worker—New York City, October 2014. MMWR Morb Mortal Wkly Rep 2015;64:321-3

hour, code 19-1041) assuming that 50 epidemiologists spent a total of 30 days working on investigations for the three cases originating in Dallas. An overhead multiplier of 100% is used to estimate employee benefits and overhead costs.

Persons placed under movement restrictions are usually not permitted to go to public areas such as grocery stores and pharmacies. In addition, homeless contacts may need to be provided with temporary housing to facilitate active monitoring.⁴⁹ Some States posted police officers at specific addresses at an estimated cost of \$1,000 per day.⁵⁰ The estimated average cost for the services required to monitor and sustain persons with restricted movement is estimated to be \$500 per person-day for 21 days. In addition, 7 one-day school closures were reported. HHS/CDC does not have any data on school sizes and assumes that the average school size is 300 students and that opportunity costs of a one-day school closure can be estimated based on a parent or guardian losing one half-day of work (4 hours) for every student. Parent and guardian opportunity costs are

⁴⁹ Smith CL, Hughes SM, Karwowski MP, Chevalier MS, Hall E, Joyner SN, et al. Addressing Needs of Contacts of Ebola Patients During an Investigation of an Ebola Cluster in the United States – Dallas, Texas, 2014. Morbidity and Mortality Weekly Report (MMWR). 2015;64(5).

⁵⁰ West, M.G. The high cost of quarantine The Wall Street Journal. October 29, 2014. <http://www.wsj.com/articles/the-high-cost-of-quarantine-and-who-pays-for-it-1414546114>. Accessed June 13, 2016.

estimated using the average wage rate in the United States (\$23.23 per hour).⁵¹ The cost to treat an Ebola patient has been reported to be about \$650,000⁵² at the Nebraska Medical Center and has been estimated to exceed \$1 million.⁵³ HHS/CDC estimates the treatment cost to be the midpoint of these estimates (\$825,000 per case). It is not clear if this estimate includes the cost of waste disposal associated with Ebola treatment. The cost of waste disposal has been estimated to be as much as \$100,000 per Ebola patient-day.⁵⁴ HHS/CDC assumes the cost of waste disposal is not included in the reported treatment costs and that waste disposal over a 10-20 period of treatment would add another \$1 million to the cost of treatment. This results in an average cost of treatment and waste disposal of \$1.825 million per patient.

Table 3. Costs Associated with First Incident Ebola Case in Texas and Ohio			
Category	Number	Cost	Notes

⁵¹ http://www.bls.gov/oes/current/oes_nat.htm

⁵² Sun L.H. Cost to treat Ebola in the U.S.: \$1.16 million for 2 patients. Washington Post November 18, 2014 https://www.washingtonpost.com/news/post-nation/wp/2014/11/18/cost-to-treat-ebola-in-the-u-s-1-16-million-for-2-patients/?utm_term=.283370dc6c47 Accessed 6/10/2016

⁵³ Worstall T. The Free Market Won't Produce An Ebola Cure; So Should Government Instead? Forbes: August 8, 2014. <http://www.forbes.com/sites/timworstall/2014/08/08/the-free-market-wont-produce-an-ebola-cure-so-should-government-instead/#f8f45d46cac5> Accessed June 13, 2016.

⁵⁴ LaMantia, J. Hospitals bleed money as they fight Ebola. Crain's New York Business. November 10, 2014. http://www.craigslist.com/article/20141110/HEALTH_CARE/141119994/hospitals-bleed-money-as-they-fight-ebola. Accessed June 14, 2016.

Health care workers missing work	147	\$659,736	Assume all persons with travel restriction missed time at work/productivity (21 days)
Community	41	\$114,292	
Air travelers	20	\$55,752	
Restricted movement support costs	208	\$2,184,000	Assume support costs for movement restrictions or home quarantine are \$500 per person-day for 21 days
Public health response	50 (assumed)	\$887,280	Assume 50 public health workers worked full time on response for 30 days
School closure	7	\$195,132	7 schools for 1 day, assume 300 students each and one parent lost one half day of productivity per student
Ebola treatment	3	\$5,475,000	Assume treatment cost = \$1,825,000 per patient
Total		\$9,571,192	

Table 4. Costs Associated with Second Incident Ebola Case in New York			
Category	Number	Cost	Notes
Health care workers missing work	0	\$0	Assume all persons with travel restriction missed time at work
Community	3	\$8,363	
Air travelers	0	\$0	

Restricted movement support costs	3	\$31,500	Assume support costs for movement restrictions or home quarantine are \$500 per person-day for 21 days
Public health response	5 (assumed)	\$62,832	Assume 5 public health workers worked full time on response for 21 days
School closure	0	\$0	
Ebola treatment	1	\$1,825,000	Assume treatment cost = \$1,825,000
Total		\$1,927,695	

The difference (\$7.7 million) in total estimated costs associated with the first incident case in a traveler from West Africa (\$9.6 million) and the second incident case (\$1.9 million) show the potential benefits associated with the Federal, State and local activities implemented to link patients to appropriate care to mitigate the transmission risk.

At the time the Ebola enhanced entry risk assessment and management program was put in place, HHS/CDC could not accurately estimate the expected number of travelers from West Africa that would become sick with Ebola after arrival

in the United States. In retrospect, efforts to contain the transmission of Ebola from countries with widespread transmission were very effective at limiting risk. Among all 300,000 travelers departing countries with widespread transmission via commercial airlines, only four Ebola cases were reported, none of which were symptomatic during travel. Although less than 20% of such travelers were destined for the United States, two of the four cases occurred in the United States.

Operationally, the U.S. enhanced entry risk assessment and management program succeeded as a mechanism to assess individual risk, educate travelers, and facilitate post-arrival management of travelers including active or direct active monitoring by public health authorities. Funneling of travelers from countries with Ebola outbreaks to selected airports rather than diverting airplanes was substantially less disruptive to the travel industry and to the FAA's operation of the air traffic control system. The ability to track and monitor travelers in any U.S. State or territory, including their movement among States, resulted in rapid identification and evaluation of approximately

1,400 symptomatic travelers, none of whom had Ebola diagnosed.⁵⁵

One unquantifiable potential benefit would be the ability for State health departments to rapidly identify individuals that had been in countries with widespread transmission in the previous 21 days. Due to HHS/CDC's efforts to collect all contact information at entry and transmitting such data to State health departments, the States could in turn develop a database to inform healthcare facilities whether or not any patients had been in an Ebola-affected country within the previous 21 days. In the absence of such a verification system, health care facilities may have delayed urgent health care by spending time trying to figure out if an ill person had been in an Ebola-affected country and whether special testing and isolation procedures would be necessary if a patient presented with symptoms consistent with Ebola, but travel history was unknown.

During the period when the incident cases were diagnosed in the United States, CDC observed a large increase in the number of clinical inquiries for children

⁵⁵ Cohen, N. J., C. M. Brown, F. Alvarado-Ramy, H. Bair-Brake, G. A. Benenson, T.-H. Chen, A. J. Demma, N. K. Holton, K. S. Kohl, A. W. Lee, D. McAdam, N. Pesik, S. Roohi, C. L. Smith, S. H. Waterman and M. S. Cetron (2016). "Travel and Border Health Measures to Prevent the International Spread of Ebola." MMWR (Supplement): 65(3);57-67.

with suspected Ebola. However, the vast majority did not have an epidemiological link. Most inquiries regarded children who traveled from an unaffected African country or who had contact with a person from an unaffected African country. After the introduction of the Ebola entry risk assessment program, the number of such inquiries declined precipitously⁵⁶, although it is not possible to determine how much of the impact was due to the risk assessment and active monitoring compared to the lack of incident cases in the United States and broad efforts to inform clinicians of Ebola risk characteristics.

Public Willingness to Pay for Ebola Prevention Measures

HHS/CDC was unable to conduct a willingness to pay survey to assess the U.S. public's willingness to expend Federal resources to minimize Ebola risks. However, survey evidence suggests that the public would probably be willing to pay some amount to reduce risk from Ebola to as close to zero as possible. Soon after Ebola was transmitted to two

⁵⁶ Goodman, A. B., E. Meites, E. H. Anstey, K. E. Fullerton, A. Jayatilleke, W. Ruben, E. Koumans, A. M. Oster, M. P. Karwowski, E. Dziuban, R. D. Kirkcaldy, M. Glover, L. Lowe, G. Peacock, B. Mahon and S. E. Griesse (2015). "Clinical Inquiries Received by CDC Regarding Suspected Ebola Virus Disease in Children – United States, July 9, 2014–January 4, 2015." Morbidity and Mortality Weekly Report (MMWR) 64(36): 1006-1010.

health care workers in the U.S., a poll showed that Americas felt Ebola was an urgent health problem for the entire country. Among a list of health care issues facing the country, only health care costs and access to care ranked higher than Ebola in the public's mind. In comparison, both heart disease and cancer were ranked below Ebola despite a significantly greater probability that any individual would suffer from these conditions than contract Ebola.⁵⁷

Public opinion related to disease outbreaks can influence policy leader attitudes related to the response of the outbreak - potentially redirecting the focus of activities and public funding to areas of limited public benefit. In a review of over 175 public opinion polls in 2014, researchers highlighted several reasons for this public perception.

Survey respondents did not understand or trust information provided regarding the mode of transmission and therefore they felt particularly vulnerable. About 45% were either somewhat worried or very worried that they or someone in their family could become sick with Ebola. The media also played a role in increasing the public's concern

⁵⁷ SteelFisher GK, Blendon RJ, Lasala-Blanco N. Ebola in the United States - Public Reactions and Implications. N Eng J Med. 2015;373:789-91.

- three major news networks aired approximately 1000 Ebola-related segments between mid-October to early November, 2014. According to the survey, public trust in scientists and government was at an all-time low.⁵⁸

Considering the U.S. population as a whole (319 million), an average willingness to pay per person of \$17 would be sufficient to justify the entire \$5.4 billion Federal Ebola response. This amount would cover the costs of Federal government activities to reduce Ebola transmission in affected countries, to support exit screening at international airports, research programs for Ebola vaccines and medicines, to implement domestic programs to identify and prepare U.S. hospitals and laboratories for Ebola testing and treatment, to implement the Ebola enhanced entry risk assessment and management program at U.S. airports, and to provide Federal support for active monitoring activities in U.S. States. The \$5.4 billion budget allocation included \$1.147 billion for domestic Ebola response activities (other than research and development) including the \$96 million for the Ebola enhanced entry risk assessment and management program. Thus, if international, research, and development

⁵⁸ SteelFisher GK, Blendon RJ, Lasala-Blanco N. Ebola in the United States – Public Reactions and Implications. N Eng J Med. 2015;373:789-91.

activities are excluded, U.S. public willingness to pay would have to be greater than \$3.65 per person for all domestic activities or \$0.34 for just the enhanced entry risk assessment and management program.

In the NPRM, HHS/CDC had solicited public comment on average willingness to pay to reduce Ebola risk in the United States to near zero if another international outbreak of Ebola with widespread transmission occurs in the future. HHS/CDC received comments from an organization representing flight attendants indicating that they believe it is in the public interest to reduce the Ebola risk in the United States to near zero in the event of a future outbreak and that there is no reason to believe that achieving this objective will require unsustainable levels of funding. HHS/CDC also received comments from several individuals regarding the high cost of the measures taken to reduce the risk of Ebola transmission in the United States during the 2014-2016 Ebola outbreak in West Africa. Several of these commenters indicated they had zero willingness to pay for future public health measures in the event of a large Ebola outbreak.

HHS/CDC believes that the risk of significant transmission of Ebola in the United States is low and that Federal, State, and local public health interventions reduced such risks to almost effectively zero. However, as discussed above, outbreaks of new diseases can lead to significant costs if disease-related anxiety leads to reduced productivity. Thanks in part to vigorous Federal responses to communicable disease threats, the United States has never experienced a time-limited introduction of a new communicable disease with significant transmission. This analysis would not apply to a communicable disease threat like the novel H1N1 influenza pandemic that would infect a significant number of U.S. citizen regardless of HHS/CDC efforts. However, other relatively high income countries have had to deal with very costly outbreaks of SARS and MERS.

The 2003 SARS outbreak was initiated in Guandong, China in late 2002 and led to the exportation of cases to multiple countries, including Australia, Canada, Hong Kong, Singapore and the United States. Significant transmission occurred in Hong Kong, Canada, and Singapore. The introduction of SARS led to reductions in the number of people traveling to these countries. Survey respondents indicated that they were less likely to engage in

activities such as eating at restaurants or going to shopping malls. Forecasted Gross Domestic Product (GDP) in 2003 decreased by 3.7 billion US dollars in Hong Kong, 3.2-6.4 billion US dollars in Canada, and 4.9 billion US dollars in Singapore due to the SARS outbreak.⁵⁹ In Canada and Singapore, GDP growth was estimated to decrease by 1% for the year 2003. In the second quarter of 2003, GDP growth in China and Hong Kong was estimated to have decreased by 3% and 4.75%, respectively.⁶⁰ The estimated losses to the tourism industry alone in Beijing, China was around 1.4 billion US dollars.⁶¹

The MERS outbreak in South Korea started with a case in an international traveler returning from the Middle East at the end of May 2015 and ended with the official announcement of the World Health Organization in December 2015. A total of 186 laboratory-confirmed infections, including 38 deaths, was reported, and more than 16,000 people kept in-house quarantine.⁶² This outbreak represents

⁵⁹ Keogh-Brown M.R. and Smith R.D., The economic impact of SARS: How does the reality match the predictions? Health Policy. 2008; 88: 110-120.

⁶⁰ Keogh-Brown M.R. and Smith R.D., The economic impact of SARS: How does the reality match the predictions? Health Policy. 2008; 88: 110-120.

⁶¹ Beutels P., Jia N, Zhou Q., et al., The economic impact of SARS in Beijing, China. Tropical Medicine and International Health, 2009, 12 Suppl 1: 85-91.

⁶² Korea Centers for Disease Control and Prevention. Middle East Respiratory Syndrome Coronavirus Outbreak in the Republic of Korea, 2015. Osong Public Health Research Perspective. 2015;6(4):269-78.

an infectious disease outbreak associated with international travel in a high income country. Since this outbreak recently occurred in 2015, it may provide a useful extrapolation of what might happen if HHS/CDC does not act swiftly to contain a quarantinable communicable disease threat.

HHS/CDC assumes an outbreak similar in magnitude to the Korean MERS outbreak is more likely to happen in the United States if HHS/CDC were to stop enforcing its quarantine and isolation authorities, stop conducting contact investigations among travelers exposed to quarantinable communicable diseases, and if it were unable to implement enhanced entry risk assessment and management programs if warranted by a quarantinable communicable disease outbreak in another country. HHS/CDC cannot quantify the change in risk to the United States that would result, but believes the Korean MERS outbreak is a useful example of the unpredictable course of quarantinable communicable disease outbreaks in the United States.

HHS/CDC estimates that all patients would be hospitalized resulting in treatment costs of around \$2.9 million inpatient based on 186 laboratory-confirmed infections and ten days of hospitalization per case. HHS/CDC assumes that the inpatient cost is \$1,542 per day

based on the costs of treating multidrug resistant tuberculosis in the United States (Table 5).⁶³

Table 5. Cost of hospitalization MERS Outbreak Example, 2015 USD			
Number of people who are infected (A) ^a	Daily Inpatient costs (B) ^b	Median duration of hospitalization (C) ^a	Cost of hospitalization (A x B x C)
186	\$1,542	10	\$2,868,843
^a Korea Centers for Disease Control and Prevention. Middle East Respiratory Syndrome Coronavirus Outbreak in the Republic of Korea, 2015. Osong Public Health Research Perspective. 2015;6(4):269-78. ^b Marks S.M., Flood J., Seaworth, B., et al. Treatment practices, outcomes, and costs of multidrug-resistant and extensively drug-resistant tuberculosis, United States, 2005-2007. Emerging Infectious Disease. 2014; 20(5):812-820.			

The costs associated with excess mortality of the outbreak are estimated at \$357.2 million based on the 38 reported MERS-associated deaths reported and a \$9.4 million estimate for the value of a value of statistical life. Using a range of \$4.3 million to \$14.2 million for the value of statistical life, the cost of MERS-associated deaths can be estimated at \$163 – \$540 million (Table 6).

⁶³ Marks S.M., Flood J., Seaworth, B., et al. Treatment practices, outcomes, and costs of multidrug-resistant and extensively drug-resistant tuberculosis, United States, 2005-2007. Emerging Infectious Disease. 2014; 20(5):812-820.

Table 6. Mortality cost, MERS Outbreak Example, 2015 USD				
	Best estimate	Lower bound	Upper bound	References
Number of deaths (A)	38	38	38	Korea CDC 2015 ^a
Value of statistical life (B)	\$9.4 million	\$4.3 million	\$14.20 million	Value of statistical life
Mortality cost (A x B)	\$357.2 million	\$163.4 million	\$539.6 million	N/A
^a Korea Centers for Disease Control and Prevention. Middle East Respiratory Syndrome Coronavirus Outbreak in the Republic of Korea, 2015. Osong Public Health Research Perspective. 2015;6(4):269-78.				

To arrest the progress of the Korean MERS outbreak as quickly as possible, at least 16,000 people underwent in-house quarantine in South Korea.⁶⁴ HHS/CDC assumes that State and local public health departments may implement

⁶⁴ Korea Centers for Disease Control and Prevention. Middle East Respiratory Syndrome Coronavirus Outbreak in the Republic of Korea, 2015. Osong Public Health Research Perspective. 2015;6(4):269-78.

similar measures if faced with a large outbreak of a newly-introduced quarantinable communicable disease in the United States. The South Korean government recommended 14 days of in-house quarantine based on the incubation period of MERS coronavirus and HHS/CDC assumes that State and local health departments in the United States would implement similar measures. The average wage reported in the Bureau of Labor Statistics, May 2015 Occupational Employment Statistics is \$23.23 per hour.⁶⁵ Assuming the productivity losses associated with in-home quarantine can be estimated based on the average hourly wage, HHS/CDC estimates the productivity losses at \$41.6 million (Table 7).

Table 7. Cost of quarantine, 2015 USD		
Description	N	Reference
Number of people who undergo house quarantine(A)	16,000	Korea CDC 2015 ^a
Number of days undergo house quarantine per person (B)	14	Korea CDC 2015 ^a
Working hours per day (C)	8	Assumption
Hourly labor cost (D)	\$23.23	Bureau of Labor Statistics ^b

⁶⁵ Bureau of Labor Statistics
(http://www.bls.gov/oes/current/oes_nat.htm).

Cost of quarantine (A x B x C x D)	\$41,628,320	N/A
^a Korea Centers for Disease Control and Prevention. Middle East Respiratory Syndrome Coronavirus Outbreak in the Republic of Korea, 2015. Osong Public Health Research Perspective. 2015;6(4):269-78. ^b Bureau of Labor Statistics (http://www.bls.gov/oes/current/oes_nat.htm)		

As of June 10th 2015, a reported 918,000 students, under 19 years of age, were affected by school closure due to the MERS outbreak in South Korea.⁶⁶ HHS/CDC cannot predict whether an outbreak with a magnitude similar to the MERS outbreak in South Korea would lead to significant school closures in the United States, but notes that school closures occurred in the United States after the initial Ebola cases in the United States were diagnosed.

During the 2009 H1N1 pandemic in the United States, HHS/CDC initially recommended dismissal of students for at least seven days⁶⁷ after the diagnosis of an H1N1 case in a student. Later, HHS/CDC revised the recommendation and school closing was no longer recommended.⁶⁸ For the H1N1

⁶⁶ Cho K.Y., Yoo J.S. Forecasting Economic loss associated with MERS outbreak in South Korea, 2015. KERI Insight. 15-20.

⁶⁷ Cauchemez S., Van Kerkhove M.D., Archer B.N. et al. School closures during the 2009 influenza pandemic: national and local experiences. BMC Infectious Disease. 2014; 14: 207.

⁶⁸ Cauchemez S., Van Kerkhove M.D., Archer B.N. et al. School closures during the 2009 influenza pandemic: national and local experiences. BMC Infectious Disease. 2014; 14: 207.

outbreak, around 17% of households reported lost work time because of school closure in New York City.⁶⁹ In the absence of better data, HHS/CDC assumes schools would be closed for an average of seven days and that each closed school day results in 0.17 missed workdays for a parent. HHS/CDC estimates the productivity loss of parents due to school closure at \$203 million (Table 8).

Table 8. Cost of school closure, 2015 USD		
Description	N	Reference
Number of students under 18 years old who were affected by school closure (A)	918,000	KERI Insight 2015 ^a
School closure days (B)	7	Assumption
Number of loss days of parents per children (C)	0.17	Borse et al. 2011 ^b
Working hours per day (D)	8	Assumption
Hourly labor cost (E)	\$23.23	Bureau of Labor Statistics ^c
Cost of quarantine (A x B x C x D x E)	\$203,015,033	N/A
^a Cho K.Y., Yoo J.S. Forecasting Economic loss associated with MERS outbreak in South Korea, 2015. KERI Insight. 15-20.		

⁶⁹ Borse H.R., Behraves C.B., Dumanovsky T. et al., Closing schools in response to the 2009 pandemic influenza A H1N1 virus in New York City: Economic impact on households. Clinical Infectious Disease: 2011; 52 (Supple 1) S168-S172.

^b Borse H.R., Behraves C.B., Dumanovsky T. et al., Closing schools in response to the 2009 pandemic influenza A H1N1 virus in New York City: Economic impact on households. *Clinical Infectious Disease*: 2011; 52 (Supple 1) S168-S172.

^c Bureau of Labor Statistics

(http://www.bls.gov/oes/current/oes_nat.htm)

In addition to the measurable impacts directly tied to the MERS outbreak. South Korea experience a significant decrease in the number of foreign travelers. The outbreak started in May 2015, but the biggest impacts were observed from June to August when the number of travelers decreased by 26.5% to 53.5% relative to 2014 (Table 9).⁷⁰ As the outbreak subsided, the number of travelers returned to previous trends. By September 2015, South Korea only received 10% fewer travelers compared to September 2014. HHS/CDC examined travel data to Dallas in October 2014 (corresponding to the time period in which three Ebola cases were reported), but found no significant difference relative to October 2013. This indicates that the Ebola cases in the United States were not as disruptive as the MERS outbreak cases in South Korea.

⁷⁰ Trends of foreign travelers, South Korean international travelers, tourism income, and tourism expenditure in December 2015, Korea Tourism Organization

Table 9: Number of foreign travelers who visited South Korea during the MERS outbreak (2014 versus 2015, 1,000 travelers) ⁷¹			
	2014	2015	Change
June	1,274	751	-41.0%
July	1,355	630	-53.5%
August	1,454	1,069	-26.5%

Given all of the above information, South Korean economic modelers attempted to estimate the impact of the MERS outbreak on South Korean GDP in 2015 and estimated that the MERS outbreak alone reduced GDP by 0.26%.⁷² If a similar size outbreak occurs in the United States and results in a 0.26% loss to GDP, the economic cost could be extrapolated to be $0.0026 \times \$17.95 \text{ trillion}^{73} = \41.3 billion.

⁷¹ Trends of foreign travelers, South Korean international travelers, tourism income, and tourism expenditure in December 2015, Korea Tourism Organization

⁷² Cho, K., Yoo, J., Forecasted economic losses due to MERS outbreak in South Korea, KERI Insight.

⁷³ U.S. Central Intelligence Agency. The World Factbook. United States Economy. <https://www.cia.gov/library/publications/the-world-factbook/geos/us.html>. Accessed June 13, 2016.

Summary Ebola Enhanced Entry Risk Assessment and Management Program

The above summary demonstrates the types of analyses that HHS/CDC would undergo when deciding to implement enhanced entry risk assessment and management programs in the future. HHS/CDC will weigh the costs of such programs, the public willingness to accept risks associated with incident cases of quarantinable communicable diseases, the ability of enhanced entry risk assessment and management programs to reduce such risks, and the economic costs of a significant outbreak of a newly-introduced quarantinable communicable disease in the United States. HHS/CDC cannot easily assess how the U.S. public will respond to communicable disease threats and how anxiety associated with communicable disease threats may impact the broader economy.

At the time the Ebola risk assessment program was implemented, HHS/CDC had already been supporting the implementation of exit screening in countries with widespread Ebola transmission for two months. HHS/CDC began support efforts after an ill traveler flew on a commercial flight and introduced Ebola to Nigeria in July 2014. The exit screening efforts in countries with widespread transmission may have resulted in a significant reduction

in the number of exported Ebola cases. Only four cases of Ebola (among approximately 300,000 travelers from August 2014) were exported by countries with widespread transmission after the implementation of exit screening and none of these Ebola patients were symptomatic during commercial travel. This can be compared to estimates of 2.8 infected travelers departing Liberia, Sierra Leone, and Guinea each month in the absence of an exit screening program.⁷⁴

The willingness and ability of affected countries to implement effective exit screening will also be considered by HHS/CDC when deciding whether to implement an enhanced entry risk assessment and management program in the future. It will always be a challenge to weigh the costs of public health interventions to the benefits of avoiding a large outbreak of a newly-introduced communicable disease. However, HHS/CDC intends to use available evidence such as that summarized above when making decisions.

More Restrictive Alternative: Suspension of Entry during Period West Africa Ebola Outbreak

⁷⁴ Bogoch II, Creatore MI, Cetron MS, Brownstein JS, Pesik N, Miniota J, et al. Assessment of the potential for international dissemination of Ebola virus via commercial air travel during the 2014 west African outbreak. Lancet. 2015;385:29-35.

The more restrictive alternative relative to the final rule would be for the United States to temporarily suspend the entry of travelers into the United States in the event of widespread transmission of quarantinable communicable diseases. A number of U.S. politicians advocated for this response to the 2014-16 Ebola outbreak in Liberia, Sierra Leone, and Guinea.⁷⁵ Some States actively discouraged persons from visiting their States including one example in which prospective participants at a large tropical medicine scientific conference were advised not to travel to a particular State to attend the conference if they had been in one of the countries with widespread transmission within the previous 21 days.⁷⁶ The costs and benefits of this alternative are difficult to weigh. Presumably, the estimated costs incurred to implement the Ebola enhanced entry risk assessment and management program would not have been incurred representing potential avoided costs of about \$109 million (Table 5). In addition, State and local health departments would not have incurred costs associated with active monitoring of individuals arriving from Ebola-affected countries for a period of 21 days. HHS/CDC does

⁷⁵ McAuliff M. Lawmakers ignore experts, push for Ebola travel ban. The Huffington Post. October 16, 2014.

http://www.huffingtonpost.com/2014/10/16/congress-ebola_n_5997214.html

⁷⁶ Olliaro P, Lasry E, Tiffany A. Out of (West) Africa—Who Lost in the End? Am J Trop Med Hyg 2015 Feb 4; 92(2): 242-243. 2015;92(2):242-3.

not have any data to estimate these costs, but the costs were probably at least twice the costs for HHS/CDC to implement the Ebola Enhanced entry risk assessment and management program. The costs of State-level active monitoring are estimated as a range from 2 to 4 times the cost of the Ebola enhanced entry risk assessment and management program. The benefits (\$327 to \$545 million) for the more restrictive alternative are summarized in Table 10.

Table 10. Benefits of More Restrictive Alternative (Suspension of Entry)			
	Best estimate	Lower bound	Upper bound
Ebola Enhanced entry risk assessment and management program	\$109,003,711	\$109,003,711	\$109,003,711
Avoided cost of State-level active monitoring	\$327,011,133	\$218,007,422	\$436,014,844
Total benefits	\$436,014,844	\$327,011,133	\$545,018,555

Effect on Ebola Risk in the United States

HHS/CDC cannot fully quantify the impact of a travel suspension on the risk of incident Ebola cases in the United States. Modeling studies suggest that travel

restrictions would likely have only delayed, but not prevented the spread of Ebola to new countries.⁷⁷

The implementation of travel suspensions would have delayed efforts to stop the outbreak in West Africa by requiring all U.S. volunteers as well as Federal employees to spend 21 days in a designated safe facility or other location outside the United States after working in countries with widespread Ebola transmission. This would surely have dis-incentivized participation in the response. In addition, HHS/CDC cannot predict whether other countries would have followed the U.S. lead in suspending travel. However, HHS/CDC believes that travel suspensions would have delayed outbreak response efforts and may have been more likely to lead to additional spread of Ebola especially to neighboring countries in Africa.

Under this alternative, traveler opportunity costs would be much greater because any travelers to countries with widespread Ebola transmission would no longer be allowed to enter the United States for a period of 21 days. If there is no decline in travelers, each traveler loses approximately 21 days of productivity as a result of the

⁷⁷ Poletto C, Gomes M, Pastore y Piontti A, Rossi L, Bioglio L, Chao D, et al. Assessing the impact of travel restrictions on international spread of the 2014 West African Ebola epidemic. *Euro Surveill.* 2014;19(42):pii: 20936

suspension, traveler opportunity costs can be estimated by
38,334 travelers x 8 hours per day x 21 days x \$23.23
(average U.S. wage rate) = \$150 million. These costs alone
could more than offset the cost of Ebola Enhanced entry
risk assessment and management program. The cost for those
travelers to spend an additional 21 days at a secure
location would probably be similar to the opportunity cost
estimate from above or more depending of operating a
designated safe facility or the cost of staying at another
location outside the United States.

However, this simplistic analysis probably does not
accurately reflect the implications of a travel suspension.
Suspension of entry would probably significantly reduce the
number of U.S. volunteers willing to travel to West Africa
to mitigate the Ebola outbreak closer to its sources. This
would delay the progress made in suppressing the outbreak
and increase risk of exportation to other countries.

HHS/CDC cannot predict how other countries may have
responded to the U.S. decision to suspend entry. If other
countries implemented similar restrictions, there may have
been a chain of reaction leading to a significant decrease
in the number of global volunteers to the most affected
countries. In this scenario, the 2014-16 Ebola outbreak in
West Africa would have almost certainly persisted for a

much longer period of time. HHS/CDC cannot estimate the long term impact for the affected countries, the West African region, or the costs to the U.S. government or its people.

While HHS/CDC is not able to estimate a dollar value of diminished trade in general, the estimated trade volumes prior to the outbreak are available and summarized in Table 11. The total annual value of trade for the three Ebola-affected countries in West Africa is \$574 million and ranges from \$125 million with Sierra Leone to \$270 million with Liberia.⁷⁸

Table 11. Summary of U.S. trade with Guinea, Liberia, Sierra Leone, and China ^a						
Country	Trading Partner Rank	Value US Exports to country	Description of US exports	Value of US imports to country	Description of US Imports	Total value imports + exports
Guinea	153	\$80M	Vehicles, machinery	\$99M	Metals and precious stones	\$179M

⁷⁸ <https://ustr.gov/countries-regions/africa/west-africa/liberia;>
<https://ustr.gov/countries-regions/africa/west-africa/guinea;>
<https://ustr.gov/countries-regions/africa/west-africa/sierra-leone>
 Accessed June 13, 2016

Liberia	142	\$173M	Machinery, iron/ steel, vehicles	\$97M	Rubber, salt/sulfur, precious stones	\$270M
Sierra Leone	162	\$83M	Machinery, vehicles, meat	\$42M	Ores, metals precious stones	\$125M
^a Data extracted from the U.S. Office of the Trade Representative ⁷⁹						

It is likely that U.S. economic losses would be much less than the numbers reported in Table 12 because U.S.-based importers and exporters would still be able to import or export some goods or services while the temporary travel delay remains in place. There may also be some substitution of countries by U.S. firms, for example if a particular good is made or grown in more than one country, U.S. firms might shift their purchasing away from one trade partner to the other. However, once purchasing is shifted there may be future difficulties once the suspension of entry is lifted if there are negative political consequences.

⁷⁹ <https://ustr.gov/countries-regions/africa/west-africa/liberia>;
<https://ustr.gov/countries-regions/africa/west-africa/guinea>;
<https://ustr.gov/countries-regions/africa/west-africa/sierra-leone>
 Accessed June 13, 2016

In the absence of data HHS/CDC assumes that the cost of lost trade for a one-year period can be estimated by a range of 0.1%, 1%, or 10% of lost trade (minimal to maximum, Table 12). Generally, the losses in the three countries with widespread Ebola transmission are estimated to range from about \$0.55 million to \$55 million.

Table 12. Hypothetical trade losses due to a travel delay				
Country	Total value imports + exports	Assumed financial losses to US stakeholders as % of total trade		
		10%	1%	0.10%
Guinea	\$179M	\$17.9M	\$1.79M	\$0.179M
Liberia	\$270M	\$27.0M	\$2.70M	\$0.270M
Sierra Leone	\$125M	\$12.5M	\$1.25M	\$0.125M
Subtotal	\$574M	\$57.4M	\$5.74M	\$0.547M

Table 13. Quantified costs of More Restrictive Alternative (Suspension of Entry)			
	Best estimate	Lower bound	Upper bound
Opportunity costs to travelers	\$149,643,000	\$74,821,500 ^a	\$149,643,000

Lodging costs for 21 days outside the United States or at a designated safe facility ^b	\$149,643,000	\$74,821,500	\$149,643,000
Trade costs	\$5,470,000	\$547,000	\$55,470,000
Total quantified costs	\$304,756,000	\$150,190,000	\$354,756,000
^a This lower bound assumes that half of the travelers decided not to go to West Africa ^b The estimated lodging costs are assumed to be similar in magnitude to the opportunity costs.			

Comparing the costs in Table 10 and benefits in Table 13, the most easily quantified benefits may be greater than the most easily quantified costs. However, given the potential other costs associated with prolonging the length of the Ebola outbreak in West Africa, the potential for other countries to implement travel restrictions after the United States, and the potential that delayed cessation of the Ebola outbreak could have led to serious political and economic outcomes in West Africa, HHS/CDC believes that the suspension of entry would have been a poor alternative to the implementation of the Ebola enhanced entry risk assessment and management program to reduce the risk of

Ebola transmission in the United States. Suspension of entry could enhance the United States future vulnerability to communicable disease threats if other countries would have observed this suspension of entry and tried to conceal communicable disease outbreaks within their borders. This potentially reduced ability to address future communicable disease threats in combination with the realization that only two Ebola cases associated with international commercial travel occurred in the United States under the status quo, HHS/CDC believes that implementation of travel suspensions will lead to more costs than benefits relative to the status quo. However, HHS/CDC cannot quantify all of the costs and benefits of travel suspensions. HHS/CDC received one comment from a flight attendants' union indicating support for suspensions of entry in the future for special circumstances. Specifically, the union believes future suspensions of entry may be warranted in the event of an outbreak of a highly transmissible, high mortality/morbidity disease with minimal treatment options, emanating from a small well-defined region or country. The union further suggests that the period of suspended entry would allow sufficient time for development of adequate response measures and training for affected personnel.

2. Payment for Care and Treatment (42 CFR 70.13/71.30)

The revisions to 42 CFR 70.13/71.30: Payment for Care and Treatment are not expected to lead to a change in HHS/CDC policy under which HHS/CDC may act as the payer of last resort for individuals subject to medical examination, quarantine, isolation, and conditional release under Federal orders. The primary benefit of codification is increased transparency around HHS/CDC policies to assist in paying for treatment for individuals under Federal orders.

The provisions included in the final rule are similar to a Memorandum of Agreement between a number of hospitals and HHS/CDC. Under the terms of the Memorandum of Agreement, the hospital can be reimbursed for incurred medical expenses subject to HHS/CDC's discretion, availability of appropriations, and limited to what a hospital would bill Medicare. The Memorandum of Agreement also indicates that HHS/CDC should be the payer of last resort.

HHS/CDC issued 12 isolation orders between Jan 1, 2005 and May 10, 2016, which would correspond to an average of about 1 order per year over the past 11.3 years. HHS/CDC has information on payments made for 3 of the 12 cases. In

most cases, HHS/CDC makes payment directly to healthcare facilities, sometimes in lieu of payments that would be made by State or local health departments. Among the three instances for which HHS/CDC has some data on payments for treatment, care, and transportation of individuals under Federal orders:

- In one case, HHS/CDC paid \$7,000 for a patient's care after splitting the cost with a local health department.
- In a second case, HHS/CDC paid over \$200,000 of the treatment costs.
- In a third case, HHS/CDC paid healthcare facilities directly for treatment and transport of an individual who had been paroled into the United States. In this situation, HHS/CDC paid approximately \$80,000 for this patient's transport and treatment.

We do not have sufficient data regarding payment for treatment for the 9 other individuals under Federal orders in the previous 11.3 years. HHS/CDC's expected annual payments for care and treatment are estimated to be between 0 and \$1,000,000 in any given year under the current baseline. This upper bound cost would correspond to a year in which HHS/CDC would have to incur the costs of two patients at \$500,000 per patient. This roughly corresponds

to the average cost to treat an extremely drug-resistant tuberculosis case (XDR-TB).⁸⁰ Alternatively, this could represent a situation in which HHS/CDC may have to pay a significant fraction of the total costs for one very complicated illness associated with a quarantinable communicable disease not endemic to the United States (e.g., Ebola).

To estimate the average annual payments for care and treatment by HHS/CDC, the average payment for the three cases with known payment information can be assumed to be incurred annually (corresponding to the average number of isolation orders that HHS/CDC issues each year). In this case, the average annual cost to the Federal government would be $(\$7,000 + \$80,000 + \$200,000)/3 \text{ years} = \sim \$96,000$ per year. If instead HHS/CDC assumes zero payments by HHS/CDC for the other nine cases for which it is unclear whether or not HHS/CDC paid any amount, the average annual cost would be $(\$7,000 + \$80,000 + \$200,000)/12 \text{ years} = \sim \$24,000$ per year. HHS/CDC can estimate with some certainty that the current annual average costs to the Federal government are probably somewhere in the range of \$24,000

⁸⁰Marks SM, Flood J, Seaworth B, Hirsch-Moverman Y, Armstrong L, Mase S, et al. Treatment Practices, Outcomes, and Costs of Multidrug-Resistant and Extensively Drug-Resistant Tuberculosis, United States, 2005–2007. *Emerging Infectious Diseases*. 2014;20(5):812–20.

to \$100,000 and not likely to exceed \$1,000,000 in any one year.

HHS/CDC has not incurred any costs for the care and treatment of any individuals besides for those under Federal isolation orders.

When HHS/CDC assumes responsibility to pay for treatment as the payer of last resort, another entity, typically a healthcare facility or State/local health department, would incur a benefit exactly equal to the amount of the HHS/CDC payment. This is referred to as a transfer payment, because from the perspective of the U.S. economy, there is zero net cost or benefit, simply a transfer from the Federal government to another entity.

The codification of 42 CFR 70.13 and 42 CFR 71.30 is not expected to change HHS/CDC's policy to continue to act as the payer of last resort. However, it may be possible that in the absence of codification, a precedent-setting event, such as a lawsuit, may occur in which HHS/CDC must take on additional responsibility to pay for the care and treatment of individuals under Federal orders. HHS/CDC's best estimate (and lower bound) of the impact of the changes to 42 CFR 70.13 and 42 CFR 71.30 is zero net cost or benefit to HHS/CDC or to healthcare facilities. The upper bound estimate corresponds to a 50% increase in

HHS/CDC's average cost estimate for payments for care and treatment ($50\% \times \$96,000 = \$48,000$). In this case, without the final rule, HHS/CDC could incur additional costs of up to \$48,000 per year. If HHS/CDC is incurring additional costs, healthcare facilities would receive a corresponding benefit in receiving payments from HHS/CDC. Thus, without the final rule, healthcare facilities may receive up to an average \$48,000 in additional payments from HHS/CDC for the care and treatment of individuals under Federal orders. Thus, with the final rule, an upper bound estimate of benefits to HHS/CDC would be \$48,000 from the implementation of the final rule. The corresponding upper bound estimate of costs to healthcare facilities associated with implementation of the final rule would be \$48,000. An extreme upper bound economic impact of the final rule for any one year would be a benefit to HHS/CDC of avoided payments equal to \$500,000 and a corresponding cost to healthcare facilities of \$500,000 representing losses associated with treatment costs incurred for one additional XDR-TB case⁸¹ (Table 14). XDR-TB is very expensive to treat, because it can take up to two years to resolve. This amount

⁸¹ Marks S.M., Flood J., Seaworth, B., et al. Treatment practices, outcomes, and costs of multidrug-resistant and extensively drug-resistant tuberculosis, United States, 2005-2007. *Emerging Infectious Disease*. 2014; 20(5):812-820.

would be similar to the cost to treat one Ebola case. The cost to treat an Ebola patient has been reported to be about \$650,000⁸² at the Nebraska Medical Center and has been estimated to exceed \$1 million⁸³ if the cost of Ebola waste disposal is not included. However, because of the severity of Ebola, it is unlikely than an Ebola patient would have to be placed under a Federal order to seek treatment. MERS or SARS are examples of other diseases for which it is possible that patients may be placed under Federal orders; however, the costs of treating these diseases are expected to be considerably less than for XDR-TB or Ebola.

Table 14. Estimated Costs and Benefits Associated with Changes to 42 CFR 70.13/71.30: Payment for Care and Treatment				
		Benefit to HHS/CDC resulting from final rule	Cost to U.S. individuals or healthcare facilities resulting	Net cost/ benefit

⁸² Sun L.H. Cost to treat Ebola in the U.S.: \$1.16 million for 2 patients. Washington Post November 18, 2014

⁸³ Worstall T. The Free Market Won't Produce An Ebola Cure; So Should Government Instead? Forbes: August 8, 2014.
<http://www.forbes.com/sites/timworstall/2014/08/08/the-free-market-wont-produce-an-ebola-cure-so-should-government-instead/#f8f45d46cac5>
 Accessed June 13, 2016.

			from final rule	
Final Rule	Best estimate	\$0	\$0	\$0
	Lower bound	\$0	\$0	\$0
	Upper bound	\$48,000	\$48,000	\$0
	Extreme upper bound	\$500,000	\$500,000	\$0
Less Restrictive Alternative (Cost estimate to pay for all Travelers sent to hospitals for evaluation during a potential enhanced entry risk assessment and management program)	Best estimate	(\$1,885,000)	\$1,885,000	\$0
	Lower bound	(\$471,250)	\$471,250	\$0
	Upper bound	(\$9,425,000)	\$9,425,000	\$0
More Restrictive Alternative	Best estimate	\$48,000	\$48,000	\$0

(HHS/CDC never pays for care or treatment for persons under Federal orders)	Lower bound	\$24,000	\$24,000	\$0
	Upper bound	\$96,000	\$96,000	\$0

HHS/CDC examines two alternatives to codification of its current policy that individuals under Federal orders will utilize third party resources first. Under the first, less restrictive alternative, HHS/CDC would pay for individuals to be tested at hospitals if referred from an enhanced entry risk assessment and management program at airports in the future (i.e. similar to the 2014-16 Ebola enhanced risk assessment program). Under the more restrictive alternative HHS/CDC would never offer to pay for treatment and care.

Besides the final rule analysis included in Table 14, the Federal burden to pay for care and treatment may have included persons sent to hospitals from airports for further evaluation during the Federal government's Ebola enhanced entry risk assessment and management program. Over the 16 month period of this program, a total of 29 travelers out of 38,344 screened (0.08%) were recommended

for transport from the airport to a hospital for further testing. All travelers complied voluntarily and Federal orders were not issued. HHS/CDC does not have any data to estimate the cost of transportation to and evaluation at hospitals. The cost to treat Ebola patients was reported to be about \$30,000 per day at the Nebraska Medical Center and about \$50,000 per day at the National Institutes of Health.⁸⁴ If the daily cost of evaluation is estimated to be similar to the cost of treating Ebola patients (i.e. \$30,000 - \$50,000 per day) and it is assumed that evaluation requires 24-48 hours, a lower bound cost estimate for evaluation would be $\$30,000/\text{day} \times 1 \text{ day} = \$30,000$ and an upper bound cost estimate could be calculated from $\$50,000/\text{day} \times 2 \text{ days} = \$100,000$. The midpoint cost estimate is \$65,000. For 29 patients at the midpoint cost estimate, the total cost is 29 patients x \$65,000 per patient = \$1,885,000.

States received Federal assistance to establish hospitals as Ebola assessment or treatment centers during the period when risk assessments at airports identified travelers with symptoms consistent with Ebola, and

⁸⁴ Sun L.H. Cost to treat Ebola in the U.S.: \$1.16 million for 2 patients. Washington Post November 18, 2014 https://www.washingtonpost.com/news/post-nation/wp/2014/11/18/cost-to-treat-ebola-in-the-u-s-1-16-million-for-2-patients/?utm_term=.283370dc6c47 Accessed 6/10/2016

travelers and others with potential exposure were being monitored in communities. Because these hospitals received direct or indirect Federal assistance to become Ebola assessment or treatment centers, it is possible that some of the marginal costs of isolating these individuals from other patients were not assessed to travelers or their insurance carriers, but rather covered by this Federal grant money.

For the less restrictive alternative, HHS/CDC assumes a best estimate that is the same as the expected cost for hospital follow-up as part of the 2014-16 Ebola enhanced risk assessment program. This is not an annual cost since HHS/CDC does not perceive that it is likely to implement enhanced risk assessment programs on an annual basis in the future. For the lower bound estimated cost in a one-year period if an enhanced risk assessment program is implemented, HHS/CDC assumes a cost equal to 25% of that estimated for the Ebola enhanced risk assessment program or \$471,250. For an upper bound estimate in any one year, HHS/CDC assumes that the program costs five times more than that estimate for the Ebola risk assessment program or \$9,425,000.

If HHS/CDC has to pay these costs, given its fixed budget, other HHS/CDC programs would have to receive less

funding. One example of a program that HHS/CDC supports is an overseas vaccination program for refugees. This program was recently introduced by the Division of Global Migration and Quarantine with assistance from interagency partners. Since vaccination is often compulsory for children to attend public schools, most refugee children would have to be vaccinated after arrival in the United States even if HHS/CDC is unable to support overseas vaccination. According to unpublished data, the cost to provide vaccines in countries from which refugees travel to the United States is much lower than the U.S. vaccination costs even using Medicaid reimbursement rates. The 2015 price of measles mumps and rubella vaccine available from UNICEF, who supplies most countries from which U.S.-bound refugees travel, is \$1.08 - \$3.25.⁸⁵ In comparison, the same vaccine costs \$19.90 when publicly procured in the United States.⁸⁶ HHS/CDC estimates that the cost of vaccine procurement and delivery for refugees is at least half as expensive overseas compared to domestic vaccination after arrival. In addition, U.S.-bound refugees tend to be at much greater risk of communicable diseases than other international

⁸⁵ <http://www.unicef.org/supply/files/MMR.pdf> accessed 6/15/2016

⁸⁶ http://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/price-list/2015/2015-07-01.html#modalIdString_CDCTable_0
Accessed 6/15/2016

travelers. One study found that the costs associated with a single case imported by a refugee was \$25,000.⁸⁷

At the same time, U.S. healthcare payers or State/local health departments would not have to incur the marginal costs that would be paid by HHS/CDC. This could lead to reduced out-of-pocket payments by those that need to be tested or treated and reduced payments for their health insurers. In some situations, costs may be covered as charitable care by treatment facilities if patients are unable to pay.

For the more restrictive alternative, HHS/CDC considers a scenario in which it would never have to pay for care and treatment. This would reduce HHS/CDC's current estimated payment of \$48,000 per year to zero and healthcare treatment facilities or health departments would like have to pay an equivalent amount. The lower bound is half of the estimate of current payments (\$24,000) and upper bound is double the average annual payments (\$96,000). The societal cost of this alternative is difficult to measure and would depend on whether treatment facilities would begin to refuse to admit patients subject to Federal orders, but not in dire need of treatment (e.g.,

⁸⁷ Coleman M, Garbat-Welch L, Burke H, Weinberg M, Humbaugh K, Tindall A, et al. Direct costs of a single case of refugee-imported measles in Kentucky. *Vaccine*. 2012;30(2):317-21.

an undocumented immigrant with infectious tuberculosis with non-life-threatening symptoms).

3. §71.63 Suspension of entry of animals, articles, or things from designated foreign countries and places into the United States

In this final rule, HHS/CDC is elucidating explaining its authority to temporarily suspend entry of animals, articles or things from designated foreign countries and places into the United States. HHS/CDC notes that animals can include dead animals that have not been rendered non-infectious. For example, an animal rendered non-infectious through taxidermy using approved processes could be imported. HHS/CDC cannot predict how often such authority may be used in the future or for what purpose. HHS/CDC exercised this authority on June 11, 2003, when under 42 CFR 71.32(b), HHS/CDC implemented an immediate embargo on the importation of all rodents from Africa (order Rodentia).⁸⁸ Simultaneously, but unrelated to provisions included in this final rule, the Director of CDC and the

⁸⁸ Federal Register 62353 Vol. 68, No. 213 Tuesday, November 4, 2003. P. 62353-69

Commissioner of Food and Drugs, under 42 CFR 70.2 and 21 CFR 1240.30 respectively, issued a joint order prohibiting, until further notice, the transportation or offering for transportation in interstate commerce, or the sale, offering for sale, or offering for any other type of commercial or public distribution, including release into the environment, of:

- Prairie dogs (Cynomys sp.);
- Tree squirrels (Heliosciurus sp.);
- Rope squirrels (Funisciurus sp.);
- Dormice (Graphiurus sp.);
- Gambian giant pouched rats (Cricetomys sp.);
- Brush-tailed porcupines (Atherurus sp.), and
- Striped mice (Hybomys sp.).⁸⁹

Both provisions were necessary to prevent transmission of monkeypox, a rare, zoonotic, viral disease that occurs primarily in the rain forest countries in Central and West Africa. (A zoonotic disease is a disease of animals that can be transmitted to humans under natural conditions.) The illness was first noted in monkeys in 1958, but, in Africa, serologic evidence of monkeypox infection has been found in many other species, including some species of primates,

⁸⁹ Federal Register 62353 Vol. 68, No. 213 Tuesday, November 4, 2003. P. 62353-69

rodents, and lagomorphs (which includes such animals as rabbits). African rodents are considered to be the most likely natural host of the monkeypox virus.⁹⁰

The temporary ban was later codified as a permanent restriction on importation of African rodents and other animals that may carry the monkeypox virus with an exception, which allows importation for scientific, exhibition, or educational purposes if a written request for such importation is approved by CDC (existing 42 CFR 71.56). This suspension of import was codified in an interim final rule published on November 4, 2003.⁹¹

Since the African rodent embargo in 2003, HHS/CDC has implemented only one other embargo. On January 13, 2004, the Department of Health and Human Services (HHS) announced an immediate embargo on the importation of civets (Family: Viverridae) to the United States. At the time, civets had been identified as a possible link to SARS transmission in China.⁹²

⁹⁰ Khodakevich, L., Jezek, Z. and Messinger, D., ``Monkeypox Virus: Ecology and Public Health Significance,`` Bulletin of the World Health Organization, 66: 747-752, 1988. This reference identifies several species of squirrels as playing a major role as a reservoir for the monkeypox virus and Federal Register 62353 Vol. 68, No. 213 Tuesday, November 4, 2003. P. 62353-69

⁹¹ Federal Register 62353 Vol. 68, No. 213 Tuesday, November 4, 2003. P. 62353-69

⁹² <http://www.cdc.gov/sars/media/civet-ban.pdf> Accessed on 10/28/2016.

HHS/CDC does not have any data on the number of illegal imports of African rodents or civets during the time the temporary embargos have been in place and no way to quantify the impact of codification of this authority. The African rodent embargo predated the implementation of HHS/CDC's Quarantine Activity Reporting System, which is used to document its activities. For civets, HHS/CDC has data on four attempted importations for the period from October 13, 2005 through June 10, 2016. Among the four attempted importations, three were allowed to enter the United States with a special permit for science, education or exhibition. The fourth shipment was for commercial purposes. This shipment was denied entry and the animals were returned to the source country. The importer was aware of the civet embargo, but did not realize the animals in question were part of the same family (Viverridae) that are prohibited.

The temporary embargo on African rodents implemented on June 11, 2003 provides an example of how HHS/CDC has used existing regulatory authority under 42 CFR 71.32(b), which states that "Whenever the (CDC) Director has reason to believe that any arriving carrier or article or thing on board the carrier is or may be infected or contaminated with a communicable disease, he/she may require detention,

disinfection, disinfection, fumigation, or other related measures respecting the carrier or article or thing as he/she considers necessary to prevent the introduction, transmission, or spread of communicable diseases." The language under 71.63 would codify how this authority may be applied in the future. Since this provision does not impose any new regulatory burden, the mostly likely economic impact is no change from the current baseline. A qualitative benefit of 71.63 is improved understanding of how and why HHS/CDC may suspend entry of animals, articles, or things in the future. An estimate of the economic impact of the temporary embargo of African rodents provides an example of the potential economic impact of future restrictions that HHS/CDC may deem necessary to protect public health.

Costs of the African Rodent Embargo

The costs associated with a suspension of imports can be estimated based on the lost value to consumers and producers associated with not being able to import, sell, barter, or exchange African rodents. At the time of prohibition, African rodents were imported primarily for commercial, or science, education and exhibition purposes. In 2002, a total of 11,587 live rodents were imported, and

1,378 of them (around 12%) were from Africa.⁹³ In 2013, the total number of imported live rodents were 173,761. During this period, there was a shift from wild-caught species, including those of African origin, to other rodent species shipped from multiple countries outside of the African continent.⁹⁴ The percentage of wild-captured imports declined from 75% during 1999 to less than 1% during 2013.⁹⁵ Although the total market for imported rodents increased by approximately 15 times (1500%) between the embargo of African rodents in 2003 and 2013, HHS/CDC believes that the market for African rodents would probably not have expanded at the same rate. One reason is that the market for African rodents would likely be more of a niche market for exotic pets compared to the overall market for domestic rodents. As a point of comparison, imports from Asian countries experienced a smooth decline during 1999–2013.⁹⁶ A second reason is that consumer demand for African rodents would

⁹³ Lankau E.W., Sinclair J.R. Schroeder B.A., Galland G.G., Marano N. Public health implications of changing rodent importation patterns–United States, 1999–2013, *Transboundary and Emerging Diseases*. 2015.

⁹⁴ Schroeder, B., J. McQuiston, R. Marquis, G. Galland, and N. Marano, 2008: Anticipating the next monkeypox: trends in rodent importation, 1999–2006. *International Conference on Emerging Infectious Diseases*, Atlanta GA (abstract, 2008).

⁹⁵ Lankau E.W., Sinclair J.R. Schroeder B.A., Galland G.G., Marano N. Public health implications of changing rodent importation patterns–United States, 1999–2013, *Transboundary and Emerging Diseases*. 2015.

⁹⁶ Lankau E.W., Sinclair J.R. Schroeder B.A., Galland G.G., Marano N. Public health implications of changing rodent importation patterns–United States, 1999–2013, *Transboundary and Emerging Diseases*. 2015.

likely decline after the association of African rodents with the risk of contracting monkeypox virus was clearly demonstrated in the U.S. market.

To provide a conservative estimate of the economic cost of the prohibition on imports of African imports, HHS/CDC uses the average number of African rodent imports in the three years prior to the import suspension to estimate the number of imports as the baseline if the import embargo had not been implemented. On average, 959 African rodents per year were imported between 2000 and 2002.

HHS/CDC assumes that the annual cost of the African rodent import embargo can be subdivided into the following three categories: 1) African rodents imported using a special permit from HHS/CDC, 2) African rodents that are replaced by other regions' imported substitutes, and 3) African rodents that cannot be imported with special permits or substituted. The summary of the costs for each category are included in Table 15 and summarized subsequently.

Table 15. Summary of the Annual Incremental Costs of the African Rodents Embargo, 2015 USD	
Source of cost	Costs

Importing African rodents using a special permit from HHS/CDC	\$744
Use of substitute rodents from other regions	\$11,900
Lost consumer surplus due to African rodents unavailability	\$6,390
Total	\$19,034

Incremental costs of importing African rodents using a special permit from HHS/CDC for scientific, educational, or exhibition purposes

African rodents that otherwise would be prohibited are eligible for a special permit from the CDC director if they are imported for scientific, educational, or exhibition purposes. Approximately 65 African rodents per year were imported from 2004 to 2013.⁹⁷ The HHS/CDC assumes that all these imported African rodents after the ban are used for scientific, educational, or exhibition purposes.

HHS/CDC estimates that the permitting process imposes additional costs that would not be incurred in the absence

⁹⁷ Lankau E.W., Sinclair J.R. Schroeder B.A., Galland G.G., Marano N. Public health implications of changing rodent importation patterns-United States, 1999-2013, Transboundary and Emerging Diseases. 2015.

of the embargo. On an annual basis, the annual cost to obtain a special permit from HHS/CDC will result in about \$372 in incremental costs based on an assumption that the average hourly wage importer's hourly wage is \$31 and African rodents arrive in three separate shipments over the course of an average year. Thus, HHS/CDC assumes that around 20 African rodents are included in each shipment (Table 16). The analysis does not include costs to appeal a permit denial.

Table 16. Per-Animal Incremental Cost to request Special Permits to Import African Rodents, 2015 USD

Importer Time Per Shipment (Hours) ^a (A)	Importer's Hourly Labor Cost (B)	Shipments imported with Special Permit (C)	Number of African rodents per shipment (D)	Overhead multiplier (E)	Importer Cost to Request Special Permit (A x B x C x E)
4	\$31	3	20	100%	\$744

^a The analysis assumes a greater time burden to request a special permit to import animals that are prohibited because more information is required as a part of this request, including detailed descriptions of travel conditions and other measures taken to prevent the spread of disease.

Incremental Costs Associated with the Use of Substitute Rodents

Commercially imported African rodents are expected to be replaced either by imported rodents from other regions or by increased U.S. production of rodents. Most African rodents are exotic species, and are not commonly imported rodents relative to the more commonly imported hamsters, guinea pigs, or cavyes.⁹⁸ HHS/CDC assumes that all substitutes would be imported from countries other than Africa and would not be replaced by domestically produced substitutes.

The estimated price of imported non-African rodents is \$20. According to 2012 data contained in the U.S. Fish and Wildlife Service's (USFWS) Law Enforcement Management Information System (LEMIS), 75 percent of rodents imported in 2008 were hamsters, and another 3 percent were chinchillas. A sample of prices for rodents advertised online yielded an average cost of about \$15 for hamsters and an average cost of \$142 for chinchillas. The weighted average price of these animals is around \$20. Since African

⁹⁸ Lankau E.W., Sinclair J.R. Schroeder B.A., Galland G.G., Marano N. Public health implications of changing rodent importation patterns-United States, 1999-2013, Transboundary and Emerging Diseases. 2015.

rodents are exotic species, HHS/CDC assumes that the price of African rodents is higher than the average price of imported non-African rodents. Thus, HHS/CDC uses the average price of chinchillas, which is about seven times greater than the estimated price of more commonly purchased rodents. In addition to the potential price increase associated with imports from other regions, U.S. consumers may also derive less utility from substitutes for African rodents. HHS/CDC estimates substitution costs by assuming that these costs are 10% of the estimated price of African rodents (based on chinchillas). As a result, U.S. consumers would have to pay approximately \$14 more or lose \$14 in utility for each substituted rodent import in place of the African rodents that would be purchased in the absence of an embargo (Table 17).

Table 17. Incremental Cost of Using Other Imported Substitutes in Place of African Rodents, 2015 USD		
Incremental Cost Per African Rodent ^a (A)	Number of Rodents ^b Substituted (B)	Total Incremental Cost (A x B)
\$14	850	\$11,900

^a \$142 x 10%

^b 894 of commercially imported African rodents x 95%

Incremental costs of lost use due to African rodents'
unavailability

HHS/CDC assumes that substitutes are not available for 5% of commercially imported African rodents. The absence of these animals will result in lost profit for the affected importers and lost utility to the affected consumers.

HHS/CDC assumes that the average price can be used to estimate these costs, although HHS/CDC acknowledges that this may be an underestimate because lost consumer surplus is likely to be greater than the average price. HHS/CDC estimates the cost of lost consumer surplus associated with the lack of acceptable substitutes for U.S. consumers who can no longer import African rodents at $45 \times \$142 = \$6,390$ (Table 18).

Table 18. Incremental Cost of Lost Use Due to African Rodents Unavailability, 2015 USD		
Incremental Cost Per Unavailable African Rodent ^a (A)	Number of African Rodents Becoming Unavailable ^b (B)	Total Incremental Cost (A x B)
\$142	45	\$6, 390
^a HHS/CDC adapted price of chinchillas for the price of unavailable African rodents ^b 894 commercially imported African rodents x 5%		

Benefits of the African Rodent Embargo

The economic benefits of the African rodent embargo are likely much greater than the estimated costs. The primary benefits are improvements to human and animal health in the United States, averted public health measures necessary to contain a monkeypox outbreak, and averted costs to other animal markets in case of transmission of monkeypox from African rodents to other species through intermingling in the pet industry. The 2003 monkeypox outbreak resulted in a total of 71 cases that were

clinically or laboratory confirmed.⁹⁹ Among the 71 total cases, 16 patients (23%) with monkeypox infections were admitted to hospitals for treatment or for isolation. Two patients had serious clinical illness, but subsequently recovered and no deaths associated with monkeypox were reported.¹⁰⁰ The two severe cases occurred in children who required intensive care, one for severe monkeypox-associated encephalitis (encephalitis is an inflammation of the brain), and one with profound painful cervical (neck) and tonsillar adenopathy (adenopathy refers to an enlargement of the glands) and diffuse pox lesions, including lesions in the throat.¹⁰¹ Otherwise, the clinical symptoms of monkeypox included skin lesions with fever (temperature above 38°C, 100.4°F), drenching sweats and severe chills, headache, sore throat and persistent coughing. Other less common symptoms included lymphadenopathy (swollen glands), mild chest tightness,

⁹⁹Centers for Disease Control and Prevention (CDC). Update: Multistate outbreak of Monkeypox—Illinois, Indiana, Kansas, Missouri, Ohio, and Wisconsin, 2003. *Morb Mort Weekly Rep*, . 2003;52:642 – 6.

¹⁰⁰ Centers for Disease Control and Prevention (CDC). Update: Multistate outbreak of Monkeypox—Illinois, Indiana, Kansas, Missouri, Ohio, and Wisconsin, 2003. *Morb Mort Weekly Rep*, . 2003;52:642 – 6.

¹⁰¹ Federal Register 62353 Vol. 68, No. 213 Tuesday, November 4, 2003. P. 62353-69

tonsillar erosion, general body malaise, myalgia (muscle aches), back pain and nasal congestion.¹⁰²

The number of monkeypox cases was increasing over an approximately 3-week period from the identification of the first case on May 15, 2003 through the week ending June 8, 2003. The number of cases declined subsequently; the date of onset for the last case was June 20, 2003.¹⁰³ In the United States, individuals apparently began contracting monkeypox, primarily as a result of contact with prairie dogs that had contracted monkeypox from diseased African rodents. Investigations indicated that a Texas animal distributor imported a shipment of approximately 800 small mammals from Ghana on April 9, 2003, and that shipment contained 762 African rodents, including rope squirrels (*Funiscuirus* sp.), tree squirrels (*Heliosciurus* sp.), Gambian giant pouched rats (*Cricetomys* sp.), brushtail porcupines (*Atherurus* sp.), dormice (*Graphiurus* sp.), and striped mice (*Hybomys* sp.). Some animals were infected with monkeypox, and CDC laboratory testing confirmed the presence of monkeypox in several rodent species, including

¹⁰² Sejvar JJ, Chowdary Y, Schomogyi M, Stevens J, Patel J, Karem K, et al. Human Monkeypox Infection: A Family Cluster in the Midwestern United States. *Journal of Infectious Diseases*. 2004;190:1833-40.

¹⁰³ Centers for Disease Control and Prevention (CDC). Update: Multistate outbreak of Monkeypox—Illinois, Indiana, Kansas, Missouri, Ohio, and Wisconsin, 2003. *Morb Mort Weekly Rep* 2003;52:642 -

one Gambian giant pouched rat, three dormice, and two rope squirrels. Of the 762 rodents from the original shipment, 584 were traced to distributors in six States. A total of 178 African rodents could not be traced beyond the point of entry in Texas because records were not available.¹⁰⁴

Non-native animal species, such as African rodents, can create serious public health problems when they introduce a new disease, such as monkeypox, to the native animal and human populations. The transportation, sale, or distribution of an infected animal, or the release of an infected animal into the environment can result in the further spread of disease to other animal species and to humans. Several States issued orders or emergency rules to prohibit the importation, sale, distribution, release,

¹⁰⁴ Centers for Disease Control and Prevention (CDC). Update: Multistate outbreak of Monkeypox—Illinois, Indiana, Kansas, Missouri, Ohio, and Wisconsin, 2003. *Morb Mort Weekly Rep*, . 2003;52:642 - 6.; *Federal Register* 62353 Vol. 68, No. 213 Tuesday, November 4, 2003. P. 62353-69.

disposal, and/or display of prairie dogs and certain rodents.^{105,106,107,108,109,110}

The monkeypox outbreak was contained in the United States after CDC and the public health departments in the affected States, together with the U.S. Department of Agriculture, the Food and Drug Administration, and other agencies, participated in a variety of activities that prevented further spread of monkeypox.

To assist with the investigation and outbreak response, CDC took the following steps in addition to the embargo on the importation of African rodents:

- Activated its Emergency Operations Center.
- Deployed teams of medical officers, epidemiologists, and other experts to several States to assist with the investigation.

¹⁰⁵ State of Colorado, Wildlife Commission, ``Emergency Regulation,`` dated July 10, 2003.

¹⁰⁶ State of Illinois, ``Executive Order in Response to Orthopox Outbreak,`` dated June 7, 2003.

¹⁰⁷ State of Indiana, Board of Animal Health, Emergency Rule, dated June 9, 2003.

¹⁰⁸ State of Michigan, Department of Community Health, ``Order Finding Imminent Danger to the Public Health and Requiring Corrective Action,`` dated June 13, 2003, and later amended on June 27, 2003.

¹⁰⁹ State of North Dakota, State Board of Animal Health, ``In the matter of: Monkeypox in Prairie Dogs and Gambian Giant pouched Rats,`` Order No. 2003-04, dated June 11, 2003.

¹¹⁰ State of Wisconsin, Department of Agriculture, Trade, and Consumer Protection, ``Emergency Rule,`` dated June 9, 2003.

- Conducted extensive laboratory testing on specimens from humans and animals thought to have been exposed to monkeypox.
- Issued interim U.S. case definitions for human monkeypox and for animal monkeypox.
- Issued interim guidelines on infection control and exposure management for patients in the health care and community settings.
- Issued an immediate embargo and prohibition on the importation, interstate transportation, sale, and release into the environment of certain rodents and prairie dogs.
- Provided ongoing assistance to State and local health departments in investigating possible cases of monkeypox in both humans and animals the United States.
- Worked with State and Federal agencies to trace the origin and distribution of potentially infected animals.
- Issued an interim guidance on the use of smallpox vaccine (which also can be used to protect people against monkeypox), cidofovir (an antiviral medication), and vaccinia immune globulin (an

antibody product obtained from the blood of people who have received the smallpox vaccine) in the setting of an outbreak of monkeypox.

- Issued interim guidelines for veterinarians.
- Issued interim guidance for persons who have frequent contact with animals, including pet owners, pet shop employees, animal handlers, and animal control officers.¹¹¹

These activities suggest the scale of the response required to contain monkeypox and the potential threat posed by the importation of African rodents. The public health response is estimated to require at least 20 HHS/CDC employees over a 2.5 month period. These employees are assumed to be compensated at the GS-13, step 5 level on average. In addition, the total number of personnel from public health departments in the six affected States are assumed to at least equal the number of HHS/CDC employees. The average wage rate for public health departments is estimated based on 2015 U.S. average wage rates for epidemiologists reported in the May 2015 National Occupational Employment and Wage Estimates from the Bureau

¹¹¹ <http://www.cdc.gov/poxvirus/monkeypox/outbreak.html> Accessed 5/2/2016

of Labor Statistics (\$36.97, category 19-1041).¹¹² Total costs for the public health response include a 100% multiplier to account for overhead costs for these employees, but do not include potential travel and per diem costs that may have been incurred to investigate the outbreak. The total costs to HHS/CDC and public health departments are summarized in Table 19.

Table 19. Estimated Costs of the Public Health Response for the 2003 Monkeypox Outbreak in the United States, 2015 USD					
	Number of employees	Duration (months)	Average hourly wage rate	Overhead multiplier	Total cost
HHS/CDC employees	20	2.5	\$47.36	100%	\$757,760
State or local health departments	20	2.5	\$36.97	100%	\$591,520
Total					\$1,349,280

The list of HHS/CDC activities referenced above include guidance provided to veterinarians, persons who have frequent contact with animals including pet owners, pet shop employees, animal handlers, and animal control

¹¹² http://www.bls.gov/oes/current/oes_nat.htm Accessed 5/2/2016

officers. It is likely that all of these stakeholders incurred costs as a result of the monkeypox outbreak; however, HHS/CDC does not have data to quantify most of these costs. HHS/CDC does have some data for one set of affected stakeholders. The size of the prairie dog market was estimated to be approximately \$4.5 million in 2003,¹¹³ which would correspond to \$5.8 million in 2015 USD after adjustment using the U.S. Consumer Price Index. Considering only the disruption to the prairie dog market, HHS/CDC estimates that the cost to this market would be at least 25% of the total market size in any year in which monkeypox transmission was associated with sales of prairie dogs. This large cost is estimated because infection of prairie dogs led to significant restrictions on interstate transport of prairie dogs and because several States issued orders or emergency rules to prohibit the importation, sale, distribution, release, disposal, and/or display of prairie dogs. This one-time 25% reduction would correspond to an annual cost of about \$1.5 million just to this one market in the event of a re-introduction of monkeypox to the United States and transmission within the prairie dog population.

¹¹³ Federal Register 62353 Vol. 68, No. 213 Tuesday, November 4, 2003. P. 62353-69.

The treatment costs for individuals diagnosed with monkeypox or exposed to infected persons or animals include hospitalization, outpatient treatment, medications, vaccinations (with smallpox vaccine), laboratory diagnosis, and the opportunity costs to individuals who contract monkeypox and cannot undertake their normal daily activities. Laboratory diagnosis of monkeypox can involve multiple approaches including combined Polymerize Chain Reaction (PCR) tests, enzymes-linked immunosorbent assays (ELISA) tests, DNA extraction of tissues to perform molecular tests and others. Most of the patients with monkeypox disease were treated with antibiotics (ciprofloxacin and doxycycline) and a few patients received intravenous acyclovir and valacyclovir medications.¹¹⁴ The costs of treating monkeypox were not systematically documented.¹¹⁵

Table 20 provides a rough estimate of potential illness costs associated with an outbreak of monkeypox of similar size to the outbreak that occurred in 2003. The documented costs include 56 cases treated on an outpatient

¹¹⁴ Ligon BL. Monkeypox: A review of the history and emergence in the Western hemisphere. *Seminars in Pediatric Infectious Diseases*. 2004;15:280-7.

¹¹⁵ Kroeger T. Economic Impacts of Live Wild animal Imports in the United States. *Defenders of Wildlife*; 2004.

basis in emergency rooms at an estimated cost of \$1,455 per patient.¹¹⁶ This estimate is based on the U.S. average cost for an outpatient hospital visit for any illness and is probably a very conservative estimate of the outpatient cost of treating monkeypox. Hospitalization costs are estimated at \$16,516 per patient for each of 16 cases based on the average cost of hospitalization for any illness.¹¹⁷ Again, this cost estimate is probably very conservative for monkeypox treatment.

All individuals (outpatients and inpatients) who contract the disease are estimated to lose an average of 12 days of productive activity. This assumption is based on a clinical report that on average infected individuals were ill for between 3 to 24 days.¹¹⁸ To be conservative, HHS/CDC only includes lost productivity costs for adults. Among laboratory confirmed monkeypox cases, 11 out of 35 (31%) patients occurred in patients less than 18 years old. Applying this ratio to the total number of cases (71), approximately 49 adults would incur lost productivity

¹¹⁶ Healthcare Costs Institute. Healthcare Costs and Utilization Report. Washington DC: Health Care Costs Institute; 2011.

¹¹⁷ Healthcare Costs Institute. Healthcare Costs and Utilization Report. Washington DC: Health Care Costs Institute; 2011.

¹¹⁸ Reed KD, Melski JW, Graham MB, Regnery RL, Sotir MJ, Wegner MV, et al. The detection of monkeypox in humans in the western hemisphere. N Engl J Med 2004;350:342-50.

costs. For each adult, average productivity costs are estimated based on the U.S. average hourly salary (\$23.23) reported in the 2015 Occupational Employment Statistics from the U.S. Bureau of Labor Statistics¹¹⁹ and assuming an 8-hour workday. Productivity losses are then estimated based on the average wage rate x 12 days x 8 hours per day x number of monkeypox patients (\$108,531). The total illness are estimated to be about \$453,000 (Table 20).

Table 20. Illness Costs Associated with 2003 U.S. Monkeypox Outbreak, 2015 USD			
Activity	Units	Unit cost ^a	Total Costs
	(A)	(B)	A x B=(C)
Outpatient treatment, ER Visit Cost ¹²⁰	55 ¹²¹	\$1,455 per patient	\$80,025
Hospital stay ¹²²	16 ¹²³	\$16,516 per patient	\$264,256

¹¹⁹ http://www.bls.gov/oes/current/oes_nat.htm Accessed 5/2/2016.

¹²⁰ Healthcare Costs Institute. Healthcare Costs and Utilization Report. Washington DC: Health Care Costs Institute; 2011.

¹²¹ Centers for Disease Control and Prevention (CDC). Update: Multistate outbreak of Monkeypox—Illinois, Indiana, Kansas, Missouri, Ohio, and Wisconsin, 2003. Morb Mort Weekly Rep. 2003;52:642 – 6.

¹²² Healthcare Costs Institute. Healthcare Costs and Utilization Report. Washington DC: Health Care Costs Institute; 2011.

¹²³ Centers for Disease Control and Prevention (CDC). Update: Multistate outbreak of Monkeypox—Illinois, Indiana, Kansas, Missouri, Ohio, and Wisconsin, 2003. Morb Mort Weekly Rep. 2003;52:642 – 6.

Lost productivity	48.7 (69%) for 584 Days	\$161.68 per patient-day	\$108,531
Total costs			\$452,812
^a Unit costs updated to USD 2015 using the U.S. Consumer Price Index where appropriate.			

The total quantified costs associated with the 2003 monkeypox outbreak are summarized in Table 21. These include a partial accounting of the costs incurred to HHS/CDC and to local public health departments, a one-time estimate of the potential costs to the U.S. prairie dog market, and a conservative estimate of illness costs for persons infected with monkeypox (\$3.3 million).

Table 21. Estimated costs of 2003 Monkeypox Outbreak, 2015 USD	
Public health response costs	\$1,349,280
One-time costs to prairie dog market in the United States	\$1,500,000
Illness costs	\$452,812
Total	\$3,302,092

The outbreak costs reported in Table 21 represent a very conservative estimate of the potential benefits of reducing the probability of a future re-introduction of the

monkeypox virus into the United States. The total costs of such an outbreak would probably greatly exceed the conservative estimates presented in Table 21. Since the order to embargo the importation of African rodents in June 2003 and subsequent permanent restriction on the importation of African rodents codified in existing 42 CFR 71.56, the monkeypox virus has not been reintroduced to the United States. Comparing the potential benefits of an averted monkeypox outbreak in Table 21 (\$3.3 million) to the estimated costs to African rodent importers and potential consumers (Table 15, \$19,000), it is extremely likely the benefits of the African rodent import prohibition would greatly exceed the costs. However, HHS/CDC is not able to quantify the risk of re-introduction with and without the restrictions on African rodent imports. Although this final rule only seeks to codify HHS/CDC's ability to suspend entry of animals, articles, or things from designated foreign countries and places into the United States based on existing 42 CFR 71.32(b), this example demonstrates the potential costs and benefits of one such action.

Evaluation of alternatives

Two potential alternatives are considered to codification of this provision in the final rule. Under the first less restrictive alternative, HHS/CDC would not implement temporary embargos after it becomes aware of imminent risks to public health in the United States. Under this scenario, there would be no embargo on the importation of African rodents between June 11, 2003 and November 4, 2003. Under this scenario, the United States would have remained at risk for the re-introduction of monkeypox virus and the need to eliminate the virus from the United States animal and human populations. This scenario is elaborated above.

The more restrictive alternative would be for HHS/CDC to no longer consider special permits to allow importation for scientific, education, and display purposes. HHS/CDC believes that limiting importations to these purposes protects public health, while allowing importation to occur in very controlled environments. If special permits were discontinued, African rodent importers would no longer have to fill out import permits at an annual cost of \$744 (Table 16). This is the cost to create three special permit applications per year.

In comparison, civet shipments with special permits occur approximately once every three years, so the annual

cost to create special permits is $\$744/9 = \83 for civets. However, importers would no longer be able to import African rodents or civets for science, education, or exhibition under the more restrictive alternative. Thus, the societal costs of disallowing importation of animals with special permits under temporary embargos would outweigh the potential cost reductions associated with the time spent filing for special permits.