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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 71

[Docket No. CDC-2026-0991]

RIN: 0920-AA88

Control of Communicable Diseases; Foreign Quarantine

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Interim final rule.

SUMMARY: The Centers for Disease Control and Prevention (CDC) within the U.S. Department of Health and Human Services (HHS) issues this interim final rule with request for comments to amend its Foreign Quarantine Regulations. This interim final rule provides a procedure for the Secretary acting through the CDC Director or other delegate to suspend the introduction of persons from designated countries or places, if required, in the interest of public health.

DATES: *Effective date:* This interim final rule is effective on May 22, 2026.
Comment date: Comments must be received by [INSERT 30 DAYS FROM DATE OF PUBLICATION].

Expiration date: Unless extended after consideration of submitted comments, this interim final rule will cease to be in effect on the earlier of (1) six months from the publication of this interim final rule, or (2) when the HHS Secretary determines there is no longer a need for this interim

final rule. The Secretary will publish a document in the Federal Register announcing the expiration date.

ADDRESSES: You may submit comments, identified by CDC-2026-0991, by the following method:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to *http://regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *http://www.regulations.gov*.

Any comment that is submitted will be shared with the Department of Homeland Security and the Department of State and will also be made available to the public. Comments must be identified by CDC-2026-0991. Because of staff and resource limitations, all comments must be submitted electronically to *www.regulations.gov.* Follow the "Submit a comment" instructions.

Warning: Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments may be posted on the internet and can be retrieved by most internet search engines. No deletions, modifications, or redactions will be made to comments received.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including personally identifiable or confidential business information that is included in a comment.

FOR FURTHER INFORMATION CONTACT: Division of Global Migration Health, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS-H16-4, Atlanta, Georgia 30329. Telephone: 1-800-232-4636.

SUPPLEMENTARY INFORMATION:

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I. BACKGROUND:

The Centers for Disease Control and Prevention (CDC), a component of the U.S. Department of Health and Human Services (HHS), is amending the regulations that implement section 362 of the Public Health Service (PHS) Act, 42 U.S.C. 265, as amended, as part of its response to the 2026 Ebola Disease Outbreak in the Democratic Republic of Congo (DRC), Uganda, and South Sudan. Section 362 provides that if the Secretary "determines that by reason of the existence of any communicable disease in a foreign country there is serious danger of the introduction of such disease into the United States, and that this danger is so increased by the introduction of persons or property from such country that a suspension of the right to introduce such persons and property is required in the interest of the public health," he has the authority, in accordance with regulations approved by the President, "to prohibit, in whole or in part, the introduction of persons and property from such countries or places as he shall designate in order to avert such danger, and for such period of time as he may deem necessary for such purpose." PHS Act 362,

42 U.S.C. 265. Pursuant to a delegation of the Secretary's authority, the CDC Director has promulgated regulations under section 362 to suspend the introduction of persons and property into the United States. Current regulations, however, provide an exception to the suspension of introduction into the United States for lawful permanent residents (LPR) (42 CFR 71.40(f))

CDC's experience with Ebola disease is that the disease is a severe and often fatal illness caused by viruses in the Ebola family. Ebola disease outbreaks occur mainly in parts of sub-Saharan Africa and can spread rapidly in communities with limited healthcare resources. The particular Ebola disease at issue in this outbreak, the Bundibugyo virus, is a rare form of Ebola first identified during an outbreak in Bundibugyo District, Uganda, in 2007. Bundibugyo virus is one of several species within the orthoebolavirus family and causes symptoms similar to other forms of Ebola, including fever, weakness, vomiting, diarrhea, and, in severe cases, hemorrhagic complications and organ failure. The disease spreads through direct contact with infected bodily fluids or contaminated materials.

The incubation period for Ebola disease caused by the Bundibugyo virus is typically between 2 and 21 days, with most people developing symptoms within 4 to 10 days after exposure. During this incubation period, infected individuals do not spread the virus until symptoms begin. Screening for Ebola disease caused by Bundibugyo virus focuses on identifying symptoms and possible exposure history, such as recent travel to affected areas or contact with infected individuals. Suspected patients are evaluated for symptoms including fever, weakness, vomiting, diarrhea, and bleeding, and laboratory confirmation is performed using specialized tests such as PCR (polymerase chain reaction) to detect the virus in blood and other body fluid samples. Health authorities also use temperature checks, contact tracing, and isolation procedures to prevent transmission.

There are currently no widely approved vaccines or specific antiviral treatments for the Bundibugyo virus that causes Ebola disease. Treatment mainly consists of supportive care,

including intravenous fluids, electrolyte replacement, oxygen support, pain and fever management, and treatment of secondary infections. Early medical care significantly improves survival chances. Robust public health measures such as early detection, rapid isolation, strong infection prevention measures (i.e., use of personal protective equipment (PPE)), and monitoring of contacts are critical to controlling outbreaks and reducing deaths. Given the complexities of global disease outbreaks, including the current Ebola disease outbreak in the DRC, Uganda and South Sudan, the logistics of trying identify cases at the numerous ports of entry (POE) of the United States (air, land, and sea), and the fact that there are no approved vaccines or specific antiviral treatments for this strain of Ebola disease, CDC needs a more efficient regulatory mechanism to exercise its section 362 authority and suspend the introduction of persons other than U.S. Citizens and U.S. Nationals who would otherwise pose a serious danger of introduction of Ebola disease into the United States.

Past Experience With Migration and Communicable Disease

International travel and migration play a significant role in the global transmission of infectious biological agents or their toxic products that pose risks for vulnerable populations. Travelers can serve as unwitting vectors of disease and thereby increase the risk of communicable disease transmission and of the introduction of quarantinable communicable disease into the United States. The risk increases when travelers are in congregate settings, such as carriers (i.e., ships, aircraft, trains, and road vehicles) or terminals with shared sitting, sleeping, eating, or recreational areas, all of which are conducive to disease transmission.

The speed and far reach of global travel were factors in prior outbreaks that expanded to numerous continents. Examples include: The H1N1 influenza pandemic in 2009; severe acute respiratory syndrome (SARs) coronavirus in 2003; tuberculosis; measles; Middle East Respiratory Syndrome (MERS-CoV) in 2012; Ebola Virus Disease in 2014 and 2018, and

COVID-19 in 2020. All these high-consequence diseases posed significant public health risks, especially given the compressed timeframes in which the outbreaks initially occurred.

In addition, global travel has increased dramatically since prior infectious disease outbreaks. In 2025, international visitations to the U.S. totaled over 68 million; in 2020 when this regulation was amended to introduce the suspension of introduction of persons into the United States, that number totaled only 19.8 million. The dramatic increase in global travel to the United States, likely spurred by individuals having the freedom to travel again following the COVID-19 pandemic, make the availability of the most efficient and comprehensive mechanism for exercising the section 362 authority all the more important to the protection of the public health going forward.

The Current Outbreak of Ebola Disease

Presently, there is a confirmed ongoing outbreak of Ebola disease caused by the Bundibugyo virus in DRC and Uganda. The current outbreak is centered in eastern DRC's Ituri Province, where hundreds of suspected cases and dozens of deaths have been reported. Conflict, weak health infrastructure, and relatively porous borders in the region are complicating containment efforts.

Uganda has confirmed imported cases linked to travel from DRC, including one case detected in Kampala, imported from a traveler from DRC. Ugandan authorities have activated emergency response systems, expanded surveillance, and strengthened screening at borders and health facilities. Uganda has significant prior experience managing Ebola disease outbreaks, including the Sudan virus strain outbreak in 2025, which improved preparedness and response capacity.

South Sudan has not reported confirmed cases in the current outbreak, but it is considered at high risk because of its close border with affected areas in eastern DRC and Uganda, limited healthcare infrastructure, and cross-border population movement. Regional and international

agencies, including WHO and Africa CDC, are supporting preparedness measures, surveillance, and coordination among the three countries to prevent wider spread. Despite these efforts there is a risk that the outbreak could spread beyond these three countries, and ultimately reach the United States, through international travel by infected individuals during the virus's incubation period, when they have been exposed but are not yet showing symptoms. Travelers moving between affected countries and major international transit hubs could unknowingly carry the virus before becoming ill.

DRC, Uganda, and South Sudan are connected to the global aviation network through a series of regional and international transit hubs that provide pathways into the United States. Travelers departing from outbreak-affected regions frequently transit through densely populated metropolitan airports such as Addis Ababa Bole International Airport (ADD), Jomo Kenyatta International Airport (NBO) in Nairobi, Hamad International Airport (DOH) in Doha, Dubai International Airport (DXB), and Istanbul Airport (IST), all of which maintain extensive passenger connectivity to major U.S. gateway airports including John F. Kennedy International Airport (JFK), Washington Dulles International Airport (IAD), Hartsfield-Jackson Atlanta International Airport (ATL), Chicago O'Hare International Airport (ORD), and Los Angeles International Airport (LAX). These international transportation corridors support continuous movement of travelers between Central and East Africa and major U.S. metropolitan centers, increasing the likelihood that individuals exposed to Ebola virus disease could enter the United States before symptoms become apparent. Complex multi-leg itineraries and the rapid pace of international travel create substantial challenges for identifying potentially infected travelers before arrival.

The risk of Bundibugyo virus disease introduction into the United States is heightened by the virus's incubation period, which can extend up to 21 days, allowing infected individuals to travel internationally while asymptomatic and therefore unlikely to be detected through routine

symptom-based screening measures. A traveler infected in outbreak regions of DRC and Uganda may transit through multiple countries and major international airports before developing fever or other clinical signs of disease. Upon arrival in major U.S. metropolitan areas, travelers who become symptomatic could interact with crowded airport environments, domestic transportation systems, healthcare facilities, hotels, or community settings prior to diagnosis and isolation. Because modern aviation networks enable rapid movement from outbreak zones to the United States within one to two days, even a limited number of infected travelers could create significant public health response demands, particularly if exposure events occur in high-density urban environments. The interconnected nature of global air travel therefore presents a credible pathway for Bundibugyo virus disease importation into the United States, underscoring the importance of aggressive surveillance, traveler monitoring, airport screening, healthcare preparedness, and rapid containment capabilities.

Travelers utilizing air transit pathways originating in or passing through DRC, Uganda, and South Sudan include non-U.S. citizens, foreign contract workers, humanitarian personnel, business travelers, students, refugees, and third-country nationals moving through international aviation hubs in Africa, the Middle East, and Europe. Many travelers entering U.S.-bound itineraries from these pathways may do so under temporary visas, refugee or asylum processing mechanisms, international organizational travel, or multi country itineraries that obscure their original point of departure. As a result, public health screening and border security systems face heightened operational complexity in identifying travelers with recent exposure histories linked to Ebola-affected regions, particularly when travelers originate from or transit through multiple jurisdictions prior to arrival at major U.S. metropolitan airports.

On May 18, 2026, the Director General of WHO declared that the outbreak of Ebola Disease caused by the Bundibugyo virus is a Public Health Emergency of International Concern under the International Health Regulations. Also on May 18, 2026, the CDC issued an initial order

suspending the entry of covered aliens into the United States pursuant to section 362 (42 USC 265) of the Public Health Service Act, as amended, and 42 CFR Part 71.40.

Restricting entry of LPRs, in addition to other non-U.S. citizens, who originate from or have recently traveled through DRC, Uganda, and South Sudan would reduce the volume of higher-risk international arrivals requiring public health monitoring and follow-up. Limiting the number of potentially exposed travelers entering through major U.S. ports of entry, federal, state, and local public health authorities could concentrate finite surveillance, screening, contact tracing, quarantine management, and medical monitoring resources on returning U.S. citizens. Such an approach would reduce operational strain on airport screening systems, CDC quarantine stations, public health laboratories, and healthcare facilities, many of whom may not have experience treating highly pathogenic diseases, responsible for evaluating suspected Bundibugyo virus disease cases. It would also improve the ability of authorities to conduct detailed exposure assessments, ensure compliance with monitoring requirements during the 21-day incubation period, rapidly identify symptomatic individuals, and allocate specialized isolation and treatment capacity more effectively. In the context of a rapidly evolving Bundibugyo virus disease outbreak with significant international mobility, prioritizing surveillance efforts toward a smaller and more traceable traveler population would strengthen the overall effectiveness of U.S. disease containment and border health security operations.

Travelers Health Notices (THNs) and Health Alert Network notices (HANs) have also been issued by the CDC with respect to travel from or through the affected countries.

This outbreak continues to highlight why CDC needs an efficient and comprehensive regulatory mechanism to suspend the introduction of all persons who would otherwise increase the serious danger of the introduction of a quarantinable communicable disease into the United States. Section 362 currently provides the authority to prohibit the “introduction” of persons into the United States, while the implementing regulations found at 42 CFR Part 71.40 provide

exceptions to that authority. Despite continued attempts to mitigate and end the outbreak, cases and deaths have rapidly propagated and multiplied, crossing international borders with ease. In the immediate term, given what is currently known about the outbreak, persons traveling from other foreign countries and jurisdictions, including LPRs, may increase the opportunity for introduction of Ebola disease into the United States.

At this time, there is no approved vaccine or therapeutic for the Bundibugyo virus causing the current outbreak of Ebola disease. The Secretary acting through the CDC Director or other delegate needs a robust, efficient, and comprehensive mechanism for exercising its authority under section 362 and other applicable authorities to suspend the introduction of persons into the United States, including LPRs, should the public health require it. In issuing orders pursuant to this interim final rule, the Secretary acting through the CDC Director or other delegate would coordinate with the Secretary of State in order to ensure compliance with the international legal obligations of the United States and to take due account of U.S. national and security interests. CDC would also coordinate with the Department of Homeland Security to operationalize and implement the order.

Other Public Health Risks

The suspension authority is also critical to CDC because there is always a risk of another emerging, or re-emerging, quarantinable communicable disease that may harm the American public. Currently, CDC is responding to multiple outbreaks of quarantinable communicable disease: Andes virus, a strain of Hantavirus, and now the Ebola disease. Another continuous risk of quarantinable communicable disease comes in the form of pandemic influenza (as opposed to seasonal influenza), which occurs when a novel, or new, influenza virus strain spreads over a wide geographic area and affects an exceptionally high proportion of the population. In such circumstances, the strain of virus is new, there is usually no available vaccine, and humans do not typically have immunity to the virus, often resulting in a more severe illness. The severity

and unpredictable nature of an influenza pandemic require public health systems to prepare constantly for the next occurrence. Whenever a new strain of influenza virus appears, or a major change to a preexisting virus occurs, individuals may have little or no immunity, which can lead to a pandemic when the virus passes easily from human to human and causes serious illness or death. The most recent influenza pandemics include H1N1 in 2009-2010, the 1968-1969 Hong Kong Flu, the 1957-1958 Asian Flu, and the 1918-1919 Spanish Flu.

It is difficult to predict the impact that another emerging, or re-emerging, quarantinable communicable disease would have on the U.S. public health system. The 2009 H1N1 pandemic caused between 100,000 and 600,000 deaths worldwide, while the 1918-1919 Spanish Flu was estimated to have caused over 50 million deaths worldwide. The COVID-19 pandemic from 2020-2023 caused approximately 7.11 million deaths world-wide, disrupted the global economy, the ability to live everyday life normally, separated families and friends for, in some cases, several years, and caused untold harm to individual mental health. Although advances in health care quality have greatly improved, the dramatic increases in global mobility in the 21st century have increased the rate at which a communicable disease can spread. Modern pandemics, spread through international travel, can engulf the world in three months or less. Moreover, pandemics can last from 12 to 18 months (or longer in the case of COVID-19) and are not considered one-time events.

The introduction of another emerging, or re-emerging, quarantinable communicable disease into the United States is always a risk. The PHS Act section 362 suspension authority has proven critical to prior CDC efforts, as well as those of its Federal, State, and local partners to contain or mitigate public health risks. CDC expects to mitigate the risk in the future by issuing a Final Rule, after considering comments, to implement a permanent regulatory structure regarding the potential suspension of introduction of persons, including LPRs, into the United States in the

event a serious danger of the introduction of a quarantinable communicable disease arises in the future.

II. STATUTORY AUTHORITY:

The primary legal authority supporting this rulemaking is section 362 of the PHS Act, which is codified at 42 U.S.C. 265. Under section 362, the Secretary has the authority—if he were to determine that the existence of a communicable disease in a foreign country creates a serious danger of the introduction of such disease into the United States, and that this danger is increased by the introduction of persons or property from such country such that suspension of introduction is necessary to protect the public health—to suspend, in accordance with regulations approved by the President, such period of time as he may deem necessary for such purpose.

In addition to section 362, other sections of the PHS Act are relevant to this rulemaking, including section 311, 42 U.S.C. 243; section 361, 42 U.S.C. 264; section 365, 42 U.S.C. 268; and section 367, 42 U.S.C. 270. Section 311 authorizes the Secretary to accept State and local assistance in the enforcement of quarantine rules and regulations and to assist States and their political subdivisions in the control of communicable diseases. Section 361 authorizes the Secretary to make and enforce such regulations that in the Secretary's judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States. It also permits the “apprehension, detention, or conditional release of individuals” in order to prevent the “introduction, transmission, or spread” of such communicable diseases as may be specified from time to time in Executive Orders of the President upon the recommendation of the Secretary, in consultation with the Surgeon General. Section 365 provides that it shall be the duty of designated customs officers and of Coast Guard officers to aid in the enforcement of quarantine rules and regulations. Section 367 authorizes the application of certain sections of the PHS Act and promulgated regulations (including penalties

and forfeitures for violations of such sections and regulations) to air navigation and aircraft to such extent and upon such conditions as deemed necessary for safeguarding public health.

III. PROVISIONS OF AMENDED § 71.40(f)

This interim final rule will implement amendments to section 71.40(f).

Although section 362 applies to "persons," this interim final rule does not apply to U.S. citizens or U.S. nationals consistent with the constitutional limitations on the Federal Government's authority to restrict the return of its own citizens and nationals. U.S. citizens possess a fundamental constitutional right to enter the United States.

That does not render CDC without tools to address the public health risks posed by returning U.S. citizens and U.S. nationals who may have been exposed to quarantinable communicable diseases, including Ebola. Congress provided CDC with the authority to prohibit the introduction of persons who would increase a serious danger of introducing into the United States a quarantinable communicable disease, when required in the interest of the public health. CDC believes that, at present, quarantine, isolation, and conditional release, in combination with other authorities, while not perfect solutions, can mitigate any transmission or spread of communicable diseases, including Ebola caused by the Bundibugyo virus through the introduction of U.S. citizens into the United States, as that population is likely to be limited, and given the finite nature of the resources to support those actions. Section 71.40(f) therefore states that this interim final rule shall not apply to U.S. citizens and U.S. nationals. Determining the appropriate protections for U.S. citizens and U.S. nationals requires a complex balancing of numerous interests and would benefit from additional consideration and public comment. HHS does not want such concerns to delay the issuance of this interim final rule, which would enable the CDC Director to issue orders that would have the effect of slowing the introduction, transmission, and

spread of quarantinable communicable diseases, including Ebola caused by the Bundibugyo virus in the United States.

The interim final rule will apply to lawful permanent residents. HHS and CDC have determined that permitting the Director of CDC or other Secretarial delegate the discretion to prohibit entry of certain lawful permanent residents is reasonably required in the interest of public health. In making that determination, HHS and CDC considered that many lawful permanent residents may maintain stronger ties to families and communities outside the United States than do U.S. citizens and nationals, such that prohibiting their entry is comparatively less burdensome to lawful permanent residents than to U.S. citizens or nationals. Moreover, lawful permanent residents may have comparatively deeper ties to their home countries or regions than do American citizens, whose connections to those countries or regions may be more fleeting. And those closer connections, more frequent visits, and additional time spent in relevant countries or region may increase the risk of exposure to pathogens in their home countries or regions during public health emergencies. HHS and CDC have also considered that, conversely, U.S. citizens and nationals would be more negatively affected by being prohibited from entering the United States.

Furthermore, HHS and CDC have determined that the interim final rule should apply to lawful permanent residents given resource constraints. Containing quarantinable communicable diseases on U.S. soil is highly resource-intensive, requiring specialized and isolated facilities with limited capacity. In their judgment, HHS and CDC have determined that current section 71.40 may not provide the Director of CDC or other Secretarial Delegate the flexibility needed to manage the influx of persons from designated foreign countries or places. Given the above analysis of the relative burdens faced by U.S. citizens, U.S. nationals, and lawful permanent residents, HHS and CDC have determined that the best balance between ensuring the Director of

CDC has the ability to properly allocate resources and taking into account the interests of persons entering the United States is to draw the line at lawful permanent residents.

As with current section 71.40, this interim final rule only provides discretion to the Director of CDC to suspend the entry of covered aliens; it does not automatically prohibit the introduction of any individua into the United States.

IV. RATIONALE FOR ISSUANCE OF AN INTERIM FINAL RULE WITH IMMEDIATE EFFECTIVENESS

Agency rulemaking is governed by section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553). Section 553(b) requires that, unless the rule falls within one of the enumerated exemptions, HHS must publish a notice of proposed rulemaking in the **Federal Register** that provides interested persons an opportunity to submit written data, views, or arguments, prior to finalization of regulatory requirements. Section 553(b)(3)(B) of the APA authorizes a department or agency to dispense with the prior notice and opportunity for public comment requirement when the agency, for "good cause," finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. In addition, because this interim final rule represents a critical part of the dialogue between the United States and the Governments of the affected countries, DRC, Uganda, and South Sudan, as well as potential implementing partners Mexico and Canada, in preventing the spread of Ebola disease caused by Bundibugyo virus, it involves a "foreign affairs function of the United States." 5 U.S.C. 553(a)(1).

As noted above, the United States and the affected countries of DRC, Uganda, and South Sudan, along with other countries have taken necessary measures to try to contain or slow the transmission or spread of this Ebola disease outbreak. Such public health actions, especially the actions by the Secretary, have been taken to attempt to slow introduction and transmission of the

disease into the United States, which benefit the public health, preserve limited public and private resources, particularly in the areas of quarantine and isolation, and give the U.S. public health system additional time to implement further measures to protect and support the public.

Nevertheless, these measures have not completely stopped (and will not completely stop) global travelers, and other persons crossing from one country into another country, from spreading Ebola disease caused by the Bundibugyo virus across country boundaries. This interim final rule's expanded discretion to exercise the suspension authority is therefore critical to slowing the introduction of Ebola disease into the United States. The United States is at a mitigation juncture where suspending the introduction of persons, including LPRs, from certain countries or places may be required in the interest of the public health, because it could materially reduce the transmission and spread of Ebola disease in the United States and the need for limited resources to implement any necessary public health actions. Because persons can have Ebola disease and be asymptomatic (although not infectious until symptomatic) at the time of introduction into the United States, and because specialized testing is needed to confirm infection with the disease, it is impracticable to confirm who is infected with Ebola disease and who is not infected with Ebola disease as persons move into the United States. Similarly, Federal quarantines or isolations of all such persons pending test results would be impracticable due to the potential numbers of persons involved if this necessary limitation is not imposed, logistical challenges, and CDC resource and personnel constraints.

Given that the outbreak has been declared a public health emergency of international concern, and that quick action is crucial to preventing spread of the disease, it would be impracticable and contrary to the public health—and, by extension, the public interest—to delay the necessary changes to this implementing regulation until a full public notice-and-comment process is completed.

Pursuant to 5 U.S.C. 553(b)(3)(B), and for the reasons stated above, HHS therefore concludes that there is good cause to dispense with prior public notice and the opportunity to comment on this rule before finalizing this rule. For the same reasons, HHS has determined, consistent with section 553(d) of the APA, that there is good cause to make this interim final rule effective immediately upon filing at the Office of the Federal Register.

V. REQUEST FOR COMMENT:

HHS requests comment on all aspects of this interim final rule, including its likely costs and benefits and the impacts that it is likely to have on the public health, as compared to the current requirements under 42 CFR part 71.

VI. REGULATORY IMPACT ANALYSIS:

Executive Orders 12866 and 13563 and Regulatory Flexibility Act

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, and public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a regulation (1) having an annual effect on the economy of $100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as "economically significant"); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel

legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. This interim final rule is economically significant for the purposes of Executive Orders 12866 and 13563. CDC, however, is proceeding under the emergency provision at Executive Order 12866 Section 6(a)(3)(D) based on the need to move expeditiously during the current outbreak and public health emergency of international concern to limit the introduction of Ebola disease into the United States.

The Regulatory Flexibility Act (RFA) generally requires that when an agency issues a proposed rule, or a final rule pursuant to section 553(b) of the APA or another law, the agency must prepare a regulatory flexibility analysis that meets the requirements of the RFA and publish such analysis in the **Federal Register**. 5 U.S.C. 603, 604. Specifically, the RFA normally requires agencies to describe the impact of a rulemaking on small entities by providing a regulatory impact analysis. Such analysis must address the consideration of regulatory options that would lessen the economic effect of the rule on small entities. The RFA defines a “small entity” as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA); (2) a nonprofit organization that is not dominant in its field; or (3) a small government jurisdiction with a population of less than 50,000. 5 U.S.C. 601(3)-(6). Except for such small government jurisdictions, neither State nor local governments are “small entities.” Similarly, for purposes of the RFA, individual persons are not small entities. The requirement to conduct a regulatory impact analysis does not apply if the head of the agency “certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.” 5 U.S.C. 605(b). The agency must, however, publish the certification in the **Federal Register** at the time of publication of the rule, “along with a statement providing the factual basis for such certification.” *Id.* If the agency head has not waived the requirements for a regulatory flexibility analysis in accordance with the RFA's waiver provision, and no other RFA exception applies, the agency must prepare the regulatory flexibility analysis and publish it in the **Federal Register** at the time of promulgation or, if the rule is promulgated in response to an emergency that makes

timely compliance impracticable, within 180 days of publication of the final rule. 5 U.S.C. 604(a), 608(b).[19]

This interim final rule establishes a regulatory mechanism for the exercise of the PHS Act section 362 suspension authority, which directly applies against persons and not State, local, or tribal governments, or the private sector. Accordingly, HHS and CDC certifies that this interim final rule would likely impact only persons, and that it would, therefore, not have a significant economic impact on a substantial number of small entities. In addition, for the reasons set forth in this document pertaining to the Ebola disease outbreak, the Secretary finds that this interim final rule is being promulgated in response to an emergency that makes timely compliance with the provisions of section 604 impracticable.

Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (Unfunded Mandates Act) (2 U.S.C. 1532) requires that covered agencies prepare a budgetary impact statement before promulgating a rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. Currently, that threshold is approximately $193 million. If a budgetary impact statement is required, section 205 of the Unfunded Mandates Act also requires covered agencies to identify and consider a reasonable number of regulatory alternatives before promulgating a rule. HHS has determined that this interim final rule is not expected to result in expenditures by State, local, and tribal governments, or by the private sector, that meets or exceeds the threshold in any one year because it only establishes a regulatory mechanism for the exercise of the PHS Act section 362 suspension authority, which applies against persons and not State, local, or tribal governments, or the private sector. Accordingly, HHS has not prepared a budgetary impact statement or specifically addressed the regulatory alternatives considered.

National Environmental Policy Act (NEPA)

HHS has determined that the amendments to 42 CFR part 71 will not have a significant impact on the human environment. **Executive Order 12988: Civil Justice Reform**

HHS has reviewed this rule under Executive Order 12988 on Civil Justice Reform and has determined that this interim final rule meets the standard in the Executive Order.

Executive Order 13132: Federalism

This interim final rule has been reviewed under Executive Order 13132, Federalism. Under 42 U.S.C. 264(e), Federal public health regulations do not preempt State or local public health regulations, except in the event of a conflict with the exercise of Federal authority. Other than to restate this statutory provision, this rulemaking does not alter the relationship between the Federal government and State/local governments as set forth in 42 U.S.C. 264. The longstanding provision on preemption in the event of a conflict with Federal authority (42 CFR 70.2) is left unchanged by this rulemaking. Furthermore, there are no provisions in this regulation that impose direct compliance costs on State and local governments. Therefore, HHS believes that the interim final rule does not warrant additional analysis under Executive Order 13132.

Plain Language Act of 2010

Under the Plain Language Act of 2010 (Pub. L. 111-274, October 13, 2010), executive Departments and Agencies are required to use plain language in documents that explain to the public how to comply with a requirement the Federal Government administers or enforces. HHS/CDC has attempted to use plain language in promulgating this interim final rule, consistent with the Federal Plain Writing Act guidelines.

Congressional Review Act

The Congressional Review Act defines a "major rule" as "any rule that the Administrator of the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget finds has resulted in or is likely to result in—(A) an annual effect on the economy of $100,000,000 or more; (B) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (C) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets." 5 U.S.C. 804(2). This Office of Information and Regulatory Affairs has determined that this interim final rule is a major rule for purposes of the Congressional Review Act. As this rule is promulgated under the "good cause" exemption of the Administrative Procedure Act, there is not a delay in its effective date under the Congressional Review Act.

Assessment of Federal Regulation and Policies on Families

Section 654 of the Treasury and General Government Appropriations Act of 1999 requires Federal departments and agencies to determine whether a proposed policy or regulation could affect family well-being. If the determination is affirmative, then the Department or agency must prepare an impact assessment to address criteria specified in the law. HHS has determined that this interim final rule will not have an impact on family well-being, as defined in the Act.

Paperwork Reduction Act of 1995

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Ch. 3506; 5 CFR 1320 Appendix A.1), HHS has reviewed this interim final rule and has determined that there are no new collections of information contained therein.

List of Subjects in 42 CFR Part 71

Apprehension, CDC, Communicable diseases, Conditional release, Ill person, Isolation, Non-invasive, Public health emergency, Public health prevention measures, Qualifying stage, Quarantine, Quarantinable communicable disease.

For the reasons set forth in the preamble, the Department of Health and Human Services, on behalf of the Centers for Disease Control and Prevention, amends 42 CFR part 71 as follows:

PART 71 – FOREIGN QUARANTINE:

1. The authority citation for part 71 continues to read as follows:

Authority: Secs. 215 and 311 of the Public Health Service (PHS) Act, as amended (42 U.S.C. 216, 243); secs. 361-369, PHS Act, as amended (42 U.S.C. 264-272).

2. Amend § 71.40 by revising paragraph (f) to read as follows:

§ 71.40 Suspension of the right to introduce and prohibition of the introduction of persons into the United States from designated foreign countries or places for public health purposes.

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(f) This section shall not apply to U.S. citizens and U.S. nationals.

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Robert F. Kennedy, Jr.,

Secretary,

Department of Health and Human Services.

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