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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 71

[Docket No. CDC-2020-0033]

RIN 0920-AA76

Control of Communicable Diseases; Foreign Quarantine: Suspension of Introduction of Persons into United States from Designated Foreign Countries or Places for Public Health Purposes

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

ACTION: Interim final rule with request for comments.

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 CDC 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 11:59PM EDT on March 20th, 2020.

Comment date: Written comments are invited and must be submitted on or before 30 days from the date of publication of this interim final rule in the **Federal Register**.

Expiration Date: Unless extended after consideration of submitted comments, this interim final rule will cease to be in effect on the earlier of (1) one year 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 Docket No. CDC-2020-0033, 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 **RIN 0920-AA76**. 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: Kyle McGowan, Office of the Chief of Staff, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS H21-10, Atlanta, GA 30329. Telephone: 404-498-7000; email: cdcregulations@cdc.gov.

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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 part of its response to Coronavirus Disease 2019 (COVID-19). Section 362 provides that if the Secretary¹ “determines

¹ The statute assigns this authority to the Surgeon General of the Public Health Service. However, Reorganization Plan No. 3 of 1966 abolished the Office of the Surgeon General and transferred all statutory powers and functions of the Surgeon General and other officers of the Public Health Service and of all agencies of or in the Public Health Service to the Secretary of Health, Education, and Welfare, now the Secretary of Health and Human Services, 31 FR 8855, 80 Stat. 1610 (June 25, 1966), *see also* Pub. L. No. 96-88, 509(b), 93 Stat. 695 (codified at 20 U.S.C.

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,² “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 property into the United States. Current regulations, however, only address suspension of the introduction of property into the United States and the procedures to quarantine or isolate persons. That is, current regulations permit CDC to quarantine or isolate persons entering the United States, but they do not address the suspension of the introduction of persons into the United States under section 362.

CDC’s experience with COVID-19 is that, under some circumstances, quarantine or isolation is not a viable solution for protecting the public health from the introduction of a communicable disease from another country. For example, the arrival in U.S. ports of cruise ships with numerous passengers requiring quarantine or isolation has presented complex logistical challenges, consumed disproportionate agency resources, and taken CDC personnel away from other critical parts of the domestic and international response to COVID-19. To continue to respond promptly and effectively to the public health emergency presented by

3508(b)). References in the PHS Act to the Surgeon General are to be read in light of the transfer of statutory functions and re-designation. Although the Office of the Surgeon General was re-established in 1987, the Secretary of HHS has retained the authorities previously held by the Surgeon General.

² Executive Order 13295 assigned the functions of the President under section 362 to the Secretary of HHS.

COVID-19, CDC needs a more efficient regulatory mechanism to exercise its section 362 authority and suspend the introduction of persons who would otherwise pose a serious danger of introduction of COVID-19 into the United States.

Even though COVID-19 is present in certain locations within the United States, the suspension of the introduction of persons into the United States may be required in the interest of public health to avert the danger of further introduction of the disease into the same or other locations in the United States. For example, hypothetically, the introduction of COVID-19 into the United States would occur if two infected persons disembarked in a large metropolitan city in the Midwest from an international flight. Another vector for further introduction of COVID-19 into the United States would be a group of two infected persons who entered that Midwestern state by land after crossing the border from Canada. Suspension of the introduction of those two persons into the United States at the land border would mitigate the serious and increased danger of further introduction of COVID-19 in the United States. The same public health analysis would apply if two infected persons walked across the land border from Canada into a Northeastern State.

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.³ Travelers can serve as unwitting vectors of disease, and thereby increase the risk of communicable disease transmission and of the introduction of communicable disease into the

³ See, e.g., Institute of Medicine (US) Forum on Microbial Threats, “Infectious Disease Movement in a Borderless World: Workshop Summary,” National Academies Press (US); 2010, *available at* <https://www.ncbi.nlm.nih.gov/books/NBK45728/> (hereinafter “Infectious Disease Movement in a Borderless World”); Wilson, ME. Travel and the Emergence of Infectious Diseases. *Emerging Infectious Diseases*. 1995;1(2):39-46. doi:10.3201/eid0102.950201; Tatem, A. J., Rogers, D. J. & Hay, S. Global Transport Networks and Infectious Disease Spread. *Adv. Parasitology* 62, 293–343 (2006).

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.⁴

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; and Ebola Virus Disease in 2014 and 2018.⁵ All of these high-consequence diseases posed significant public health risks, especially given the compressed timeframes in which the outbreaks occurred.

For example, the Federal response to the H1N1 influenza pandemic in 2009 would have benefitted from the availability of an efficient mechanism for suspending the introduction of persons into the United States. The initial cases of H1N1 occurred in Mexico, before the first confirmed cases in the United States. Retrospective research findings in Mexico indicated that transmission of the virus in Mexico involved person-to-person spread with multiple generations of transmission.⁶

Like 2009 H1N1, COVID-19 is a pandemic. But the new coronavirus is more infectious than 2009 H1N1.⁷ Indeed, it appears that the virus may at times be transmitted by persons who

⁴ *E.g.*, <https://wwwnc.cdc.gov/travel/yellowbook/2020/travel-by-air-land-sea/cruise-ship-travel> (noting that the “often crowded, semi-enclosed environments onboard ships can facilitate the spread of person-to-person, foodborne, or waterborne diseases”); CDC, “Interim US Guidance for Risk Assessment and Public Health Management of Persons with Potential Coronavirus Disease 2019 (COVID-19) Exposures: Geographic Risk and Contacts of Laboratory-confirmed Cases,” Updated March 7, 2020, *available at* <https://www.cdc.gov/coronavirus/2019-ncov/php/risk-assessment.html>.

⁵ Infectious Disease Movement in a Borderless World (noting that “swine-origin H1N1 has spread globally, its movement hastened by global air travel” and [i]t is easy to see how travelers could play a key role in the global epidemiology of infections that are transmitted from person to person, such as HIV, SARS, tuberculosis, influenza, and measles”) (citing Hufnagel L, Brockmann D, Geisel T. Forecast and Control of Epidemics in a Globalized World. *Proceedings of the National Academy of Sciences*. 2004;101(42):15124–15129).

⁶ <https://www.cdc.gov/h1n1flu/cdcresponse.htm>.

⁷ *See generally*, CDC, “2009 H1N1 Pandemic Timeline,” *available at* <https://www.cdc.gov/flu/pandemic->

are asymptomatic. As discussed below, COVID-19 is also more likely to cause death in high-risk individuals.

In addition, global travel has increased dramatically since prior infectious disease outbreaks. By 2018, international visitations to the U.S. totaled over 20 million more per year than in 2009, when the 2009 H1N1 pandemic occurred, and 10 million more per year than in 2014, when the Ebola Virus Disease outbreak occurred.⁸ These differences make the availability of an efficient mechanism for exercising the section 362 authority all the more important to the protection of the public health going forward.

The Current Outbreak of COVID-19

COVID-19 is a communicable disease caused by a novel (new) coronavirus, SARS-CoV-2, that was first identified as the cause of an outbreak of respiratory illness that began in Wuhan, Hubei Province, People's Republic of China ("PRC"). The virus is thought to be transmitted primarily by person-to-person contact through respiratory droplets produced when an infected person coughs or sneezes. It may also be transmitted through contact with surfaces or objects. While much is still unknown about the transmission of COVID-19, asymptomatic transmission may also occur.

Manifestations of severe disease have included severe pneumonia, acute respiratory distress syndrome (ARDS), septic shock, and multi-organ failure. According to the World Health Organization (WHO), as of March 17, 2020, approximately 4.1% of reported COVID-19 cases have resulted in death globally. This mortality rate is higher among seniors or those with

resources/2009-pandemic-timeline.html; Van Kerkhove, Maria D et al. Estimating age-specific cumulative incidence for the 2009 influenza pandemic: a meta-analysis of A(H1N1)pdm09 serological studies from 19 countries. *Influenza and Other Respiratory Viruses* vol. 7,5 (2013): 872-86, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5781221/>; CDC, Interim Clinical Guidance for Management of Patients with Confirmed Coronavirus Disease (COVID-19), available at <https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-guidance-management-patients.html>.

⁸ https://travel.trade.gov/outreachpages/download_data_table/Fast_Facts_2018.pdf

compromised immune systems. Older adults and people who have severe chronic medical conditions like hypertension, heart, lung, or kidney disease are also at higher risk for more serious COVID-19 illness. Early data suggest older people are twice as likely to have serious COVID-19 illness.

As of March 17, 2020, there were over 179,100 cases of COVID-19 globally in over 150 locations (including countries), resulting in over 7,425 deaths; more than 4,225 cases have been identified in the United States, with new cases being reported daily and with at least 75 deaths due to the disease. Continued introduction into the United States of persons from foreign countries where COVID-19 exists presents a danger of disease transmission in congregate settings such as carriers or terminals, which may, in turn, result in a danger of disease transmission in contiguous areas.⁹

Unfortunately, at this time, there is no vaccine that can prevent infection with COVID-19, nor are there therapeutics for those who become infected. Treatment is currently limited to supportive (or palliative) care to manage symptoms while the body fights off the disease. Hospitalization may be required in severe cases and mechanical respiratory support may be needed in the most severe cases. The ease of COVID-19 transmission presents a risk of a surge in hospitalizations for COVID-19, which would limit hospital capacity available to treat other serious conditions.

Testing is available to confirm suspected cases of COVID-19 infection. Testing generally requires specimens collected from the nose, throat, or lungs; such specimens can only be analyzed in a laboratory setting. However, commercial test results are typically available

⁹ See *supra* n.4; see also CDC, Travelers from Countries with Widespread Sustained (Ongoing) Transmission Arriving in the United States, available at <https://www.cdc.gov/coronavirus/2019-ncov/travelers/after-travel-precautions.html>.

within three to four days. Currently, the time required to obtain test results—coupled with the incubation period of the disease—makes it impracticable to confirm whether each person moving into the United States is infected with COVID-19 at the time of the movement. Widespread, compulsory Federal quarantines or isolations of such persons pending test results are impracticable due to the numbers of persons involved, logistical challenges, and CDC resource and personnel constraints.

On January 30, 2020, the Director General of WHO declared that the outbreak of COVID-19 is a Public Health Emergency of International Concern under the International Health Regulations.¹⁰ The following day, the Secretary of HHS declared COVID-19 a public health emergency under the PHS Act.¹¹ On March 11, 2020, the WHO declared COVID-19 a pandemic. On March 13, 2020, the President issued a Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak.¹² As of March 16, 2020, all 50 states and several local and territorial jurisdictions declared states of emergency.

Global efforts to slow disease transmission have included sweeping measures to limit travel and exposure to COVID-19. A number of countries, such as Russia, Australia, the Philippines, Japan, and Israel, have imposed stringent restrictions on travelers who have recently been to the PRC. On March 17, 2020, the European Union approved a plan to ban all nonessential travel into its bloc for a minimum of 30 days. Many countries are asking persons to

¹⁰ Statement on the second meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak of novel coronavirus (2019-nCoV) (January 30, 2020), *available at* [https://www.who.int/news-room/detail/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-\(2019-ncov\)](https://www.who.int/news-room/detail/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov)).

¹¹ HHS, “Determination that a Public Health Emergency Exists,” *available at* <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>.

¹² “Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak,” March 13, 2020, *available at* <https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>.

self-quarantine for 14 days (a period estimated to encompass the incubation period for the disease) following return from foreign countries or places with sustained community transmission.

The President has exercised his authority in section 212(f) of the Immigration and Nationality Act (“INA”), 8 U.S.C. 1182(f), to suspend entry into the United States of certain foreign nationals who have recently visited PRC (excluding the Special Administrative Regions of Hong Kong and Macau), the Islamic Republic of Iran, the Schengen Area (comprised of 26 countries in Europe), the United Kingdom (excluding overseas territories outside of Europe), and the Republic of Ireland, within 14 days preceding their entry or attempted entry into the United States due to concerns of person-to-person transmission of COVID-19. CDC has issued Level 3 Travel Health Notices recommending that travelers avoid all nonessential travel to PRC (excluding the Special Administrative Regions of Hong Kong and Macau), the Islamic Republic of Iran, the Republic of Korea, and the Schengen Area. The U.S. Department of State has issued a Global Level 3 Health Advisory directing U.S. citizens to reconsider all travel abroad due to the global impact of COVID-19 and Level 4 Travel Advisories (Do Not Travel) for PRC (excluding the Special Administrative Regions of Hong Kong and Macau), Iran, and certain regions of Italy. In addition, CDC has recommended that travelers, particularly those with underlying health conditions, avoid all cruise ship travel worldwide. The U.S. Department of State has similarly issued guidance that U.S. citizens should not travel by cruise ship at this time. On March 16, 2020, the Federal government announced guidelines recommending that the public should avoid discretionary travel; discretionary shopping trips; social visits; gatherings in groups of more than 10 people; and eating or drinking at bars, restaurants, and food courts. Numerous States and cities have gone further and shut down restaurants, bars, nightclubs, and theaters. On

March 18, 2020, the United States and Canada announced plans to, by mutual consent, close the U.S.-Canadian border to nonessential travel.

The COVID-19 pandemic highlights why CDC needs an efficient regulatory mechanism to suspend the introduction of persons who would otherwise increase the serious danger of the introduction of a communicable disease into the United States. Section 212(f) of the Immigration and Nationality Act (“INA”) applies to the “entry” of aliens, but section 362 instead provides the authority to prohibit the “introduction” of persons into the United States. Despite the unprecedented global efforts at mitigating or slowing the transmission of COVID-19, cases of COVID-19 have rapidly propagated and multiplied, crossing international borders with ease. As of March 17, 2020, CDC reported that 229 of the confirmed cases of COVID-19 in the United States with an established source of exposure were travel-related as opposed to community transmission, accounting for almost half of the 474 cases with an established source of exposure; another 3,752 cases remain under investigation. As of March 14, 2020, travelers from Japan have exported at least 20 COVID-19 cases to eight countries. As of March 14, 2020, travelers from the Islamic Republic of Iran have exported at least 145 COVID-19 cases to 17 other countries, as reported by the WHO, and travelers from the Schengen Area have exported 624 COVID-19 cases to 70 countries, including to the United States. In the near future, persons traveling from other foreign countries and jurisdictions may compound the serious danger of further introduction of COVID-19 into the United States.

To summarize, CDC knows that COVID-19 infection transmits easily, spreads quickly through global travel, and can have a high mortality rate for some of the most vulnerable members of society. At this time, there is no vaccine, therapeutic, or rapid testing for the disease. CDC needs a robust, efficient mechanism for exercising its authority under section 362

and other applicable authorities to suspend the introduction of persons into the United States, should the public health require it. In issuing orders pursuant to this interim final rule, CDC 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.

Other Public Health Risks

Beyond the current COVID-19 pandemic, the suspension authority is also critical to CDC because there is always a risk of another emerging, or re-emerging, communicable disease that may harm the American public. One such risk is 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 requires 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, communicable disease would have on the U.S. public health system. The 2009 H1N1 pandemic caused between 100,000 and 600,000 deaths worldwide,¹³ while the 1918-1919 Spanish Flu was estimated to

¹³ <https://www.cdc.gov/flu/pandemic-resources/2009-h1n1-pandemic.html>.

have caused over 50 million deaths worldwide.¹⁴ Although advances in health care quality have greatly improved since 1918, 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 and are not considered one-time events.

The introduction of another emerging, or re-emerging, communicable disease into the United States is always a risk. The PHS Act section 362 suspension authority would be critical to any effort by CDC and its Federal, State, and local partners to contain or mitigate the risk. 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 into the United States in the event a serious danger of the introduction of 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 Secretary¹⁵ 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,¹⁶ such introduction for determined periods of time.

¹⁴ <https://www.cdc.gov/flu/pandemic-resources/1918-pandemic-h1n1.html>.

¹⁵ *See supra* at n.1.

¹⁶ *See supra* at n.2.

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.¹⁷ 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.¹⁸

¹⁷ The terms "officer of the customs" and "customs officer" are defined by statute to mean, "any officer of the United States Customs Service of the Treasury Department (also hereinafter referred to as the "Customs Service") or any commissioned, warrant, or petty officer of the Coast Guard, or any agent or other person, including foreign law enforcement officers, authorized by law or designated by the Secretary of the Treasury to perform any duties of an officer of the Customs Service." 19 U.S.C. 1401(i). Although this provision refers to the Secretary of the Treasury, the Homeland Security Act transferred to the Secretary of Homeland Security all "the functions, personnel, assets, and liabilities of . . . the United States Customs Service of the Department of the Treasury, including the functions of the Secretary of the Treasury relating thereto . . . [,]" 6 U.S.C. 203(1), such that reference to the Secretary of the Treasury should be read to reference the Secretary of Homeland Security.

¹⁸ HHS quarantine authorities also apply to vessels. *See, e.g.*, PHS Act 364 (providing for quarantine stations at anchorages and vessel quarantine inspections), 366 (providing for bills of health for vessels, authorizing issuance of regulations applicable to vessels, and certificate of a quarantine officer before a vessel can enter any U.S. port to discharge cargo or land passengers).

III. Provisions of New § 71.40

This interim final rule will implement section 362 and other applicable provisions of the PHS Act to enable the CDC Director to suspend the introduction of persons into the United States consistent with the statute and applicable law.

Section 71.40(a) sets forth the statutory requirements for the CDC Director to suspend the introduction of persons into the United States. The provision establishes that the CDC Director may prohibit the introduction into the United States of persons from designated foreign countries (or one or more political subdivisions and regions thereof) or places, only for such period of time that the Director deems necessary for the public health, by issuing an order in which the Director determines that:

(1) By reason of the existence of any communicable disease in a foreign country (or one or more political subdivisions or regions thereof) or place, there is serious danger of the introduction of such communicable disease into the United States, and

(2) This danger is so increased by the introduction of persons from such country (or one or more political subdivisions or regions thereof) or place that a suspension of the introduction of such persons into the United States is required in the interest of the public health.

Section 71.40(b) sets forth definitions of several terms used in § 71.40. CDC defines the “introduction into the United States of persons” from a foreign country (or one or more political subdivisions or regions thereof) or place” as the movement of a person from a foreign country (or one or more political subdivisions or regions thereof) or a place, or series of foreign countries or places, into the United States so as to bring the person into contact with others in the United States, or so as to cause the contamination of property in the United States, in a manner that the Director determines to present a risk of transmission of the communicable disease to persons or

property, even if the communicable disease has already been introduced, transmitted, or is spreading within the United States.

Section 362 refers to the “introduction of persons” from foreign countries. CDC defines “introduction into the United States of persons” from a foreign country (including one or more political subdivisions or regions thereof) or place to clarify that “introduction” can encompass those who have physically crossed a border of the United States and are in the process of moving into the interior in a manner the Director determines to present a risk of transmission of a communicable disease. This additional mechanism to halt the travel of such persons and rapidly moving them outside the United States constitutes preventing their “introduction” into the United States for purposes of § 71.40.

Similarly, Section 362 refers to the “introduction of [a communicable disease] into the United States.” CDC defines “serious danger of the introduction of such communicable disease into the United States” to mean the potential for introduction of vectors of the communicable disease into the United States, even if persons or property in the United States are already infected or contaminated with the communicable disease. CDC establishes this definition to clarify that, even if persons or property (*e.g.* animals) in the United States are already infected or contaminated with a communicable disease in some localities, the potential for introduction of additional vectors that would introduce, transmit, or spread the disease in the same or different localities can present a serious danger of the introduction of the disease into the United States. Suspension of the introduction of persons into the United States may be required, in the interest of public health, to avert the increased danger that results from further introduction, transmission, or spread of the disease within the United States.

Finally, for purposes of this section, CDC defines the term “place” to include any location specified by the Director, including any carrier, whatever the carrier’s nationality. CDC does this in order to remove all doubt that when this interim final rule refers to “place,” it refers not just to territory within or outside of a country, but also to carriers, as that term is defined in 42 C.F.R. 71.1, whatever the carrier’s nationality.

CDC will establish the requirement to suspend the introduction of persons into the United States from certain designated places for certain periods of time by means of an order executed by the CDC Director. In § 71.40(c), CDC describes the required contents of such order. In any § 71.40 order, the CDC Director must designate:

- The foreign countries (or one or more designated political subdivisions or regions thereof) or places from which the introduction of persons is being suspended.
- The period of time or circumstances under which the introduction of any persons or class of persons into the United States is being suspended.
- The conditions under which that prohibition on introduction should be effective in whole or in part, including any relevant exceptions that the CDC Director determines are appropriate.

CDC might at times rely on (1) State and local authorities who agree to help implement orders issued pursuant to § 71.40, or (2) other Federal agencies to implement and execute the orders issued under this section. Accordingly, in § 71.40(d), CDC establishes that, before issuing any § 71.40 order, CDC may coordinate with the appropriate State and local authorities or other Federal agency (or agencies). If the order will be implemented in whole or in part by State and local authorities under 42 U.S.C. 243(a), the Director’s order may explain the procedures and standards by which those State or local authorities are expected to aid in the

order's enforcement. Similarly, if the order will be implemented in whole or in part by designated customs officers (including officers of the Department of Homeland Security with U.S. Customs and Border Protection who exercise the authorities of customs officers) or the United States Coast Guard under 42 U.S.C. 268(b), or another Federal department or agency, the CDC Director, in coordination with the Secretary of Homeland Security or the head of the other applicable department or agency, shall explain in the order the procedures and standards by which any authorities or officers or agents are expected to aid in the enforcement of the order, to the extent that they are permitted to do so under their existing legal authorities.

Section 71.40(e) provides that this section does not apply to members of the armed forces of the United States and associated personnel for whom the Secretary of Defense provides assurance to the Director that the Secretary of Defense, through measures such as quarantine, isolation, or other measures maintaining control over such individuals, is preventing the risk of transmission of a communicable disease to persons or property in the United States. CDC includes this exception because the Secretary of Defense has authority and means to prevent the introduction of a communicable disease into the United States from his personnel returning from foreign countries. Therefore, this interim final rule need not apply to Department of Defense personnel.

Although section 362 applies to "persons," this interim final rule will not apply to U.S. citizens or lawful permanent residents. 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 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 COVID-19

caused by the introduction of U.S. citizens or lawful permanent residents into the United States. Section 71.40(f) therefore explains that this interim final rule shall not apply to U.S. citizens and lawful permanent residents. Determining the appropriate protections for U.S. citizens and lawful permanent aliens 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 COVID-19 in the United States.

V. 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 Mexico and Canada in preventing the spread of COVID-19 along our shared borders, it involves a “foreign affairs function of the United States.” 5 U.S.C. 553(a)(1).

As noted above, the United States and numerous other countries have taken unprecedented measures to try to contain or slow the transmission or spread of COVID-19. Such public health actions, especially the actions by the President and the Secretary, have slowed the

introduction and transmission of the disease into the United States, which has benefitted the public health, preserved limited public and private resources, and given 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 global travelers, and other persons crossing from one country into another country, from spreading COVID-19 across national boundaries and around the globe. The introduction of persons from foreign countries with COVID-19 outbreaks is continuing to cause the introduction of COVID-19 into disparate locations within the United States. The suspension authority is therefore critical to slowing the introduction of COVID-19 into such disparate locations within the United States. The United States is in a phase where suspending the introduction of persons from certain countries or places may be required in the interest of the public health, because it could still materially reduce the transmission and spread of COVID-19 in the United States. Because persons can have COVID-19 and be asymptomatic at the time of introduction into the United States, and because the completion of testing for COVID-19 may take three to four days, it is impracticable to confirm who is infected with COVID-19 and who is not infected with COVID-19 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 numbers of persons involved, logistical challenges, and CDC resource and personnel constraints.

In addition, whereas section 212(f) of the INA applies to the “entry” of aliens, section 362 applies to the “introduction” of persons into the United States. Therefore, although 212(f) has been effective in slowing the transmission or spread of COVID-19 in the United States, section 362 provides CDC with a mechanism tied specifically to persons who increase the danger of introducing COVID-19 into the United States.

Given the national emergency caused by COVID-19, it would be impracticable and contrary to the public health—and, by extension, the public interest—to delay these implementing regulations 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.

IV. 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 public health emergency to limit the number of new cases of COVID-19.

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 believe 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 COVID-19 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. CDC will assess the potential impacts—including economic effects—of this action on all small entities. Based on that assessment, the Secretary will either certify that the rule will not have a significant economic impact on a substantial number of small entities or publish a final regulatory flexibility analysis.

Unfunded Mandates Reform Act

¹⁹ An agency head may delay the completion of the regulatory impact analysis requirements for a period of not more than 180 days after the date of publication in the Federal Register of a final rule by publishing in the Federal Register, not later than such date of publication, a written finding, with reasons therefor, that the final rule is being promulgated in response to an emergency that makes timely compliance with such requirements impracticable. If the agency has not prepared a final regulatory analysis within 180 days from the date of publication of the final rule, the RFA provides that the rule shall lapse and have no effect and shall not be re-promulgated until a final regulatory flexibility analysis has been completed by the agency. 5 U.S.C. 608(b).

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 \$154 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, of \$154 million or more 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, Communicable diseases, Conditional release, CDC, 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. Add § 71.40 to Subpart D of part 71 to read as follows:

§ 71.40 Prohibiting the introduction of persons from designated foreign countries and places into the United States.

(a) The Director may prohibit the introduction into the United States of persons from designated foreign countries (or one or more political subdivisions and regions thereof) or places, only for such period of time that the Director deems necessary for the public health, by issuing an order in which the Director determines that:

(1) By reason of the existence of any communicable disease in a foreign country (or one or more political subdivisions or regions thereof) or place there is serious danger of the introduction of such communicable disease into the United States; and

(2) This danger is so increased by the introduction of persons from such country (or one or more political subdivisions or regions thereof) or place that a suspension of the introduction of such persons into the United States is required in the interest of the public health.

(b) For purposes of this section:

(1) *Introduction into the United States* of persons from a foreign country (or one or more political subdivisions or regions thereof) or place means the movement of a person from a foreign country (or one or more political subdivisions or regions thereof) or place, or series of foreign countries or places, into the United States so as to bring the person into contact with persons in the United States, or so as to cause the contamination of property in the United States, in a manner that the Director determines to present a risk of transmission of a communicable disease to persons or property, even if the communicable disease has already been introduced, transmitted, or is spreading within the United States;

(2) *Serious danger of the introduction of such communicable disease into the United States* means the potential for introduction of vectors of the communicable disease into the United States, even if persons or property in the United States are already infected or contaminated with the communicable disease; and

(3) The term *Place*” includes any location specified by the Director, including any carrier, as that term is defined in 42 CFR 71.1, whatever the carrier’s nationality.

(c) In any order issued under this section, the Director shall designate the foreign countries (or one or more political subdivisions or regions thereof) or places; the period of time or circumstances under which the introduction of any persons or class of persons into the United States shall be suspended; and the conditions under which that prohibition on introduction, in whole or in part, shall be effective, including any relevant exceptions that the Director determines are appropriate.

(d) Before issuing any order under this section, the Director may coordinate with State and local authorities and other Federal departments or agencies as he deems appropriate in his discretion.

(1) If the order will be implemented in whole or in part by State and local authorities who have agreed to do so under 42 U.S.C. 243(a), then the Director may explain in the order the procedures and standards by which those authorities are expected to aid in the enforcement of the order.

(2) If the order will be implemented in whole or in part by designated customs officers (including officers of the Department of Homeland Security with U.S. Customs and Border Protection, who exercise the authorities of customs officers) or Coast Guard officers under 42 U.S.C. 268(b), or another Federal department or agency, then the Director shall, in coordination with the Secretary of Homeland Security or other applicable Federal department or agency head,

explain in the order the procedures and standards by which any authorities or officers or agents are expected to aid in the enforcement of the order, to the extent that they are permitted to do so under their existing legal authorities.

(e) This section does not apply to members of the armed forces of the United States and associated personnel for whom the Secretary of Defense provides assurance to the Director that the Secretary of Defense, through measures such as quarantine, isolation, or other measures maintaining control over such individuals, is preventing the risk of transmission of a communicable disease into the United States.

(f) This section shall not apply to U.S. citizens and lawful permanent residents.

Alex M. Azar II,

Secretary,

Department of Health and Human Services.

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