

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 the Right To Introduce and Prohibition 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: Final rule.

SUMMARY: The Department of Health and Human Services (HHS) issues this final rule to amend the Foreign Quarantine Regulations administered by the Centers for Disease Control and Prevention (CDC). This final rule provides a procedure for the CDC Director to suspend the right to introduce and prohibit introduction, in whole or in part, of persons from such foreign countries or places as the Director shall designate in order to avert the danger of the introduction of a quarantinable communicable disease into the United States, and for such period of time as the Director may deem necessary for such purpose.

DATES: This final rule is effective on October 13, 2020.

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I. Summary

This final rule is effective on October 13, 2020, unless the interim final rule (IFR) entitled *Control of Communicable Diseases; Foreign Quarantine: Suspension of Introduction of Persons Into United States From Designated Foreign Countries or Places for Public Health Purposes* (85 FR 16559) (Mar. 24, 2020), or the Centers for Disease Control

& Prevention’s (CDC) Order on covered aliens, *Control of Communicable Diseases; Foreign Quarantine: Suspension of Introduction of Persons into United States from Designated Foreign Countries or Places for Public Health Purposes*, (85 FR 16559) (Mar. 24, 2020), as amended, is vacated or enjoined by a court, in which case, the Secretary will publish a document in the **Federal Register** announcing an updated effective date for this rule.

The U.S. Department of Health and Human Services (HHS) finalizes the interim final rule (IFR) entitled *Control of Communicable Diseases; Foreign Quarantine: Suspension of Introduction of Persons Into United States From Designated Foreign Countries or Places for Public Health Purposes* (85 FR 16559) published on March 24, 2020, to implement section 362 of the Public Health Service (PHS) Act, 42 U.S.C. 265.

HHS/CDC implements section 362 because the Surgeon General’s statutory authority under section 362 passed by operation of law to the Secretary of Health and Human Services (HHS Secretary),¹ who delegated his or her statutory authority to the CDC Director (Director).

Through this rulemaking, HHS/CDC establishes final regulations under which the Director may suspend the right to introduce and prohibit, in whole or in part, the introduction of persons into the United States for such period of time as the Director may deem necessary to avert the serious danger of the introduction of a quarantinable communicable disease into the United States. This rulemaking does not address the “property” prong of the statute because existing regulations already do so. The final rule uses the term “quarantinable communicable disease” instead of “communicable disease” to specify that this regulation is only meant to apply to communicable diseases that are included on the

¹ The statute assigns this authority to the Surgeon General of the Public Health Service. Nevertheless, 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 8855–01, 80 Stat. 1610 (June 25, 1966), *see also* Public Law 96–88, Sec. 509(b), October 17, 1979, 93 Stat. 695 (codified at 20 U.S.C. Sec. 3508(b)). Sections 361 through 369 of the PHS Act (42 U.S.C. Sec.’s 264–272) have been delegated from the HHS Secretary to the CDC Director. 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.

Federal list of quarantinable communicable diseases, which is a subset of “communicable diseases” specified by Executive Order of the President.² Specifically, this final rule permits the Director to prohibit, in whole or in part, the introduction into the United States of persons from designated foreign countries (or one or more political subdivisions or regions thereof) or places, only for such period of time that the Director deems necessary to avert the serious danger of the introduction of a quarantinable communicable disease, by issuing an Order in which the Director determines that:

(1) By reason of the existence of any quarantinable 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 quarantinable 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 right to introduce such persons into the United States is required in the interest of public health.

The final rule defines key statutory and regulatory language to clarify when and under what circumstances the Director may exercise the section 362 authority by issuing an administrative Order. The regulatory text of this final rule sets forth only definitions and procedures. No action can or will be taken under this final rule absent an administrative Order issued by the Director.

First, the final rule defines “introduction into the United States” of persons to mean 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 or property in the United States, in a manner that the Director determines to present a risk of transmission of a quarantinable communicable disease to persons, or a risk of contamination of property with

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

This definition clarifies that “introduction” does not necessarily conclude the instant that a person first steps onto U.S. soil. The introduction of a person into the United States can occur not only when a person first steps onto U.S. soil, but also when a person on U.S. soil moves further into the United States, and begins to come into contact with persons or property in ways that increase the risk of transmitting the quarantinable communicable disease. A person’s presence in the United States may still constitute a violation of a section 362 Order regardless of the length of time the person has been present in the country in direct contravention of the Order.

The final rule next defines “[p]rohibit, in whole or in part, the introduction into the United States of persons” to mean “to prevent the introduction of persons into the United States by suspending any right to introduce into the United States, physically stopping or restricting movement into the United States, or physically expelling from the United States some or all of the persons.” This is consistent with the text and legislative history of the statute. Congress sought to provide the Executive Branch, to the maximum extent allowed under the Constitution, the power to prevent the introduction of communicable diseases into the country. The power to expel is critical to upholding the intent of Congress in situations where neither HHS/CDC, nor other Federal agencies, nor state or local governments have the facilities and personnel necessary to quarantine, isolate, or conditionally release the number of persons who would otherwise increase the serious danger of the introduction of the communicable disease into the United States. In those situations, the rapid expulsion of persons from the United States may be the most effective public health measure that HHS/CDC can implement within the finite resource of HHS/CDC and its Federal, State, and local partners. Absent the power to expel, the problem that Congress sought to avoid—the introduction of communicable diseases—may occur despite the best efforts of HHS/CDC.

The final rule defines “serious danger of the introduction of such quarantinable communicable disease into the United States” as “the probable introduction of one or more persons capable of transmitting the

quarantinable communicable disease into the United States, even if persons or property in the United States are already infected or contaminated with the quarantinable communicable disease.” The final rule recognizes that people may be capable of transmitting a quarantinable communicable disease without actually knowing it, and their movement may result in the transmission of the disease to others. This regulatory definition clarifies that, even if persons in the United States are already infected with a quarantinable communicable disease, the probable introduction of additional persons capable of transmitting the disease in the same or different localities nevertheless presents a serious danger of the introduction of the disease into the United States. This clarification is informed by HHS/CDC’s experience during the coronavirus disease 2019 (COVID–19) pandemic and the Federal government’s past use of section 362 and its predecessor statute. Because COVID–19 meets the definition for a severe acute respiratory syndrome, it is included in those quarantinable communicable diseases identified by Executive Order.

This final rule defines “place” to mean “any location specified by the Director, including any carrier, as that term is defined in 42 CFR 71.1, whatever the carrier’s flag, registry, or country of origin.” This definition clarifies that when HHS refers to “place” in this final rule, it refers to territories within or outside of a country, and also to carriers, regardless of the carrier’s flag, registry, or country of origin. A “carrier” is defined in 42 CFR 71.1 to mean “a ship, aircraft, train, road vehicle, or other means of transport, including military.”

This final rule defines “suspension of the right to introduce” to mean to cause the temporary cessation of the effect of any law, rule, decree, or order pursuant to which a person might otherwise have the right to be introduced or seek introduction into the United States.³

³ Aliens who are outside the United States have no right to entry under either the Constitution or the immigration laws. *See, e.g.*, 8 U.S.C. Sec. 1225(a)(1) (defining “applicant for admission” as an alien “who arrives in the United States”); *Sale v. Haitian Ctrs. Council, Inc.*, 509 U.S. 155, 173 (1993) (“the presumption that Acts of Congress do not ordinarily apply outside our borders would support an interpretation of [a provision providing for deportation proceedings] as applying only within United States territory.”); *United States ex. rel. Knauff v. Shaughnessy*, 338 U.S. 537, 542 (1950) (“At the outset we wish to point out that an alien who seeks admission to this country may not do so under any claim of right. Admission of aliens to the United States is a privilege granted by the sovereign United States Government. Such privilege is

² Exec. Order 13295 (Apr. 4, 2003), as amended by Exec. Order 13375 (Apr. 1, 2005) and Exec. Order 13674 (July 31, 2014) (the current list of diseases includes cholera, diphtheria, infectious tuberculosis, plague, smallpox, yellow fever, viral hemorrhagic fevers (including Lassa, Marburg, Ebola, Crimean-Congo, South American, and others not yet isolated or named), severe acute respiratory syndromes (including Middle East Respiratory Syndrome and COVID–19), and influenza caused by novel or reemerging influenza viruses that are causing, or have the potential to cause a pandemic).

Congress's use of the terms "suspension" and "right to introduce"—rather than just "introduce"—means that that section 362 grants the Director the authority to temporarily suspend the effect of any law, rule, decree, or order by which a person would otherwise have the right to be introduced or seek introduction into the U.S. The legislative history indicates that Congress, in enacting section 362's predecessor, sought to give the Executive Branch the authority to suspend immigration when required in the interest of public health. This authority is available only in rare circumstances when "required in the interest of the public health." 42 U.S.C. 265.

This final rule also sets out the information that the Director must include in any order issued pursuant to this final rule. The Director must, as practicable, consult with relevant Federal departments and agencies and provide them with a copy of any order before issuing the order, and provide guidance to the affected agencies regarding implementation of any orders issued pursuant to this final rule. Any such order must include a statement of the following:

- (1) The foreign countries (or one or more political subdivisions or regions thereof) or places from which the introduction of persons is being prohibited;
- (2) the period of time or circumstances under which the introduction of any persons or class of persons into the United States is being prohibited;
- (3) the conditions under which that prohibition on introduction will be effective, in whole or in part, including any relevant exceptions that the Director determines are appropriate;
- (4) the means by which the prohibition will be implemented; and
- (5) the serious danger posed by the introduction of the quarantinable communicable disease in the foreign country or countries (or one or more political subdivisions or regions thereof) or places from which the introduction of persons is being prohibited.

The Director may also provide that certain persons are excepted in an order. For example, the Director may except: aliens whose travel falls within the scope of section 11 of the United Nations Headquarters Agreement or who would otherwise be allowed entry into the United States pursuant to U.S. obligations under applicable international agreements; diplomatic

granted to an alien only upon such terms as the United States shall prescribe.”).

travelers; U.S. government employees; and those travelling for humanitarian purposes. The Director may also provide in an Order that another Federal agency or a state or local government implementing the order may carry out the exception in the Order under certain circumstances.

II. Policy Rationale and Factual Basis for Final Rule

This final rule is critical to protecting U.S. public health because Federal Orders requiring the quarantine,⁴ isolation,⁵ or conditional release⁶ of persons arriving into the United States from foreign countries may be inadequate to protect public health from the serious danger of the introduction into the United States of a quarantinable communicable disease. Simply put, quarantine, isolation, and conditional release have practical limitations. Federal quarantine and isolation permitted under section 361 of the PHS Act—where HHS/CDC funds and operates residential facilities with 24-hour wrap-around services for persons arriving into the United States from a foreign country—may be scalable and effective for hundreds of persons, but not thousands of them. Even then, Federal quarantine and isolation require substantial resources and are not sustainable for extended periods of time. Ordering a conditional release or, alternatively, recommending that individuals self-isolate or self-quarantine at home or elsewhere without direct public health supervision, requires fewer government resources and can be scalable and sustainable for larger populations. Conditional release orders and recommendations to self-isolate or self-quarantine may be effective for persons who have a home (or similar residence) in the United States and can provide complete and accurate contact information for use in monitoring and contact tracing by State or local public health officials. But such public health

⁴ Under 42 CFR Sec. 71.1(b), quarantine means the separation of an individual or group reasonably believed to have been exposed to a quarantinable communicable disease, but who is/are not yet ill, from others who have not been so exposed, to prevent the possible spread of the quarantinable communicable disease.

⁵ Under 42 CFR Sec. 71.1(b), isolation means the separation of an individual or group who is reasonably believed to be infected with a quarantinable communicable disease from those who are healthy to prevent the spread of the quarantinable communicable disease.

⁶ Under 42 CFR Sec. 71.1(b), conditional release means surveillance as defined under part 71 and includes public health supervision through in-person visits by a health official or designee, telephone, or through any electronic or internet-based means as determined by the Director.

measures may be ineffective for persons who lack a home (or similar residence) in the United States or contact information that is usable by public health authorities.

The issuance of conditional release orders, or recommendations to self-isolate or self-quarantine, may also be inadequate if the persons arriving into the United States must first spend time in congregate settings—such as on carriers or in certain government facilities. In congregate settings, travelers infected with a quarantinable communicable disease (whether asymptomatic or symptomatic) may spread the disease to other travelers or government personnel or private sector workers, who may, in turn, spread disease to the domestic population. In such a scenario, the subsequent separation of the original, infected traveler would not mitigate the spread of disease through other individuals who interacted with the traveler in the congregate setting.

Congress provided the Secretary an additional tool for protecting public health when a communicable disease exists in a foreign country and there is a serious danger of the introduction of the disease into the United States under section 362. As the Secretary's delegate, the Director may exercise his or her section 362 authority to avert the serious danger of the introduction of the disease by issuing an order suspending the right to introduce and prohibiting the introduction of persons from a foreign country or place. The Director has the flexibility to prohibit the introduction of some persons under section 362, while issuing orders for the quarantine, isolation, or conditional release of other persons under section 361 of the PHS Act and its implementing regulations. To achieve the purpose of section 362, the Director also has the discretion to tailor the exercise of the section 362 authority to the specific danger, which may turn on epidemiological factors, as well as the time, setting, and geographic location of the danger. This final rule establishes a flexible procedure for tailoring the exercise of the section 362 authority in response to the current COVID-19 pandemic and to address future public health threats.

The policy rationale for this final rule is grounded in HHS/CDC's experience during the COVID-19 pandemic. When HHS/CDC has acted to prevent the movement of potentially exposed persons and property into the United States, as described below, HHS/CDC has slowed the introduction of COVID-19 into the United States and reduced the exposure of government personnel

and private sector workers in congregate settings to COVID-19. HHS/CDC has also conserved the finite government resources available for the domestic response to the COVID-19 pandemic.

HHS/CDC's actions regarding the U.S. Department of Homeland Security's (DHS) U.S. Customs and Border Protection (CBP) facilities at or near the U.S. borders with Canada and Mexico, which are discussed more fully below, are one example of how this final rule enables HHS/CDC to mitigate the serious danger of the introduction of a quarantinable communicable disease into the United States. COVID-19 is present in Canada and Mexico, and there is a serious danger that persons traveling from those countries will introduce COVID-19 into CBP facilities, and ultimately the interior of the United States. CBP facilities are not structured or equipped for quarantine, isolation, or social distancing during a pandemic involving a highly contagious disease such as COVID-19. In particular, Border Patrol stations were designed for the purpose of short-term holding in a congregate setting, and those facilities generally lack the areas needed to quarantine or isolate aliens for COVID-19. The Director determined that measures such as quarantine, isolation, and social distancing would be a challenge to conduct and sustain at CBP facilities, as acknowledged in the CDC Interim Guidance on Management of Coronavirus Disease 2019 (COVID-19) in Correctional and Detention Facilities.⁷ He was concerned that infected aliens in the congregate areas of the CBP facilities might spread COVID-19 to others in the same areas. Such spread of COVID-19 within CBP facilities might result in CBP personnel needing to self-quarantine or self-isolate (or worse, cause them to become seriously ill or die), potentially degrading the ability of CBP to perform all functions necessary to fulfill its mission, and increasing the strain on local healthcare systems. The Director mitigated the public health risks in CBP facilities—and the potential downstream risks to U.S. public health and national security more broadly—by issuing an Order under section 362 prohibiting the introduction of certain “covered aliens” into CBP facilities.

HHS/CDC actions regarding cruise ships are another example of how preventing the movement of potentially

exposed persons into the United States has slowed the introduction of COVID-19 into the United States. In early 2020, cruise ships carrying thousands of crew and passengers were continuing to travel between international ports. As crew and passengers became infected with COVID-19, disembarkation in major U.S. port cities presented a danger of introduction of COVID-19 into the United States. HHS/CDC and other Federal, state, and local agencies deployed hundreds of personnel to disembark and quarantine or isolate travelers. This intervention averted the danger presented by those travelers who entered quarantine or isolation at Federal sites, but it was not sustainable operationally because of the resources needed to maintain it. Nor did such efforts mitigate COVID-19 transmission on cruise ships generally, or the continuing risk of cruise ships introducing COVID-19 into U.S. ports. HHS/CDC therefore exercised its authorities under sections 361 and 365 of the PHS Act to issue a *No Sail Order and Suspension of Further Embarkation* (85 FR 16628), published on March 14, 2020,⁸ to “prevent the spread of disease and ensure cruise ship passenger and crew health.”

Another policy rationale for this final rule is that it addresses the ever-present risk that future pandemics may present new or different challenges that demand the prompt exercise of the section 362 authority. A new virus could have a longer incubation period than severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (the virus that causes COVID-19) or cause a disease that takes longer to run its course.⁹ In such scenarios, the issuance and maintenance of Federal quarantine, isolation, and conditional release orders would consume even more resources than the 2020 interventions with cruise ships. HHS/CDC would need to have a rule implementing section 362 in place to promptly implement public health measures tailored to the danger presented by the virus. Those measures could include quarantine, isolation, or conditional release under section 361,

⁸ This Order was subsequently modified and extended on April 9, 2020 (effective, April 15, 2020) (85 FR 21004, (Apr. 15, 2020)) and July 16, 2020 (85 FR 44805, (July 21, 2020)).

⁹ HHS/CDC's experience with other viruses informs this concern. Notably, Ebola has an incubation period of 2–21 days. See Estimating the Future Number of Cases in the Ebola Epidemic—Liberia and Sierra Leone, 2014–2015, 63 MMWR Supplement 5, Ctrs. for Disease Control & Prevention, <https://www.cdc.gov/mmwr/preview/mmwrhtml/su6303a1.htm> (last updated Sep. 26, 2014) (The mean incubation period for Ebola is 6.3 days, with a median of 5.5 days and a 99th percentile at 21 days).

prohibition of the introduction of persons under section 362, or some combination of the two.

The policy rationale and factual basis for this final rule are detailed further below.

A. HHS/CDC's Experience Is That Travel and Migration Can Impact the Spread of Quarantinable Communicable Diseases

Medical and scientific knowledge have increased dramatically in the past century. But so have international travel and migration, which play a significant role in the global transmission of quarantinable communicable diseases that pose risks for vulnerable populations.¹⁰ Travelers can transmit quarantinable communicable diseases without actually knowing it, and thereby increase the risk of introduction of quarantinable communicable diseases into the United States. The risk increases significantly when travelers are in congregate settings, such as terminals or carriers with shared sitting, sleeping, eating, or recreational areas, all of which may be conducive to disease transmission.¹¹

The speed and far reach of global travel have been factors in prior outbreaks that expanded to numerous continents.¹² Examples include: Severe Acute Respiratory Syndrome (SARS), caused by a coronavirus (SARS-CoV) in

¹⁰ See, e.g., Institute of Medicine (US) Forum on Microbial Threats, *Infectious Disease Movement in a Borderless World: Workshop Summary*, Nat'l Acad.'s 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*, 1 Emerging Infectious Diseases 2, 39–46 (1995), (available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2626831/>); Tatem, A.J., Rogers, D.J. & Hay, S., *Global Transport Networks and Infectious Disease Spread*, *Adv. Parasitology* 62, 293–343 (2006), (available at: <https://www.researchgate.net/publication/7133296>).

¹¹ See, e.g., *Travelers' Health: Cruise Ship Travel*, Chapter 8, Ctrs. for Disease Control & Prevention, <https://wwwnc.cdc.gov/travel/yellowbook/2020/travel-by-air-land-sea/cruise-ship-travel> (last updated June 24, 2019) (noting that the “often crowded, semi-enclosed environments onboard ships can facilitate the spread of person-to-person, foodborne, or waterborne diseases”); *Public Health Guidance for Potential Exposure to COVID-19 Associated with International or Domestic Travel*, Ctrs. for Disease Control & Prevention, <https://www.cdc.gov/coronavirus/2019-ncov/php/risk-assessment.html> (last updated Aug. 6, 2020).

¹² 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 Nat'l Acad. of Sci.* 2004;101(42):15124–15129).

⁷ *Interim Guidance on Management of Coronavirus Disease 2019 (COVID-19) in Correctional and Detention Facilities*, Ctrs. for Disease Control and Prevention, <https://www.cdc.gov/coronavirus/2019-ncov/community/correction-detention/guidance-correctional-detention.html> (last updated Jul. 22, 2020).

2003; the H1N1 influenza pandemic in 2009; tuberculosis; measles; Middle East Respiratory Syndrome (MERS) caused by a coronavirus (MERS-CoV) in 2012; and Ebola virus disease in 2014 and 2018. All of these diseases posed significant public health risks, especially given how quickly the diseases spread.

The 2009–2010 H1N1 influenza pandemic is particularly relevant to this final rule. Although the virus was first identified mid-April 2009 in the United States, the initial cases of 2009 H1N1 influenza occurred in Mexico, and by late April 2009 transmission of the virus in Mexico involved person-to-person spread with multiple generations of transmission.¹³ The first two cases of a novel H1N1 influenza were discovered in San Diego County, California, and Imperial County, California.¹⁴ While San Diego and Imperial Counties are roughly 100 miles apart, both are less than 25 miles from the U.S.-Mexico border, which suggested cross-border transmission of the disease. Soon after, public health officials discovered additional H1N1 cases in the two California counties and two H1N1 cases in Texas, another border State.¹⁵ At the same time, CDC identified the novel virus in samples from Mexico, some of which had been collected from patients who were ill before the first two U.S. patients, which suggested cross-border transmission of the disease.¹⁶ Subsequent epidemiologic investigations indicated that outbreaks had occurred in Mexico in March and early April 2009, and that by the end of April the disease was widespread in Mexico; cases had also been identified in Canada.¹⁷ HHS/CDC estimates that

between April 12, 2009, and April 10, 2010, approximately 60.8 million cases, 274,304 hospitalizations, and 12,469 deaths occurred in the United States due to H1N1 influenza.¹⁸ It is possible that had HHS/CDC suspended the introduction of persons from Mexico into the United States early in the pandemic, fewer individuals might have fallen ill or died from H1N1 influenza.

Global travel has increased since the H1N1 influenza pandemic. By 2018, international visits to the United States totaled almost 25 million more per year than in 2009, when the H1N1 influenza pandemic occurred, and approximately 5 million more per year than in 2014, when the Ebola virus disease outbreak occurred.¹⁹ Despite the decrease in travel in 2020 due to COVID–19 concerns, HHS/CDC expects that the procedures in this final rule will be vital to public health going forward.

B. The Response of the United States to the Coronavirus Disease 2019 (COVID–19) Pandemic Shows That This Final Rule Is in the Interest of U.S. Public Health

Since the COVID–19 pandemic began, the United States has undertaken a variety of actions to limit the movement of persons into the country and thereby mitigate the danger of the introduction of COVID–19 into the country. Those actions have included the Director's exercise of the section 362 authority and have proven effective notwithstanding the contagiousness of COVID–19. This rulemaking finalizes procedures that the Director needs to exercise the section 362 authority and protect public health now and in the future.

1. COVID–19 Is a Highly Contagious Disease That Threatens Vulnerable Populations

Because the CDC Director has determined that COVID–19 meets the definition of a severe acute respiratory syndrome as listed in Executive Order 13674, COVID–19 is a quarantinable communicable disease. It is 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 the city of Wuhan in the Hubei Province of the People's Republic of China (PRC) in late 2019 and quickly spread worldwide. On January 30, 2020, the World Health Organization (WHO) declared that the outbreak of COVID–19 is a Public Health Emergency of International Concern.²⁰ The following day, the Secretary of HHS declared COVID–19 a public health emergency under the PHS Act.²¹ 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.²²

As of August 24, 2020, there were 23,057,288 confirmed cases worldwide. COVID–19 has caused over 800,000 deaths globally,²³ compared to 774 global deaths from the 2003 SARS outbreak,²⁴ 866 global deaths from MERS between April 2012 and January 2020,²⁵ and an estimated 151,700 to 575,400 deaths during the first year of the 2009 H1N1 influenza pandemic.²⁶ Compared to other respiratory diseases, the mortality scale of the COVID–19 pandemic is surpassed in modern times only by the 1918 influenza pandemic, which claimed an estimated 50 million lives around the world.²⁷

While much is still unknown about the transmission of COVID–19, it is

²⁰ WHO Director-General's statement on IHR Emergency Committee on Novel Coronavirus (2019-nCoV) (Jan. 30, 2020), WHO, [https://www.who.int/dg/speeches/detail/who-director-general-statement-on-ih-er-emergency-committee-on-novel-coronavirus-\(2019-ncov\)](https://www.who.int/dg/speeches/detail/who-director-general-statement-on-ih-er-emergency-committee-on-novel-coronavirus-(2019-ncov)) (last visited Aug. 27, 2020).

²¹ Determination that a Public Health Emergency Exists, U.S. Dep't of Health & Human Serv.'s (Jan. 31, 2020), <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>.

²² Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID–19) Outbreak, The White House (Mar. 13, 2020), <https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>.

²³ WHO Sit. Rep. 205 (Aug. 24, 2020), WHO, https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200812-covid-19-sitrep-205.pdf?sfvrsn=627c9aa8_2.

²⁴ Severe Acute Respiratory Syndrome (SARS): SARS Basics Fact Sheet, Ctrs. for Disease Control & Prevention, <https://www.cdc.gov/sars/about/fs-sars.html> (last updated Dec. 6, 2017).

²⁵ MERS situation update, January 2020, WHO, <http://www.emro.who.int/pandemic-epidemic-diseases/mers-cov/mers-situation-update-january-2020.html> (last visited Aug. 27, 2020).

²⁶ Influenza (Flu): 2009 H1N1 Pandemic (H1N1pdm09 virus), Ctrs. for Disease Control & Prevention, <https://www.cdc.gov/flu/pandemic-resources/2009-h1n1-pandemic.html> (last updated June 11, 2019).

²⁷ *Id.*; *The Deadliest Flu: The Complete Story of the Reconstruction of the 1918 Pandemic Virus*, Ctrs. for Disease Control & Prevention, <https://www.cdc.gov/flu/pandemic-resources/reconstruction-1918-virus.html> (last updated Dec. 17, 2019).

¹³ Outbreak of Swine-Origin Influenza A (H1N1) Virus Infection—Mexico, March–April 2009, Ctrs. for Disease Control & Prevention, <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5817a5.htm> (last updated June 16, 2010); *The 2009 H1N1 Pandemic: Summary Highlights, April 2009–April 2010*, Ctrs. for Disease Control & Prevention, <https://www.cdc.gov/h1n1flu/cdcresponse.htm> (last updated Aug. 3, 2010).

¹⁴ Swine Influenza A (H1N1) Infection in Two Children—Southern California, March–April 2009, Ctrs. for Disease Control & Prevention, <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5815a5.htm> (last updated Apr. 22, 2009).

¹⁵ Update: Swine Influenza A (H1N1) Infections—California and Texas, April 2009, 16 MMWR Morb Mortal Wkly Rep. 58, 435–37 (May 2009), (available at: <https://pubmed.ncbi.nlm.nih.gov/19407739/>); *The 2009 H1N1 Pandemic: Summary Highlights, April 2009–April 2010*, Ctrs. for Disease Control & Prevention, <https://www.cdc.gov/h1n1flu/cdcresponse.htm> (last updated Aug. 3, 2010).

¹⁶ *The 2009 H1N1 Pandemic: Summary Highlights, April 2009–April 2010*, Ctrs. for Disease Control & Prevention, <https://www.cdc.gov/h1n1flu/cdcresponse.htm> (last updated Aug. 3, 2010).

¹⁷ Outbreak of Swine-Origin Influenza A (H1N1) Virus Infection—Mexico, March–April 2009, Ctrs. for Disease Control & Prevention, <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5817a5.htm> (last updated May 7, 2009).

¹⁸ Sundar S. Shrestha, et al., *Estimating the burden of 2009 pandemic influenza A (H1N1) in the United States (April 2009–April 2010)*, Clin. Infect. Dis. 2011 Jan 1;52 Suppl 1:S75–82.

¹⁹ See *Fast Facts: United States Travel and Tourism Industry—2009, 2014 and 2018*, Int'l Trade Admin., (available at: https://travel.trade.gov/outreachpages/download_data_table/Fast_Facts_2009.pdf; https://travel.trade.gov/outreachpages/download_data_table/Fast_Facts_2014.pdf; https://travel.trade.gov/outreachpages/download_data_table/Fast_Facts_2018.pdf).

clear that COVID-19 is highly contagious. HHS/CDC estimates that the viral transmissibility (R_0) of COVID-19 is around 2.5, but may be as high as 4, meaning that a single infected person will on average infect between 2 to 4 others. Identifying those infected with COVID-19 can be difficult, as asymptomatic cases are currently believed to represent roughly 40% of all COVID-19 infections. The infectiousness of asymptomatic individuals is believed to be about 75% of the infectiousness of symptomatic individuals. HHS/CDC's current best estimate is that between 40 to 50% of infections are transmitted prior to symptom onset (pre-symptomatic transmission).²⁸

Symptoms of COVID-19 may include fever or chills, cough, shortness of breath or difficulty breathing, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, and diarrhea, and typically appear 2–14 days after exposure to the virus.²⁹ Manifestations of severe disease include severe pneumonia, acute respiratory distress syndrome (ARDS), septic shock, and multi-organ failure.³⁰ Mortality rates are higher among seniors and those with certain underlying medical conditions, such as chronic obstructive pulmonary disease (COPD), serious heart conditions, cancer, Type 2 diabetes, and those with compromised immune systems.³¹ There are large differences in fatality rate among age and race cohorts.³²

Early data suggest older people are more likely to have serious COVID-19 illness, with 8 out of 10 COVID-19-related deaths in the United States being

among adults over the age of 65.³³ The congregate care settings of nursing homes and long-term care facilities, where people reside in confined areas with staff rotating through, increases the risk of COVID-19 transmission. As of August 16, 2020, an estimated 49,871 nursing home residents died of COVID-19 in the United States,³⁴ representing approximately 30% of all deaths in the United States.³⁵ Prompt identification and isolation of infected persons is key to reduce further transmission in congregate settings.

2. The United States Has Taken Broad Actions To Slow the Introduction of COVID-19 Into the Country and Protect Vulnerable Populations

The United States has taken numerous actions to avert the cross-border transmission of COVID-19, including presidential proclamations suspending entry into the United States by certain foreign nationals, bringing home U.S. citizens and lawful permanent residents (LPRs) from around the world, quarantine or isolation of repatriates and cruise ship travelers, the CDC "No Sail Order" limiting cruise ship operations, temporarily limiting travel from Mexico and Canada into the United States along the United States-Mexico and United States-Canada land borders to "essential travel," and the CDC Order prohibiting the introduction of covered aliens into CBP facilities. HHS/CDC believes that the Federal quarantine and isolation may have slowed the introduction and spread of COVID-19 into the United States. But they consumed unsustainable levels of government resources in the process. In contrast, the actions taken to prevent the movement of potentially infected persons or contaminated articles into the United States have reduced the danger of COVID-19 to government personnel and private sector workers in congregate settings, and reduced the danger of the introduction of COVID-19 into the United States, while consuming more sustainable levels of government resources. The balance between the costs and benefits of actions taken to

prevent the movement of potentially infected persons or contaminated articles into the United States is one of the reasons why this final rule implementing the section 362 authority is vital to U.S. public health now and in the future.

a. Immigration and Nationality Act Section 212(f) Proclamations

The President has exercised his authority under section 212(f) of the Immigration and Nationality Act (INA), 8 U.S.C. 1182(f), and other applicable law, to issue a series of proclamations suspending entry into the country of certain aliens who were physically present in the 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), the Republic of Ireland, or the Federative Republic of Brazil within 14 days preceding their entry or attempted entry into the United States. In the proclamations, the President determined that the foreign countries were experiencing widespread person-to-person transmission of COVID-19, and the United States was "unable to effectively evaluate and monitor" travelers entering from the foreign countries, which "threaten[ed] the security of our transportation system and infrastructure and the national security," and that the unrestricted entry of foreign nationals who were physically present in those countries was therefore detrimental to the interests of the United States.³⁶ The proclamations are the first use of the 212(f) authority aimed at averting the introduction of a communicable disease into the country.³⁷

The Director assesses that the proclamations probably mitigated the introduction of COVID-19 into the United States. By suspending the entry of thousands of aliens from countries with widespread, ongoing person-to-person transmission of COVID-19, the President reduced the number of infected persons who could enter the country. As previously discussed, a

²⁸ *COVID-19 Pandemic Planning Scenarios: Updated July 10, 2020*, Ctrs. for Disease Control & Prevention, <https://www.cdc.gov/coronavirus/2019-ncov/hcp/planning-scenarios-h.pdf>.

²⁹ *Coronavirus Disease 2019 (COVID-19): Symptoms of Coronavirus*, Ctrs. for Disease Control & Prevention, <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html> (last updated May 13, 2020).

³⁰ Sevim Zaim, et al., *COVID-19 and Multiorgan Response*, 00 *Current Problems in Cardiology* 2020, (available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7187881/pdf/main.pdf>).

³¹ *Coronavirus Disease 2019 (COVID-19): People with Certain Medical Conditions*, Ctrs. for Disease Control & Prevention, https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fneed-extra-precautions%2Fgroups-at-higher-risk.html (last updated July 30, 2020).

³² See *National Center for Health Statistics: Weekly Updates by Select Demographic and Geographic Characteristics—Provisional Death Counts for Coronavirus Disease 2019 (COVID-19)*, Ctrs. for Disease Control & Prevention, https://www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.htm (last visited Aug. 31, 2020).

³³ *Coronavirus Disease 2019 (COVID-19): Older Adults*, Ctrs. for Disease Control & Prevention, <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/older-adults.html> (last updated Aug. 16, 2020).

³⁴ *COVID-19 Nursing Home Data*, Ctrs. for Medicare and Medicaid Serv.'s (submitted data as of week ending Aug. 16, 2020), <https://data.cms.gov/stories/s/COVID-19-Nursing-Home-Data/bkwz-xpvg/> (last visited Sep. 1, 2020).

³⁵ Based on 167,201 total deaths in the United States. See WHO Sit. Rep. 209, WHO (Aug. 16, 2020), https://www.who.int/docs/default-source/coronavirus/situation-reports/20200816-covid-19-sitrep-209.pdf?sfvrsn=5dde1ca2_2.

³⁶ Proclamation No. 10042, 85 FR 32291 (May 28, 2020) (amending Proclamation 10041); Proclamation No. 10041, 85 FR 31933 (May 28, 2020) (Federative Republic of Brazil); Proclamation No. 9996, 85 FR 15341 (Mar. 18, 2020) (United Kingdom and Republic of Ireland); Proclamation No. 9993, 85 FR 15045 (Mar. 15, 2020) (Schengen Area); Proclamation No. 9992, 85 FR 12855 (Mar. 4, 2020) (Islamic Republic of Iran); Proclamation No. 9984, 85 FR 6709 (Feb. 5, 2020) (PRC).

³⁷ Ben Harrington, CONG. RSCH. SERV., *LSB10458, Presidential Actions to Exclude Aliens Under INA § 212 (f)* (May 4, 2020) (available at: <https://crsreports.congress.gov/product/pdf/LSB/LSB10458>).

single infected person will on average infect between 2 to 4 others. Therefore, the reduction in the number of infected persons entering the United States probably helped prevent a larger number of people in the United States from becoming infected with COVID-19.

b. Quarantine and Isolation of Repatriates and Cruise Ship Travelers

One of the United States' early initiatives in response to the COVID-19 pandemic was to repatriate U.S. citizens (and their immediate family members) from Hubei Province, PRC, which was then the epicenter of the pandemic.³⁸ It took place in January and February 2020, and HHS/CDC is unaware of a repatriation and quarantine operation in the modern history of the United States that matched the initiative in size and scope. It involved numerous HHS agencies, including CDC, the Office of the Assistant Secretary for Preparedness and Response (ASPR), the Office of the Assistant Secretary for Financial Resources (ASFR), the U.S. Public Health Service Commissioned Corps (PHSCC), and the Administration for Children and Families (ACF).³⁹ It also involved the U.S. Department of State, the U.S. Department of Homeland Security (DHS), and the Department of Defense (DOD), as well as various State agencies.⁴⁰

The operation required the agencies to secure charter flights from the PRC to the United States, secure and prepare appropriate facilities to house individuals, transport individuals to and from these facilities, implement infection-control and infection-prevention measures at the facilities, test and medically monitor individuals, and provide "wrap-around" services for individuals (e.g., food and other necessary personal services).⁴¹ The

agencies had to secure sites because the Federal government no longer operates Public Health Service hospitals capable of acting as dedicated quarantine and isolation facilities able to house hundreds of people for multiple weeks.⁴² The securing of sites was challenging because when the agencies identified suitable facilities, local officials sometimes objected to the use of the facilities.⁴³ To provide housing for the repatriates, the agencies ultimately secured military facilities for use as quarantine sites, hotels for use as isolation sites, and beds at hospitals for persons who required medical care. Those sites accepted approximately 800 individuals, the vast majority of whom were repatriates, from Hubei Province.

During the same time frame, cruise ships—including the *Diamond Princess* (Asia), the *Grand Princess* (California to Mexico, California to Hawaii), the *Ruby Princess* (Australia), and seven Nile River cruise ships—were associated with a number of COVID-19 clusters and outbreaks.⁴⁴ In February 2020, the *Diamond Princess* experienced what, at the time, was the largest cluster of COVID-19 cases outside of PRC and included a number of U.S. citizens. HHS/CDC, the Department of State and other agencies repatriated approximately 329 travelers from the *Diamond Princess* to the United States, where they entered quarantine or isolation at Federal sites.⁴⁵ Following an

⁴² See Richard A. Bienia, M.D., M.P.H., Emanuel Stein, M.D., M.P.H., & Baroline H. Bienia, M.S., *United States Public Health Service Hospitals (1798–1981)—The End of an Era*, 308 N. Engl. J. Med. 166–168 (1983), (available at: <https://www.nejm.org/doi/full/10.1056/NEJM198301203080329?journalCode=nejm&journalCode=nejm&journalCode=nejm&journalCode=nejm&journalCode=nejm&journalCode=nejm&journalCode=nejm&journalCode=nejm&journalCode=nejm&journalCode=nejm&journalCode=nejm&journalCode=nejm&journalCode=nejm&journalCode=nejm&journalCode=nejm&journalCode=nejm>).

⁴³ On one occasion, a California city sued HHS and California. The district court, without finding a violation of law by HHS, issued a temporary restraining order preventing the use of a proposed quarantine site. TRO and Order Setting Aside Expedited Hr'g, *City of Costa Mesa v. United States*, No. 20–cv–00368 (C.D.Cal.), (Feb. 21, 2020), ECF No. 9. Since HHS had to make decisions about the use of the site quickly, the temporary restraining order and subsequent litigation operated as a veto on the use of the site.

⁴⁴ See No Sail Order and Suspension of Further Embarkation, 85 FR 16628 (Mar. 24, 2020); Frances Mao, *Coronavirus: How did Australia's Ruby Princess cruise debacle happen?*, BBC (Mar. 24, 2020), <https://www.bbc.com/news/world-australia-51999845>.

⁴⁵ *Public Health Responses to COVID-19 Outbreaks on Cruise Ships—Worldwide, February–March 2020*, Ctrs. for Disease Control & Prevention (Mar. 27, 2020), <https://www.cdc.gov/mmwr/volumes/69/wr/mm6912e3.htm>.

outbreak onboard the U.S.-bound *Grand Princess* in March 2020, HHS/CDC and other agencies conducted a massive operation to disembark and quarantine or isolate approximately 2,000 travelers from the *Grand Princess* at Federal sites. Approximately 2,300 individuals entered quarantine or isolation at Federal sites from the repatriations and disembarkations from the *Diamond Princess* and *Grand Princess* cruise ships.

To the best of HHS/CDC's knowledge, the combined Federal quarantine and isolation of individuals from the cruise ships and flights from Hubei Province, constitute the largest and most burdensome Federal quarantine and isolation operation in modern American history. Quarantine sites required support staffs of hundreds of Federal personnel and contractors working around-the-clock. The entire operation lasted approximately eight weeks and consumed thousands of working hours.

One of the key agency components of the operation was the National Disaster Medical System (NDMS), which is a federal partnership (between HHS, DOD, VA, and DHS) led by HHS/ASPR. NDMS includes a cadre of approximately 5,000 part-time Federal employees who are civilian doctors, nurses, and other healthcare professionals, and who are activated for short-term, two-week deployments in response to natural disasters and other emergencies.⁴⁶ The NDMS leverages healthcare personnel in jurisdictions unaffected by the emergency by temporarily federalizing those individuals so they may operate where local resources are overtaxed.⁴⁷ A more protracted operation may have deprived State and local health systems of the services of the NDMS personnel for extended periods of time during the COVID-19 pandemic. It would also have limited the ability of HHS/ASPR to

⁴⁶ NDMS Teams, Off. of the Assistant Sec'y for Preparedness & Response, U.S. Dep't. of Health & Human Serv.'s, Nat'l Disaster Med. Sys., <https://www.phe.gov/Preparedness/responders/ndms/ndms-teams/Pages/default.aspx> (last visited Aug. 11, 2020); *Disaster Medical Assistance Teams*, Off. of the Assistant Sec'y for Preparedness & Response, U.S. Dep't. of Health & Human Serv.'s, Nat'l Disaster Med. Sys., <https://www.phe.gov/Preparedness/responders/ndms/ndms-teams/Pages/dmat.aspx> (last visited Aug. 31, 2020).

⁴⁷ NDMS Teams, Off. of the Assistant Sec'y for Preparedness & Response, U.S. Dep't. of Health & Human Serv.'s, Nat'l Disaster Med. Sys., <https://www.phe.gov/Preparedness/responders/ndms/ndms-teams/Pages/default.aspx> (last visited Aug. 11, 2020); *Calling on NDMS*, Off. of the Assistant Sec'y for Preparedness & Response, U.S. Dep't. of Health & Human Serv.'s, Nat'l Disaster Med. Sys., <https://www.phe.gov/Preparedness/responders/ndms/Pages/calling-ndms.aspx> (last visited Aug. 31, 2020).

³⁸ *Transcript for CDC Media Telebriefing: Update on 2019 Novel Coronavirus (2019-nCoV)*, Ctrs. for Disease Control & Prevention (Jan. 31, 2020), <https://www.cdc.gov/media/releases/2020/t0131-2019-novel-coronavirus.html> (last visited Aug. 31, 2020).

³⁹ See Sarah A. Lister, Cong. Rsch. Serv., r46219, *Overview of U.S. Domestic Response to Coronavirus Disease 2019 (COVID-19)* (last updated Mar. 2, 2020), at *12 (available at: <https://crsreports.congress.gov/product/pdf/R/R46219>).

⁴⁰ *Id.* at *11–*12; David Vergun, DOD, *Other Government Departments Take Coronavirus Response Measures*, U.S. Dep't. of Def. (Jan. 31, 2020), <https://www.defense.gov/Explore/News/Article/Article/2069255/dod-other-government-departments-take-coronavirus-response-measures/>.

⁴¹ See e.g., SOC Shift Brief 2019–2020 *Coronavirus Response*, U.S. Dep't. of Health & Human Serv.'s Assistant Sec'y for Preparedness & Response (Feb. 8, 2020, 8:00 p.m. EDT) (on file with HHS); see also Proposed Courses of Action (COAs) & Activities for Grand Princess Cruise Ship, U.S. Dep't. of Health & Human Serv.'s at *2 (Mar. 6, 2020, 11:30 a.m. EDT) (on file with HHS).

re-deploy the NDMS to other emergencies (e.g., hurricanes).

Moreover, hundreds of other Federal personnel from HHS agencies—including ASPR, CDC, and the U.S. Public Health Service—were deployed for quarantine and isolation operations. The U.S. Departments of Homeland Security, Defense, and State also contributed personnel and resources. During a public health emergency, many of the agency personnel would ordinarily perform Federal coordinating functions. A more expansive or protracted field operation would have jeopardized the ability of some of the agencies to perform their ordinary functions.

While the Federal quarantine and isolation operation addressed the immediate risk of individual repatriates and cruise ship travelers introducing COVID-19 into the United States, it was not a prospective solution. That is, it did not address the continuing risk of COVID-19 transmission onboard cruise ships. Nor did it address the continuing risk of cruise ships or other vessels introducing COVID-19 into the United States in the future. An ongoing Federal quarantine and isolation operation was not a scalable or sustainable option for mitigating either of those continuing risks given the finite resources of the relevant Federal agencies and the other pressing demands of the COVID-19 pandemic response.

As explained below, CDC's experience with the Federal quarantine and isolation orders and the resulting operation has informed its decision-making regarding its No Sail Order for cruise ships, its Order prohibiting the introduction of covered aliens into the United States, and ultimately this final rule.

c. The CDC No Sail Order for Cruise Ships

In March 2020, the risk of cruise ships introducing COVID-19 into the United States remained despite the Federal quarantine or isolation of thousands of cruise ship travelers. To address this ongoing concern, on March 14, 2020, the Director issued a No Sail Order under sections 361 and 365 of the PHS Act and 42 CFR 70.2 and 71.32 for all cruise ships of a certain capacity with itineraries anticipating an overnight stay for passengers or crew that had not voluntarily suspended operation.⁴⁸ This No Sail Order was subsequently modified and extended, effective April

15, 2020,⁴⁹ and again on July 16, 2020,⁵⁰ to include cruise ships that had previously voluntarily suspended operations, as well as requiring additional measures to prevent the further introduction, transmission, and spread of disease. The current No Sail Order remains in place until September 30, 2020, or until the expiration of the Secretary's declaration that COVID-19 constitutes a public health emergency, or the Director rescinds or modifies the Order based on specific public health or other considerations, whichever occurs first.

As noted above, the No Sail Order was issued, in part, under section 361(a) of the PHS Act. Section 361(a) is a sweeping grant of authority permitting the Director to "make and enforce such regulations as in his judgment are necessary to prevent the *introduction . . . of communicable diseases from foreign countries into the States or possessions[]*." (emphasis added). One of those regulations, 42 CFR 71.32(b), is equally broad. It states that "[w]hensoever the Director has reason to believe that any arriving carrier . . . is or may be infected or contaminated with a communicable disease, he/she may require detention, disinfection, disinfestation, fumigation, or other related measures respecting the carrier . . . as he/she considers necessary to prevent the *introduction . . . of communicable diseases*." (emphasis added).

In the No Sail Order, the Director determined that he had "reason to believe that cruise ship travel may continue to introduce, transmit, or spread COVID-19." That determination rested partly on the Director's observation that numerous structural and operational features of cruise ships increase the risk of COVID-19 transmission onboard.⁵¹ First, passengers and crew intermingle closely in semi-enclosed spaces. Second, cruises host events that bring passengers and crew together in congregate settings, including group and buffet dining, entertainment, and excursions. Third, cruise ship cabins are small, increasing the risk of transmission between cabin mates. Fourth, crew members typically eat and sleep in small, crowded spaces. The infection of crew members may

lead to transmission on sequential cruises, as the crew members work and live in close quarters from one cruise to the next.⁵²

The Director also observed that cruise ships may spread COVID-19 to ports of call and passengers' home communities. During a cruise, disembarkation of passengers at sequential ports of call may spread COVID-19 to the residents of those ports. Once the cruise ends, passengers or crew who reside in either the United States or a foreign country may travel home by airplane. Any infected passengers or crew may spread COVID-19 to others while traveling home, or upon returning home, with the end result being interstate spread of COVID-19.⁵³

Finally, the Director observed that "[q]uarantine and isolation measures are difficult to implement effectively onboard a cruise ship and tend to occur after an infection has already been identified onboard a cruise. If ships are at capacity, it may not be feasible to separate infected and uninfected persons onboard the ship, particularly among the crew. Crew must keep working to keep a ship safely operating, so effective quarantine for crew is particularly challenging."⁵⁴

As part of his analysis, the Director also considered the risks to the healthcare system in the United States, and the limited government resources available for the response to COVID-19. HHS/CDC's recent experience was that the medical needs of persons with severe disease may be significant. Disembarkations of large numbers of passengers and crew with severe disease could increase the strain of COVID-19 on healthcare systems serving port cities, and divert healthcare resources and supplies away from local communities. Additionally, HHS/CDC's recent experience was that repatriating and quarantining or isolating travelers involved complex logistics, imposed financial costs on all levels of government, and diverted agency leadership, staff, and resources away from other aspects of the response to the COVID-19 pandemic.⁵⁵

The No Sail Order has proven to be a more efficient public health measure for cruise ships than quarantine or isolation. It has mitigated COVID-19 transmission onboard cruise ships, prevented cruise ships from introducing COVID-19 into the United States, preserved local health care resources, and enabled HHS/CDC to deploy its

⁴⁸ No Sail Order and Suspension of Further Embarkation, 85 FR 16628 (Mar. 24, 2020).

⁴⁹ No Sail Order and Suspension of Further Embarkation; Notice of Modification and Extension and Other Measures Related to Operations, 85 FR 21004 (Apr. 15, 2020) (this modification additionally relied on the authority of 42 CFR 71.31(b)).

⁵⁰ No Sail Order and Suspension of Further Embarkation; Second Modification and Extension of No Sail Order and Other Measures Related to Operations, 85 FR 44085 (July 21, 2020).

⁵¹ 85 FR at 16629, 16630.

⁵² *Id.* at 16629.

⁵³ *Id.* at 16630.

⁵⁴ *Id.*

⁵⁵ *Id.*

finite resources towards other aspects of the response to the COVID-19 pandemic. In contrast, the issuance of additional Federal quarantine and isolation orders of cruise ship passengers and crew would not have stopped COVID-19 transmission onboard cruise ships and would not have been scalable to the number of cruise ship passengers and crew that would have otherwise disembarked in U.S. ports.⁵⁶

HHS/CDC's experience underscores why this final rule is vital to public health. In March 2020, a regulation for exercising the authority under section 361 of the PHS Act was readily available to the Director. As a result, HHS/CDC was able to rapidly exercise its section 361 authority and issue the No Sail Order after concluding that quarantine and isolation were inadequate to address the public health risks presented by COVID-19 on cruise ships. Once CDC decided to act, it could do so promptly and was able to more efficiently manage the problem and preserve finite resources. HHS/CDC likewise needs a final rule for exercising its section 362 authority so that it can move with equal dispatch to protect U.S. public health from the introduction of quarantinable communicable diseases into the country in the future. HHS/CDC cannot predict when it will need to exercise the authority in the future, but HHS/CDC needs to be prepared nonetheless. The experience with cruise ships shows that the immediate availability of a procedure is important once a policy decision is made that an action needs to be taken.

d. Travel Restrictions at the Land Ports of Entry Along the United States-Canada and United States-Mexico Borders

On March 20, 2020, the United States temporarily limited travel from Mexico and Canada into the United States along the United States-Mexico and United States-Canada land borders to "essential travel," in order to prevent the further

⁵⁶ Indeed, Federal quarantine and isolation for PortMiami, known as "the Cruise Capital of the World," would have been unworkable standing alone. In 2019, PortMiami disembarked 3,357,590 cruise ship passengers, which equates to approximately 64,569 disembarkations per week. *CY 2019 W. Hemisphere Port Cargo and Passenger Counts*, Am. Ass'n of Port Auth., <https://www.aapa-ports.org/unifying/content.aspx?ItemNumber=21048> (last visited Aug. 11, 2020). When the annual disembarkations at other U.S. ports—including Port Everglades (FL) (1,985,337), the Galveston Wharves (TX) (1,091,341), the Port Authority of New York and New Jersey (841,261), the Port of Long Beach (CA) (695,921), and the Port of New Orleans (603,968)—are added to PortMiami, the impracticability of a Federal quarantine and isolation operation for cruise ships nationwide is obvious.

spread of COVID-19. The United States worked collaboratively with its neighbors to take this measure to protect the health and safety of its population, after the Secretary of the Department of Homeland Security determined the risk of continued transmission and spread of COVID-19 between the countries posed a "specific threat to human life or national interest."⁵⁷ The restrictions do not apply, however, to U.S. citizens or LPRs returning to the United States, or to those traveling for "essential travel," which includes travel to work, or to educational institutions, travel for emergency response, diplomatic travelers, and travel for public health purposes, among others. The restrictions do not stop legitimate trade between the three countries because it is critical to preserve supply chains that ensure that food, fuel, and medicines reach individuals.⁵⁸

These measures were originally in place for 30 days, subject to reevaluation and further extension in light of the dynamic nature of the COVID-19 pandemic. Since March 2020, the measures have been extended in 30-day increments, and are currently effective through September 21, 2020.⁵⁹ All three countries have recognized that, given the sustained human-to-human transmission of the virus, travel between the three nations places the personnel staffing the land ports of entry (POEs) between the United States, Canada and Mexico, as well as the individuals traveling through these POEs, at increased danger of exposure to COVID-19.⁶⁰

Similarly, the Director assesses that travel and migration across U.S. land borders increases the serious danger of introduction of COVID-19 into the United States. The Director further assesses that limiting travel to "essential travel" has successfully mitigated the introduction of COVID-19 into the United States for the same basic reason that the section 212(f) proclamations have proven successful. The effectiveness of these travel restrictions at land ports of entry informs this final rule, which creates a permanent procedure for the Director to use when he or she determines that a temporary prohibition on the introduction of persons into the United States across U.S. land borders is necessary to protect U.S. public health.

⁵⁷ 85 FR at 16547, 16549.

⁵⁸ *Id.* at 16548–49.

⁵⁹ 85 FR at 51633–34.

⁶⁰ *Id.* at 51633, 51635.

e. The CDC Order on Covered Aliens

As noted above, HHS issued the IFR to create a temporary procedure for the Director to invoke his or her delegated authority under section 362 and prevent the introduction of persons from a foreign country or place into the United States in order to avert the introduction of a quarantinable communicable disease into the United States.⁶¹ On the same day, the Director issued an order suspending the introduction of certain "covered aliens" from Canada and Mexico into Border Patrol stations and POEs at or near U.S. land borders for 30 days.⁶² The CDC Order was extended for an additional 30 days on April 20, 2020.⁶³ On May 19, 2020, the Director amended the CDC Order to cover not only land, but also coastal POEs and Border Patrol stations at or near the U.S. borders with Canada and Mexico. In addition, the Director extended the CDC Order indefinitely, subject to recurring 30-day reviews and eventual termination when the Director determines that continued implementation is no longer necessary to protect public health.⁶⁴ The Director has reviewed the CDC Order multiple times and determined each time that continued implementation of the CDC Order was necessary to protect U.S. public health.

The CDC Order suspends the introduction of "covered aliens" into the United States. The CDC Amended Order and Extension defines "covered aliens" as "persons traveling from Canada or Mexico (regardless of their country of origin) who would otherwise be introduced into a congregate setting in a land or coastal [POE] or Border Patrol station at or near the United States border with Canada or Mexico, subject to exceptions."⁶⁵ There are exceptions for "U.S. citizens, lawful permanent residents [(LPRs)], and their spouses and children; members of the armed forces of the United States, and

⁶¹ Control of Communicable Diseases; Foreign Quarantine: Suspension of Introduction of Persons into United States from Designated Foreign Countries or Places for Public Health Purposes, (85 FR 16559) (Mar. 24, 2020).

⁶² Order Under Sections 362 and 365 of the Public Health Service Act Suspending Introduction of Certain Persons From Countries Where a Communicable Disease Exists, (85 FR 17060) (Mar. 26, 2020) (effective date Mar. 20, 2020 at 11:59 p.m. EDT) (hereinafter "Order").

⁶³ Extension of Order Under Sections 362 and 365 of the Public Health Service Act, (85 FR 22424) (Apr. 22, 2020) (effective date Apr. 20, 2020) (hereinafter "Extension").

⁶⁴ Amendment and Extension of Order Under Sections 362 and 365 of the Public Health Service Act, (85 FR 31503) (May 26, 2020) (effective date May 21, 2020 at 12:00 a.m. EDT) (hereinafter "Amended Order and Extension").

⁶⁵ *Id.* at 31504.

associated personnel, and their spouses and children; persons from foreign countries who hold valid travel documents and arrive at a POE; or persons from foreign countries in the visa waiver program who are not otherwise subject to travel restrictions and arrive at a POE.”⁶⁶ There is also an exception for “persons whom customs officers determine, with approval from a supervisor, should be excepted based on the totality of the circumstances, including consideration of significant law enforcement, officer and public safety, humanitarian, and public health interests.”⁶⁷

In the CDC Order, the Director determined that COVID-19 is a quarantinable communicable disease that is present in numerous foreign countries, including Canada and Mexico, and poses a serious danger to public health in the United States. Covered aliens traveling to the United States from Canada and Mexico are typically held for material lengths of time in the congregate areas of Border Patrol stations and POEs while they undergo immigration processing. As a result, the introduction of covered aliens into those CBP facilities increases the serious danger of introducing COVID-19 to others in the facilities—including DHS personnel, U.S. citizens, U.S. nationals, and LPRs, and other aliens—and ultimately spreading COVID-19 into the interior of the United States.

The Director concluded that there are structural and operational impediments to quarantining and isolating covered aliens in CBP facilities that neither HHS/CDC nor CBP can overcome, especially given the large number of covered aliens that move through the congregate areas of the facilities. Border Patrol stations and POEs were designed for short-term holding of individuals in congregate settings. They were not designed and equipped with sufficient interior space or partitions to quarantine potentially infected persons, or isolate infected persons. They also are not equipped to provide on-site care to infected persons who present with severe disease. Some but not all of the facilities offer basic medical services, and all of them are heavily reliant on local health care systems for the provision of more extensive medical services to aliens. Many of the Border Patrol stations and POEs are located in remote areas and do not have ready access to local health care systems (which typically serve small, rural

populations and have limited resources).

A Federal quarantine and isolation of covered aliens would have likely required the procurement or construction and equipping of numerous permanent or temporary facilities across the Northern and Southern land borders, in close proximity to the POEs and Border Patrol stations. The facilities would have to accommodate a rotating population of covered aliens—including family units, single adults, and children with varying countries of origin, social customs, and criminal histories—for the duration of each covered alien’s quarantine or isolation period. During that period, HHS/CDC and CBP would have to shelter, feed, and provide medical services to each covered alien onsite. The burden of undertaking such a joint public health and safety mission across thousands of miles of territory during a pandemic is impracticable.

As previously discussed, to the knowledge of HHS/CDC, the largest Federal quarantine and isolation operation in modern U.S. history is the one that HHS/CDC and other agencies conducted in early 2020 for the approximately 3,200 persons who disembarked from cruise ships in U.S. ports or were repatriated from Asia. That operation would have been dwarfed by an ongoing quarantine and isolation mission for covered aliens.

CBP has informed HHS/CDC of data in support of the CDC Order. In the 75-day period *before* the issuance of the CDC Order on March 20, 2020, an average of 3,292 of individuals who would be covered aliens under the CDC Order were in custody at POEs and Border Patrol stations each day. Since March 21, 2020, the daily average has been 895 covered aliens, notwithstanding an overall 91% increase in Border Patrol enforcement encounters from 16,201 in April 2020, to 21,687 in May 2020, to 30,936 in June 2020. Between March 21 and June 29, 2020, CBP encountered more than 75,000 subjects between POEs alone, and over 68,000 of those subjects were covered aliens amenable to expulsion from the United States under the CDC Order.

HHS/CDC and CBP could not have quarantined or isolated a cumulative total of more than 68,000 covered aliens between March 21 and June 29, 2020 who were expelled pursuant to the CDC Order.⁶⁸ Nor could they have

quarantined or isolated a daily average population of 3,292 covered aliens from March 21, 2020 to the present.⁶⁹ The relevant agencies simply lack the personnel and resources to operate such a large and complex Federal quarantine and isolation program, spread over thousands of miles of territory, and a period of many months, during a global pandemic. This is especially true when HHS/CDC and CBP must prioritize their finite resources for the benefit of the public health and safety, respectively, of the domestic population.⁷⁰

While the CDC Order succeeded in reducing the average number of covered aliens in CBP custody each day, and dramatically reduced the danger of the introduction of COVID-19 into CBP facilities, the unfortunate reality is that the COVID-19 pandemic has still impacted CBP’s ability to perform its public safety mission. CBP informs HHS/CDC that, as of August 7, 2020, it

Population Totals: 2010–2019, U.S. Census Bureau, <https://www.census.gov/data/datasets/time-series/demo/popest/2010s-total-cities-and-towns.html> (last visited Aug. 31, 2020).

⁶⁹ If CDC and CBP had undertaken a Federal quarantine and isolation operation for covered aliens, the daily average population of covered aliens in custody and subject to quarantine or isolation may have exceeded 3,292 for at least two reasons. First, CBP’s enforcement encounters increased monthly after March 20, 2020. Second, many covered aliens would have spent longer in Federal quarantine and isolation than they would have spent in CBP custody before the COVID-19 pandemic.

⁷⁰ HHS/CDC considered whether it could avert the serious danger of the introduction of COVID-19 into CBP facilities through COVID-19 testing. Specifically, HHS/CDC considered the asymptomatic transmission of COVID-19; the lack or limited availability of diagnostic testing for COVID-19; the time required to obtain diagnostic test results; the need to prioritize testing resources for the domestic population; the impracticability of implementing quarantine, isolation, and social distancing in CBP facilities; and resource constraints. HHS/CDC concluded that the better option for public health was to prohibit the introduction of covered aliens into the congregate areas in CBP facilities.

HHS/CDC expects to face similar policy decisions in the future. In any pandemic caused by a novel virus that spreads asymptotically there will be a period when diagnostic testing is not widely available due to the time necessary to create, manufacture, distribute, administer, and receive the results of diagnostic tests. Even then, it may be appropriate to prioritize diagnostic testing for some populations over others, and diagnostic testing may produce at least some false negatives. Plus, diagnostic testing is a snapshot in time. An uninfected person who undergoes diagnostic testing and enters a congregate setting pending test results may become infected by others. An asymptomatic, infected person who undergoes diagnostic testing and enters a congregate setting may infect others. While surveillance testing can be an effective alternative, it can consume tremendous resources.

As HHS/CDC’s experience here shows, a prohibition on the introduction of persons into congregate settings may be a better option for protecting public health than testing, particularly when finite testing resources must be prioritized for the domestic population.

⁶⁸ To put that number in context, the U.S. Census Bureau estimates that the population of Rockville, Maryland (a suburb of Washington, DC) in 2019 was approximately 68,079 people. *City & Town*

⁶⁶ *Id.*

⁶⁷ *Id.*

has had 1,806 employees test positive for COVID-19, a 56% increase compared to the 1,158 who tested positive on July 7, 2020. Tragically, ten employees and one CBP contractor have died from COVID-19 as of the same day. CBP does not have the capability to identify the mechanism by which each CBP employee or contractor becomes infected; CBP employees or contractors may become infected through exposures that occurred in their communities through interactions outside of work or in their workplaces, including Border Patrol stations and POEs. In any event, when CBP employees test positive and do not require inpatient care, they must self-isolate at home until they recover and are no longer contagious.

CBP also has a large, rotating group of employees who are self-quarantined based on potential exposure to COVID-19. CBP informs HHS/CDC that over 1,500 CBP employees were quarantined as of the end of June, and the impact was more pronounced at the Southwest border, where 975 U.S. Border Patrol employees, representing approximately 6% of the Southwest border personnel, were quarantined as of July 9, 2020.

Overall, based on information provided by CBP to HHS/CDC, the COVID-19 pandemic has impacted the Laredo Border Patrol Sector and the Laredo Field Office along the Southwest border area the most of any CBP area of responsibility. As of July 16, 2020, Border Patrol had a cumulative total of 91 personnel in the Laredo Sector test positive for COVID-19. Border Patrol also had 134 personnel, representing 7% of its workforce in the Laredo Sector, in self-quarantine. To maintain border security notwithstanding the loss of personnel, the Border Patrol has had to increase the number of shifts for law enforcement officers at Border Patrol checkpoints, reassign other personnel to checkpoints, and suspend certain law enforcement trainings. Similarly, as of July 16, 2020, the Laredo Field Office (which operates the Laredo POE, as well as many other land POEs in the State of Texas) had a cumulative total of 189 employees test positive for COVID-19, and had 151 personnel (representing 5% of its workforce) in quarantine. The Laredo Field Office has mitigated the loss of personnel by shifting law enforcement officers from passenger vehicle and migrant processing (which has decreased in volume) to commercial vehicle processing (which has generally stayed consistent).

The Director assesses that the numbers of CBP employees who test positive for COVID-19 or enter quarantine would probably be larger absent the CDC Order. While it is

difficult to quantify the difference, CBP informs HHS/CDC that any further degradation of its workforce in the Laredo Sector would jeopardize CBP's ability to execute its public safety mission.⁷¹ Because the CDC Order has prevented COVID-19 from further degrading the CBP workforce, the IFR and CDC Order have served the purpose of section 362, which is to avert an increase in the serious danger of the introduction into the United States of a quarantinable communicable disease from abroad.

Beyond the CBP workforce, CBP has provided data to HHS/CDC showing that the CDC Order has reduced the strain on the health care systems in U.S. border states at a time when those systems are trying to safeguard their own workforces from COVID-19 and prioritize health care resources for the domestic population. In the 50 days preceding the issuance of the CDC Order, CBP officers made over 1,600 trips to U.S. hospitals to take migrants to receive medical care. In the first 80 days after the issuance of the CDC Order, CBP has made only 400 such trips. This represents a 75% decrease in utilization of U.S. hospitals by migrants, which is material when hospitals in U.S. border states in mid-July were operating at or near their inpatient bed capacity for COVID-19 patients,⁷² or taking measures to absorb a surge in COVID-19 cases within the domestic population.⁷³ The Director

⁷¹ CBP, for example, informs HHS/CDC that Border Patrol might have to shift law enforcement officers from patrols of the U.S. land border to migrant custody and transportation functions, which would increase the risk of transnational criminal organizations smuggling narcotics or migrants through the Laredo Sector. The Laredo Field Office might lose its ability to timely process commercial vehicles, which would slow the flow of goods into the United States. And CBP supervisors might have to deny leave requests to maintain staffing levels, which would overtax the CBP workforce.

⁷² For example, local news media in Laredo, Texas, reported on July 11, 2020 that two acute care hospitals in the area, Laredo Medical Center and Doctor's Hospital, were in a critical situation. Laredo Medical Center was at 100 percent capacity in its COVID intensive care unit and on its non-ICU COVID patient floors, with four people in the emergency department waiting on beds. The COVID intensive care units at Doctors Hospital were approaching 100 percent capacity, and its non-ICU COVID patient floors were at 100 percent capacity. *Local hospital COVID-19 ICU at capacity*, KGNS (July 11, 2020, 12:13 a.m. EDT), <https://www.kgns.tv/2020/07/11/local-hospital-covid-19-icu-at-capacity/>. Other hospitals in Texas border communities experienced similar surges. Sarah R. Champagne, *Ten out of the 12 hospitals in Texas' Rio Grande Valley are now full*, Tex. Trib. (July 4, 2020, 6:00 p.m.), <https://www.texastribune.org/2020/07/04/texas-coronavirus-rio-grande-valley-hospitals/>.

⁷³ Allison Steinbach, *Arizona reports 4,273 new COVID-19 cases, sets new records for hospital beds in use*, Ariz. Rep. (July 14, 2020, 12:48 p.m.), <https://www.azcentral.com/story/news/local/>

assesses that the risks of COVID-19 transmission and insufficient bed capacity in health care systems serving U.S. border states would have been greater absent the Order.

The effectiveness of the CDC Order as a public health measure reinforces why this final rule is vital to public health. HHS/CDC needs a readily available procedure for exercising the section 362 authority so that it may continue to protect public health during the COVID-19 pandemic, and respond to future public health threats with equal efficacy.

3. Other Jurisdictions Have Taken Similar Actions To Slow the Introduction of COVID-19, Which Underscores Why This Final Rule Is in the Interest of U.S. Public Health

Global efforts to slow cross-border COVID-19 transmission have included public health actions substantially similar to those taken by the United States. Nations such as the European Union (EU) Member States and Schengen Area countries,⁷⁴ Australia, New Zealand, and Canada have imposed restrictions on international travelers.⁷⁵ The actions of other nations to avert the introduction of COVID-19 further corroborate the Director's view that this final rule will help HHS/CDC protect public health now and in the future.

a. The European Union and Schengen Area

EU Member States and Schengen countries have implemented restrictions on international travel similar to those imposed by the United States. Based on a recommendation by the European

arizona-health/2020/07/14/arizona-coronavirus-update-hospital-beds-fill-up-4-273-new-cases/5434525002/; Soumya Karlamangla, *'We're just overwhelmed': The view from inside hospitals as coronavirus surge hits*, L.A. Times (July 13, 2020, 5:00 a.m.), <https://www.latimes.com/california/story/2020-07-13/overwhelmed-hospitals-coronavirus-surge-california>.

⁷⁴ *Migration and Home Affairs: Schengen Area*, Eur. Comm'n (Jan. 1, 2020), https://ec.europa.eu/home-affairs/what-we-do/policies/order-and-visas/schengen_en ("Today, the Schengen Area [of the EU] encompasses most EU States, except for Bulgaria, Croatia, Cyprus, Ireland and Romania. However, Bulgaria, Croatia and Romania are currently in the process of joining the Schengen Area. Of non-EU States, Iceland, Norway, Switzerland and Liechtenstein have joined the Schengen Area."); *Travel to and from the EU during the pandemic: Travel restrictions*, Eur. Comm'n, https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/travel-and-transportation-during-coronavirus-pandemic/travel-and-eu-during-pandemic_en (last visited Aug. 31, 2020).

⁷⁵ See Andrea Salcedo, Sanam Yar, & Gina Chereus, *Coronavirus Travel Restrictions, Across the Globe*, N.Y. Times (July 16, 2020), <https://www.nytimes.com/article/coronavirus-travel-restrictions.html>.

Commission, on March 17, 2020, EU Member States agreed to restrict non-essential travel across the EU's external border for a period that has now been extended several times.⁷⁶

Restrictions on international travel into the EU and Schengen Area were quickly followed by EU Member States and Schengen Area countries closing their national borders. Such internal border controls were initially tailored to the countries hardest hit by the pandemic. For example, Austria and Switzerland closed their land borders with Italy on March 11 and 13, 2020, respectively, to prevent the entry of individuals from Italy, which was an epicenter of the COVID-19 pandemic at that time.⁷⁷ Similarly, Portugal closed its land border with Spain as part of sweeping measures to counter COVID-19 transmission.⁷⁸ Given the level of economic interdependence and commitment to the unrestricted movement of goods and persons within the EU, the closing of internal borders within the EU and Schengen Area is akin to individual U.S. States closing their borders to interstate travelers. During the height of the COVID-19 pandemic, a large number of EU Member States and Schengen countries had closed their internal borders, often times cancelling international air travel and cross-border train travel.⁷⁹

On June 11, 2020, the European Commission adopted a Communication⁸⁰ which set out an

⁷⁶ *Travel and transportation during the coronavirus pandemic: Travel restrictions*, Eur. Comm'n, https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/travel-and-transportation-during-coronavirus-pandemic/travel-and-eu-during-pandemic_en (last visited Aug. 31, 2020).

⁷⁷ *Id.*; *Member States' notifications of the temporary reintroduction of border control at internal borders pursuant to Article 25 and 28 et seq. of the Schengen Borders Code*, EU, https://ec.europa.eu/home-affairs/sites/homeaffairs/files/what-we-do/policies/borders-and-visas/schengen/reintroduction-border-control/docs/ms_notifications_-_reintroduction_of_border_control_en.pdf (last visited Aug. 31, 2020).

⁷⁸ *Id.*; *Travel and transportation during the coronavirus pandemic: Travel restrictions*, Eur. Comm'n, https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/travel-and-transportation-during-coronavirus-pandemic/travel-and-eu-during-pandemic_en (last visited Aug. 31, 2020).

⁷⁹ *Id.*; *Member States' notifications of the temporary reintroduction of border control at internal borders pursuant to Article 25 and 28 et seq. of the Schengen Borders Code*, EU, https://ec.europa.eu/home-affairs/sites/homeaffairs/files/what-we-do/policies/borders-and-visas/schengen/reintroduction-border-control/docs/ms_notifications_-_reintroduction_of_border_control_en.pdf (last visited Aug. 31, 2020).

⁸⁰ Press Release IP/20/1035, *Coronavirus: European Commission recommends partial and gradual lifting of travel restrictions to the EU after 30 June, based on common coordinated approach*

approach to progressively lift internal border controls by June 15, and to prolong the restriction on non-essential travel into the EU until June 30, 2020.⁸¹ Each Member State's internal border controls continue to be independently determined by the States themselves. Within the Schengen Area, internal border restrictions and quarantine requirements for intra-Schengen travelers began to relax in late-June 2020 as the rate of COVID-19 transmission slowed in most Schengen Area countries.⁸² Nevertheless, several Schengen Area countries with low levels of COVID-19 transmission and few confirmed cases, such as Latvia, Lithuania, and Norway, continued to require citizens from other Schengen Area countries to self-quarantine on arrival, or limit travel to specific purposes.⁸³ Schengen Area countries have also implemented varying public health interventions, such as bans on public gatherings, compulsory stay-at-home orders, closures of schools and nonessential businesses, and face mask ordinances.

On June 25, 2020, the European Commission adopted a proposal for a Council Recommendation to lift some travel restrictions for countries selected together by EU Member States.⁸⁴ Selection was based on a set of principles and objective criteria including the health situation in respective countries, the ability to apply containment measures during travel, and reciprocity considerations, taking into account data from sources such as the European Centre for Disease Prevention and Control and the WHO.⁸⁵ Based on the criteria and conditions set

(June 11, 2020) (available at: https://ec.europa.eu/commission/presscorner/detail/en/ip_20_1035).

⁸¹ *Id.*; *Travel and transportation during the coronavirus pandemic*, Eur. Comm'n, https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/travel-and-transportation-during-coronavirus-pandemic/travel-and-eu-during-pandemic_en (last visited Aug. 31, 2020).

⁸² *Id.*

⁸³ See e.g., *If returning to/entering Latvia*, Lat. Ctr. for Disease Prevention & Control, <https://www.spkc.gov.lv/lv/if-returning-toentering-latvia> (last updated July 22, 2020) (links to list last updated August 28, 2020); *The updated list of countries for mandatory 14-day isolation upon return*, Gov.t of the Rep. of Lith., <https://koronastop.lrv.lt/en/news/the-updated-list-of-countries-for-mandatory-14-day-isolation-upon-return-1> (last updated July 27, 2020); *Travel advice*, Health Ministry of Nor., <https://helsenorge.no/koronavirus/travel-advice#Travel-quarantine> (last updated Aug. 24, 2020).

⁸⁴ *Travel to and from the EU during the pandemic: Travel restrictions*, Eur. Comm'n, https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/travel-and-transportation-during-coronavirus-pandemic/travel-and-eu-during-pandemic_en (last visited Aug. 31, 2020).

⁸⁵ *Id.*

out in the Recommendation, and on the updated list published by the Council on August 7, 2020, the European Commission says EU Member States should start lifting travel restrictions at external borders for residents from 11 countries.⁸⁶

The external and internal border controls imposed in the EU and Schengen Area resemble the measures undertaken by the United States to avert the introduction of COVID-19 into the country, including the IFR and CDC Order. EU Member States have based their decisions to close and then reopen borders on the reported severity of the COVID-19 pandemic in the countries that travelers are entering from. The combination of external and internal border controls and public health interventions in the EU and Schengen Area appear to have reduced not only cross-border COVID-19 transmission but also internal community spread of the disease to the point of enabling the relaxation of some restrictions. The experiences of EU Member States and Schengen Area countries reinforce the Director's view that this final rule is an important tool for protecting public health in the United States.

b. Australia and New Zealand

Australia and New Zealand have implemented external border closures as part of their response to the COVID-19 pandemic that are much more stringent than the measures taken by the United States. On March 19, 2020, Australia closed its borders with exemptions only for Australian citizens, permanent residents, and their immediate families, including spouses, legal guardians, and dependents, as well as other certain other limited exceptions.⁸⁷ All returning citizens and residents of Australia are subject to a mandatory 14-day quarantine at designated secure facilities, such as a hotel at their port of arrival.⁸⁸ In order to manage the return of citizens and residents, Australia has capped international arrivals at 1,875 passengers per week.⁸⁹ Most visa

⁸⁶ These countries are: Australia, Canada, Georgia, Japan, New Zealand, Rwanda, South Korea, Thailand, Tunisia, Uruguay, and China (subject to confirmation of reciprocity). *Id.*

⁸⁷ Media Statement, Prime Minister of Australia announces Border Restrictions (Mar. 19, 2020) (available at: <https://www.pm.gov.au/media/border-restrictions>).

⁸⁸ *Id.*; *COVID-19 and the border: Travel restrictions*, Cmth. of Austl, Dep't of Home Aff., <https://covid19.homeaffairs.gov.au/travel-restrictions-0> (last updated Aug. 28, 2020).

⁸⁹ Media Statement, National Cabinet meets to discuss Australia's COVID-19 response, the Victoria outbreak, easing restrictions, helping Australians prepare to go back to work, and economic recovery (Aug. 7, 2020) (available at:

holders, including those providing critical or specialist medical services, including air ambulance and medical evacuations, are not allowed to enter Australia unless they apply for and are granted an exemption and it is approved in advance of travel.⁹⁰ International visitors to be granted an exemption and permitted to travel to Australia may be required to pay up to \$5,000 (AUD) to defray the cost of their quarantine.⁹¹

Australia had only 25,322 confirmed cases and 572 deaths from COVID-19 as of August 27, 2020.⁹² And as recently as June 26, 2020 Australia was planning a safe return of crowds to stadiums, arenas, and large theaters,⁹³ and had announced its intention to create a trans-Tasman COVID-safe travel zone with New Zealand.⁹⁴ Nevertheless, an outbreak in Melbourne, Victoria in July 2020, believed to be caused by infection control failures at quarantine facilities,⁹⁵ led to the imposition of

<https://www.pm.gov.au/media/national-cabinet-7aug2020>) This cap will be in effect until October 24, 2020. *Id.* A slightly lower cap of 1,475 passengers took effect on Monday July 13, 2020 and was re-evaluated and increased in late July. Media Statement, National Cabinet discusses Australia's current COVID-19 response, easing restrictions, helping Australians prepare to go back to work (July 10, 2020) (available at: <https://www.pm.gov.au/media/national-cabinet>).

⁹⁰ COVID-19 and the border: Travel restrictions, Cmlth. of Austl., Dep't of Home Aff., <https://covid19.homeaffairs.gov.au/travel-restrictions-0> (last updated Aug. 28, 2020).

⁹¹ For example, from July 17, 2020, anyone arriving in the Northern Territory from a declared COVID-19 hotspot must pay a quarantine fee of \$2,500 for an individual, or \$5,000 for family groups of two or more people in a shared accommodation for the duration of the 14-day quarantine. *Mandatory supervised quarantine fee Interstate travellers from a COVID-19 Hotspot and International Travellers*, N. Terr. Gov't, <https://coronavirus.nt.gov.au/travel/quarantine/quarantine-fee> (last updated Aug. 24, 2020).

⁹² *Coronavirus (COVID-19) at a glance—27 August 2020*, Cmlth. of Austl. Dep't of Health (Aug. 27, 2020), <https://www.health.gov.au/resources/publications/coronavirus-covid-19-at-a-glance-27-august-2020>.

⁹³ *Australian Health Protection Principal Committee (AHPPC) statement on the safe return of crowds to stadiums, arenas and large theatres*, Cmlth. of Austl. Dep't of Health (June 26, 2020), <https://www.health.gov.au/news/australian-health-protection-principal-committee-ahppc-statement-on-the-safe-return-of-crowds-to-stadiums-arenas-and-large-theatres>.

⁹⁴ Media Statement, Joint Statement—Prime Ministers Jacinda Ardern and Scott Morrison Announce Plans for Trans-Tasman COVID-SAFE Travel Zone (May 5, 2020) (available at: <https://www.pm.gov.au/media/joint-statement-prime-ministers-jacinda-ardern-and-scott-morrison-announce-plans-trans-tasman>). As of mid-August, the plans for a trans-Tasman travel “bubble” had been put on pause. *Trans-Tasman bubble ‘on pause’ amid new Covid outbreaks across Pacific*, The Guardian (Aug. 13, 2020 13:30 EDT), <https://www.theguardian.com/world/2020/aug/14/trans-tasman-travel-bubble-on-pause-amid-new-covid-outbreaks-across-pacific>.

⁹⁵ See Media Statement, National Cabinet discusses Australia's current COVID-19 response,

restrictive public health measures in Melbourne, including a compulsory stay-at-home order limiting the reasons people can leave their homes,⁹⁶ and a declaration of disaster in the State of Victoria generally.⁹⁷ Neighboring States have imposed interstate travel restrictions, including prohibiting persons traveling from Victoria from entering adjoining States.⁹⁸ Still, preliminary epidemiological analysis suggests that Australia's travel restrictions were effective in mitigating the introduction of COVID-19 into the country.⁹⁹

New Zealand has taken an even more aggressive approach than Australia. It closed its borders to “all but critical travel” in the interests of public health.¹⁰⁰ Only New Zealand citizens, their partners and dependent children, and accredited diplomats may travel to New Zealand without prior approval. New Zealand exempts a small number of categories of travelers from the ban on entering the country, including “critical humanitarian travel” granted at the discretion of New Zealand immigration authorities. Any non-citizen or legal resident seeking to enter the country

easing restrictions, helping Australians prepare to go back to work (July 10, 2020) (available at: <https://www.pm.gov.au/media/national-cabinet>); *Coronavirus: Why has Melbourne's outbreak worsened?*, BBC (July 3, 2020), <https://www.bbc.com/news/world-australia-53259356>.

⁹⁶ *Updated restrictions—11.59 p.m. Wednesday 22 July 2020*, St. Gov't of Vict., Dep't of Health & Human Serv.'s, <https://www.dhhs.vic.gov.au/updates/coronavirus-covid-19/updated-restrictions-1159pm-wednesday-22-july-2020> (last updated July 22, 2020); *Stage 4 Restrictions*, St. Gov't of Vict., Dep't of Health & Human Serv.'s, <https://www.dhhs.vic.gov.au/stage-4-restrictions-covid-19> (last updated Aug. 21, 2020).

⁹⁷ *Premier's statement on changes to regional restrictions*, St. Gov't of Vict., Dep't of Health & Human Serv.'s (Aug. 2, 2020), <https://www.dhhs.vic.gov.au/updates/coronavirus-covid-19/premiers-statement-changes-regional-restrictions>.

⁹⁸ See e.g., *Travel Restrictions*, S. Austl. St. Gov't, <https://www.covid-19.sa.gov.au/restrictions-and-responsibilities/travel-restrictions#intosa> (last visited Aug. 28, 2020) (“Travellers from Victoria, other than approved categories of Essential Travellers, are not permitted to travel to South Australia. Checkpoints or road blocks will be set up at all border crossings between South Australia and Victoria.”); *NSW-Victoria border restrictions*, N.S.W. St. Gov't, <https://www.nsw.gov.au/covid-19/what-you-can-and-cant-do-under-rules/border-restrictions#who-can-enter-nsw> (last visited Aug. 28, 2020) (“NSW has temporarily shut its border with Victoria to contain the spread of COVID-19”).

⁹⁹ Valentina Costantino et al., *The effectiveness of full and partial travel bans against COVID-19 spread in Australia for travelers from China during and after the epidemic peak in China*, J. Travel Med. (May 22, 2020), <https://academic.oup.com/jtm/article/doi/10.1093/jtm/taaa081/5842100#205346339>.

¹⁰⁰ *Border closures and exceptions*, N.Z. Immigration, <https://www.immigration.govt.nz/about-us/covid-19/border-closures-and-exceptions> (last visited Aug. 25, 2020).

under an exemption must meet a critical purpose and be approved in advance.¹⁰¹ New Zealand has suspended visa processing for offshore applicants because people who are not New Zealand citizens or residents are unlikely to meet the current entry requirements.¹⁰² New Zealand has suspended its involvement in refugee resettlement programs and stopped accepting its quota of around 1,500 refugees every year.¹⁰³

Any person still permitted to travel to New Zealand, almost exclusively citizens and residents, must submit to a medical examination and testing upon arrival, and is subject to a 14-day quarantine or isolation period at a government-managed facility.¹⁰⁴ Quarantine is required regardless of whether the individual tested negative for COVID-19 on arrival and without respect to whether the person is exhibiting any symptoms of COVID-19.¹⁰⁵ Although New Zealand has not previously charged travelers for quarantine and isolation costs, effective August 10, 2020, the government will charge \$3,100 (NZ) for one adult; \$950 (NZ) for each additional adult in the same room; and \$475 (NZ) for each additional child aged 3–17 in the same room for those kept in quarantine and isolation.¹⁰⁶ New Zealand has also closed its maritime border to all foreign ships, including cruise ships, with limited exceptions.¹⁰⁷

New Zealand's so-called elimination strategy for COVID-19, consisting of border controls, case detection and surveillance, and contact tracing and

¹⁰¹ *Id.*

¹⁰² *COVID-19: Key updates*, N.Z. Immigration, <https://www.immigration.govt.nz/about-us/covid-19/coronavirus-update-inz-response> (last visited Aug. 28, 2020).

¹⁰³ *Immigration Factsheets: COVID-19 response—Quota Refugees*, N.Z. Immigration (July 6, 2020), <https://www.immigration.govt.nz/documents/media/covid-19-quota-refugees-factsheet.pdf>; see generally *New Zealand Refugee Quota Programme*, N.Z. Immigration, <https://www.immigration.govt.nz/about-us/what-we-do/our-strategies-and-projects/supporting-refugees-and-asylum-seekers/refugee-and-protection-unit/new-zealand-refugee-quota-programme> (last visited Aug. 28, 2020); *Increasing New Zealand's Refugee Quota*, N.Z. Immigration, <https://www.immigration.govt.nz/about-us/what-we-do/our-strategies-and-projects/refugee-resettlement-strategy/rqip> (last visited Aug. 28, 2020).

¹⁰⁴ *COVID-19: New Zealanders in the UK—Frequently Asked Questions*, N.Z. Foreign Aff. & Trade, <https://www.mfat.govt.nz/en/countries-and-regions/europe/united-kingdom/new-zealand-high-commission/living-in-the-uk/covid-19-coronavirus/> (last visited Aug. 28, 2020).

¹⁰⁵ See *Id.*

¹⁰⁶ *Id.* (There is no charge for children under the age of three).

¹⁰⁷ *COVID-19 Public Health Response (Maritime Border) Order 2020*, Parl. Couns. Off. (June 30, 2020), <http://www.legislation.govt.nz/regulation/public/2020/0134/latest/whole.html#LMS363210>.

quarantine has been widely hailed as a success.¹⁰⁸ Restricting nearly all international travel and immigration, paired with domestic public health interventions, gave New Zealand time to put in place the infrastructure needed to carry out its elimination strategy.¹⁰⁹ On August 28, 2020, New Zealand announced 12 new cases of COVID-19 that are being managed in isolation, bringing the total to 130 active cases.¹¹⁰

The experiences of New Zealand and Australia, like the experiences of the EU Member States and Schengen Area countries, reinforce the CDC Director's view that this final rule is an important tool for protecting public health in the United States.

c. Canada

On March 20, 2020, the United States and Canada announced plans to, by mutual consent, temporarily limit non-essential travel along the United States-Canada land border.¹¹¹ As noted above, these measures were extended through September 21, 2020.¹¹²

Like Australia and New Zealand, Canada banned almost all other foreign nationals from entering the country. On June 30, 2020, Canada extended its public health restrictions on international travelers from countries other than the United States, and on immigration to Canada, through at least July 31, 2020.¹¹³ Most foreign nationals

cannot travel to Canada unless they are an immediate family member of a Canadian national or permanent resident, or are traveling for one of a limited number of essential purposes and are either traveling directly from the United States or exempt from travel restrictions.¹¹⁴ All foreign nationals eligible to enter Canada must undergo health assessments, and have plans to self-quarantine for 14 days, that include where they are staying, how they plan to get to where they are staying, and how they will get groceries and access essential services. Failure to have an adequate quarantine plan is grounds to be denied entry.¹¹⁵ Returning Canadians are also required to quarantine for 14 days, during which individuals are not permitted to leave quarantine except for medical attention and may not have visitors.¹¹⁶ Failure to adhere to quarantine requirements is punishable by up to six months imprisonment, a fine of up to \$750,000 (CAD), a finding of inadmissibility, removal from Canada, and a one-year entry ban.¹¹⁷

As of August 27, 2020, Canada reported over 126,000 cases of COVID-19 and over 9,000 confirmed deaths.¹¹⁸ According to a July 8, 2020 report, repatriated travelers accounted for 13 cases and no deaths. The Canadian government believes community transmission (as opposed to cross-border transmission) accounts for 85% of cases. In response to persistent, low levels of community transmission, authorities in Toronto, Ottawa, and several other Ontario cities have mandated indoor mask use. Quebec has similarly announced that masks will be mandatory in all indoor public places starting July 27, 2020.

While Canada was slower to implement public health restrictions on

international travel than the United States, Canada's restrictions are robust. By closing its border to all but essential travel with the United States and returning citizens, Canada has operationalized a self-quarantine process for arriving travelers that has mitigated the spread of COVID-19, particularly from arriving asymptomatic persons who are capable of transmitting the disease. Coupled with public health interventions, Canada's border control measures have led to a considerable reduction in COVID-19 transmission. The Canadian experience is further corroboration that this final rule is good policy and vital to CDC's ability to protect public health in the United States.

C. This Rulemaking Finalizes Procedures Necessary for HHS/CDC's Continued Protection of U.S. Public Health From the COVID-19 Pandemic and Future Threats

HHS/CDC needs this final rule to implement section 362 of the PHS Act because the IFR is not permanent. "Unless extended after consideration of submitted comments, [the IFR] will cease to be in effect on the earlier of (1) one year from the publication of [the IFR], or (2) when the HHS Secretary determines there is no longer a need for [the IFR]." ¹¹⁹ Absent such a determination, the IFR lapses by its own terms on March 20, 2021.

There are also legal actions challenging the IFR. For example, in *P.J.E.S. v. Wolf*, No. 20-cv-02245-EGS (D.D.C. filed Aug. 14, 2020), the named plaintiff has sued the HHS Secretary, the CDC Director, and others on behalf of a putative class of unaccompanied alien children. In addition to arguing that the CDC Order and the underlying IFR are contrary to statute, the putative class representative alleges that the IFR and CDC Order are arbitrary and capricious for a number of reasons. According to the named plaintiff, "Defendants have not articulated a reasoned explanation for their decision to apply [the IFR and the CDC Order] to unaccompanied children; failed to consider relevant factors in applying [the IFR and the CDC Order] to them . . . ; relied on factors Congress did not intend to be considered; failed to consider reasonable alternatives that were less restrictive; and offered no sufficient explanation for their decision to expel them from the country."¹²⁰ While the Government is defending all challenges to the IFR and the CDC

¹⁰⁸ See *COVID-19: Elimination strategy for Aotearoa New Zealand*, Ministry of Health, <https://www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-current-situation/covid-19-elimination-strategy-aotearoa-new-zealand> (last updated May 8, 2020); Anna Jones, *Coronavirus: How New Zealand went 'hard and early' to beat Covid-19*, BBC News (July 10, 2020), <https://www.bbc.com/news/world-asia-53274085>; Jason Douglas, *As Coronavirus Surges in U.S., Some Countries Have Just About Halted It*, *The Wall Street J.* (July 6, 2020), <https://www.wsj.com/articles/as-coronavirus-surges-in-u-s-some-countries-have-just-about-halted-it-11594037814>.

¹⁰⁹ See Michael G. Baker et al., *New Zealand's elimination strategy for the COVID-19 pandemic and what is required to make it work*, 133 *N.Z. Med. J.* 1512, 10 (2020), (available at: <https://www.nzma.org.nz/journal-articles/new-zealands-elimination-strategy-for-the-covid-19-pandemic-and-what-is-required-to-make-it-work>).

¹¹⁰ Media Release: NZ Ministry of Health Announces 12 new cases of COVID-19 (Aug. 28, 2020) (available at: <https://www.health.govt.nz/news-media/media-releases/12-new-cases-covid-19>).

¹¹¹ *Fact Sheet: DHS Measures on the Border to Limit the Further Spread of Coronavirus*, Dep't of Homeland Sec., <https://www.dhs.gov/news/2020/06/16/fact-sheet-dhs-measures-border-limit-further-spread-coronavirus> (last updated Aug. 14, 2020).

¹¹² 85 FR 51634 (August 21, 2020).

¹¹³ Press Release, Canada Extends Mandatory Requirements Under the Quarantine Act for Anyone Entering Canada (Jun. 30, 2020) (available at: <https://www.canada.ca/en/public-health/news/2020/06/canada-extends-mandatory-requirements-under-the-quarantine-act-for-anyone-entering-canada.html>), (last updated July 3, 2020).

¹¹⁴ *Id.*; see also *Coronavirus disease (COVID-19): Who can travel to Canada—Citizens, permanent residents, foreign nationals and refugees*, Gov't of Can., <https://www.canada.ca/en/immigration-refugees-citizenship/services/coronavirus-covid19/travel-restrictions-exemptions.html> (last updated Aug. 13, 2020).

¹¹⁵ *Id.*

¹¹⁶ *For travellers without symptoms of COVID-19 returning to Canada*, Gov't of Can., <https://www.canada.ca/en/public-health/services/publications/diseases-conditions/2019-novel-coronavirus-information-sheet.html> (last updated Aug. 7, 2020).

¹¹⁷ *Coronavirus disease (COVID-19): Who can travel to Canada—Citizens, permanent residents, foreign nationals and refugees*, Gov't of Can., <https://www.canada.ca/en/immigration-refugees-citizenship/services/coronavirus-covid19/travel-restrictions-exemptions.html> (last updated Aug. 13, 2020).

¹¹⁸ Statement from the Chief Public Health Officer of Canada On August 27, 2020, Gov't of Can., <https://www.canada.ca/en/public-health/news/2020/08/statement-from-the-chief-public-health-officer-of-canada-on-august-27-2020.html> (last updated August 27, 2020).

¹¹⁹ 85 FR 16559 (March 24, 2020).

¹²⁰ *P.J.E.S. v. Wolf*, No. 20-cv-02245-EGS, at *27-28 (D.D.C. Aug. 14, 2020), ECF No. 1.

Order, it is nonetheless possible that a district court could vacate or enjoin the IFR before the IFR lapses by its own terms on March 20, 2021.

The procedures finalized here ensure that HHS/CDC can mitigate the danger of the introduction of COVID-19 into the United States regardless of whether the IFR is vacated or enjoined, or lapses by its own terms. The procedures also ensure that HHS/CDC can act quickly to mitigate the danger of the introduction of other quarantinable communicable diseases into the United States in the future. As previously discussed, HHS/CDC cannot predict when it will need to exercise the Section 362 authority in the future; the immediate availability of procedures for exercising the authority is important once HHS/CDC decides to take action.

The public health situation in the U.S.-Mexico border region highlights the need for the procedures. The COVID-19 pandemic still presents significant challenges for the States in the region, and Mexico itself. If the procedures established by the IFR ceased to be effective, then the CDC Order on covered aliens would likewise cease to be effective, and the danger of the introduction of COVID-19 into the States in the U.S.-Mexico border region would increase. The CBP workforce and the civilian population in the U.S.-Mexico border region would face an increased risk of infection with COVID-19. The community transmission of COVID-19, the number of new COVID-19 cases, and the attendant strain on the healthcare system in the U.S.-Mexico border region would likely increase as well. The Director assesses that HHS/CDC can mitigate those consequences so long as the procedures established by the IFR remain in place.

The Director's assessment takes into account the effectiveness of the IFR and CDC Order as public health measures, recent trends in COVID-19 case counts and deaths, the experiences of the States, and the States' current reopening plans. As previously discussed, the Director assesses that the IFR and CDC Order have reduced the danger of the introduction of COVID-19 into the United States, and reduced the strain on the healthcare system in the U.S.-Mexico border region by decreasing the utilization of the healthcare system by covered aliens. The Director further assesses that the IFR and CDC Order have helped slow community transmission of COVID-19 and the number of new COVID-19 cases in the States in the U.S.-Mexico border region. While these positive impacts are difficult to quantify, it is undisputed that Mexico has experienced

community transmission for many months, the IFR and CDC Order enabled DHS to expel tens of thousands of covered aliens from Mexico who would have otherwise spent material amounts of time in congregate settings, and large numbers of those covered aliens would have otherwise been released into the States in the U.S.-Mexico border region. Given the sheer volume of covered aliens subject to the CDC Order, the Director assesses that the positive impacts of the IFR and CDC Order on community transmission and case counts in the U.S.-Mexico border region were not insubstantial.

The benefits of the IFR and CDC Order are compelling when the recent trends in COVID-19 case counts and deaths, and the recent experiences of the States in the U.S.-Mexico border region, are considered. Nationally, the numbers of COVID-19 cases have continued to decrease since mid-July, and as of August 22, 2020, six out of ten HHS surveillance regions reported decreasing or stable levels of the disease.¹²¹ Two regions reported an increase in the percentage of people testing positive for COVID-19, and two regions reported increases in influenza-like illness visits over the previous week.¹²² Deaths involving COVID-19, pneumonia, and influenza have declined, from a high of 16,957 deaths during the week ending on April 18, 2020, to 400 deaths during the week ending on August 22, 2020.¹²³ Weekly hospitalizations associated with confirmed COVID-19 cases are also down, from a high of 10.10 per 100,000 Americans in April, to a low of 2.8 per 100,000 Americans during the week ending on August 22, 2020.¹²⁴

While hospitalizations and deaths have declined overall, the number of new COVID-19 cases in certain areas of the country has surged in recent months. Those areas include the States in the U.S.-Mexico border region. Indeed, as of August 30, 2020, California and Texas lead the country with the highest 7-day case count, and Arizona has the third highest number of cases

¹²¹ *COVID View: A Weekly Summary of U.S. COVID-19 Activity (August 22, 2020)*, Ctrs. for Disease Control & Prevention, <https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html> (last updated Aug. 28, 2020).

¹²² *Id.*

¹²³ *Weekly Updates by Select Demographic and Geographic Characteristics: Provisional Death Counts for Coronavirus Disease 2019 (COVID-19)*, Ctrs. for Disease Control & Prevention, https://www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.htm (last updated Aug. 26, 2020).

¹²⁴ *Laboratory-Confirmed COVID-19-Associated Hospitalizations: Preliminary weekly rates as of Aug. 1, 2020*, Ctr. for Disease Control & Prevention, https://gis.cdc.gov/grasp/COVIDNet/COVID19_3.html (last visited Aug. 31, 2020).

per 100,000 people over that same period.¹²⁵

The surge in California was dramatic. In early July 2020, the statewide data in California demonstrated a significant increase in the community transmission of COVID-19, which prompted State officials to implement sweeping measures to protect the health of the public.¹²⁶ The State Public Health Officer and Director observed that “[i]n addition to the impact on the general population, community spread increases the likelihood of expanded transmission of COVID-19 in congregate settings such as nursing homes, homeless shelters, jails and prisons. Infection of these vulnerable populations in these settings can be catastrophic[.]”¹²⁷ The number of patients hospitalized in California due to COVID-19 increased between 50–100% in all regions in the State, with an average increase of 77% compared to mid-June.¹²⁸

During the California surge, CBP continued to apprehend covered aliens who had crossed the border from Mexico into California. Absent the IFR and CDC Order, covered aliens moving through congregate areas in Border Patrol stations and POEs in California could have been capable of transmitting the virus that causes COVID-19, thereby increasing the already serious danger of the introduction of COVID-19 into California and, by extension,

¹²⁵ *United States COVID-19 Cases and Deaths by State: Cases in Last 7 Days*, Ctrs. for Disease Control & Prevention, <https://www.cdc.gov/covid-data-tracker/#cases> (last updated Aug. 30, 2020) (California reported 36,947 cases and Texas reported 33,391 cases, followed by Florida with 20,923 cases; Arizona had the third highest case rate per 100,000 people in the United States with 2,807 cases, surpassed only by Louisiana and Florida).

¹²⁶ On July 13, 2020, the California State Public Health Officer and Director announced mandatory statewide closures of indoor operations for certain sectors, and both indoor and outdoor operations for bars and similar establishments *Guidance on Closure of Sectors in Response to COVID-19 (July 13, 2020)*, Cal. Dep't of Pub. Health, <https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/Guidance-of-Closure-of-Sectors-in-Response-to-COVID-19.aspx> (last updated July 17, 2020). In her order, she observed that “[t]he data is clear that community spread of infection is of increasing concern across the state, and continues to grow in those counties on the County Monitoring List[.]” and “[w]hile these counties [with high numbers of COVID-19 hospitalizations] are primarily located in the south and central valley, there are now counties on the monitoring list from all regions of California.” See also *Blueprint for a Safer Economy*, Cal. All, <https://covid19.ca.gov/safer-economy/#top> (last visited Aug. 31, 2020).

¹²⁷ *Guidance on Closure of Sectors in Response to COVID-19 (July 13, 2020)*, Cal. Dep't of Pub. Health, <https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/Guidance-of-Closure-of-Sectors-in-Response-to-COVID-19.aspx> (last updated July 17, 2020).

¹²⁸ *Id.*

community transmission in California. The consequences for the healthcare system in California could have been severe; a surge of infected covered aliens coming from Mexico could have further reduced the available inpatient hospital bed capacity in California, while increasing the exposure of California healthcare workers and the CBP workforce to COVID-19. Increased community transmission from covered aliens would have been contrary to the interest of U.S. public health, and would have frustrated the efforts of Californians to slow community transmission.

There are still high rates of community spread within California, though the situation has improved some since the peak of the surge in July 2020.¹²⁹ California's revised reopening guidelines explain that as of August 31, 2020, certain businesses will be able to open "with modifications, including all retail, shopping centers at maximum 25% capacity, and hair salons and barbershops indoors," even in counties where community transmission is classified as "widespread."¹³⁰ As counties step down from "widespread" to the "substantial," "moderate," or "minimal" tiers based on case and positivity rates, restrictions are progressively loosened, permitting the reopening of additional indoor businesses and in-person instruction in schools.¹³¹ Higher rates of community transmission reverse such progress: "[i]f a county's metrics worsen for two consecutive weeks, it will be assigned a more restrictive tier."¹³²

While California is making progress, it is not in the clear yet. As of August 30, 2020, the California Department of Health reported 699,909 confirmed cases of COVID-19, and 12,905 deaths. It recognized that "[a]s case numbers continue to rise in California, the total number of individuals who have serious outcomes will also increase."¹³³

The Director assesses that increased community transmission in California would likely result in increased numbers of cases, as well as increased case and positivity rates, and ultimately increased numbers of individuals who have serious outcomes. Increases in case

and positivity rates would, in turn, frustrate efforts by California counties to step down to lower tiers in the reopening guidelines and begin in-person schooling and the reopening of businesses. The Director further assesses that the introduction of covered aliens into California through congregate settings in CBP facilities would likely have a negative impact on case and positivity rates in California, which would not be in the interest of U.S. public health.

Similar to California, Arizona saw significant increases in the number of confirmed COVID-19 infections beginning in mid-May, leading the Governor of Arizona to suspend the State's phased re-opening plans and delay the phased reopening of schools until August 17, 2020.¹³⁴ The Federal government committed to constructing surge testing sites in Arizona to help meet the increased demand for diagnostic testing.¹³⁵ During mid-June, Arizona was averaging approximately 1,300 new COVID-19 infections a day;¹³⁶ and by mid-July, Arizona had one of the highest positivity rates in the nation, at nearly 27%.¹³⁷ By July 27, 2020, 10 out of the 14 counties in Arizona were in the "red zone," meaning there were more than 100 new cases for every 100,000 people, and more than 10% of the people tested for COVID-19 test positive.¹³⁸

As a result of the surge in new COVID-19 cases, Arizona's healthcare system approached capacity in terms of the number of available hospital beds and critical staff.¹³⁹ On July 1, 2020, Arizona requested 500 additional

medical personnel from FEMA, in addition to the 62 Federal medical personnel already deployed to assist with Arizona's COVID-19 response.¹⁴⁰ On July 1, in response to a petition from medical providers, the Arizona Department of Health Services activated the State's Crisis Standards of Care Plan, which establishes guidelines for the allocation of scarce healthcare resources among patients based on factors such as likelihood of survival.¹⁴¹ As of August 30, 2020, Arizona's inpatient hospital bed occupancy rate was still approximately 81%, with approximately 10% occupied by COVID-19 patients; and its ICU bed occupancy rate was approximately 77%, with approximately 15% occupied by COVID-19 patients.¹⁴²

Arizona has instituted county-specific public health benchmarks that must be achieved in order to begin the phased reopening of businesses, including bars, indoor gyms/fitness centers, indoor movie theaters, and water parks/tubing operations.¹⁴³ Under the benchmark system, businesses in counties designated as experiencing minimal or moderate transmission, as indicated by certain metrics for at least two weeks, may reopen subject to occupancy limits and other mitigation requirements.¹⁴⁴ As of August 27, 2020, only one county is experiencing minimal transmission, eight counties are experiencing moderate transmission, and six counties

¹⁴⁰ See *Vice President Pence Holds News Conference with Arizona Governor*, C-SPAN (July 1, 2020), <https://www.c-span.org/video/?473590-1/vice-president-urges-wearing-masks-amid-coronavirus-spike-arizona> (statements regarding FEMA medical personnel occur at 03:52–04:20); see also Brett Samuels, *Arizona asks for 500 additional medical personnel amid spike in virus cases*, The Hill (July 1, 2020), <https://thehill.com/homenews/state-watch/505517-arizona-asks-for-500-additional-medical-personnel-amid-spike-in-virus>.

¹⁴¹ See generally COVID-19 Implementing Crisis Standards of Care at Short-Term Inpatient Acute Care Facilities Guidance Approved by State Disaster Medical Advisory Committee (SDMAC)—4/1/2020, Ariz. Dep't of Health Serv.'s, (available at: <https://www.azdhs.gov/documents/preparedness/epidemiology-disease-control/infectious-disease-epidemiology/novel-coronavirus/sdmac/sdmac-guidance-crisis-standards-care-healthcare-facilities.pdf>); Arizona Crisis Standards of Care Plan, 3d ed. (2020), Ariz. Dep't of Health Serv.'s, (available at: <https://www.azdhs.gov/documents/preparedness/emergency-preparedness/response-plans/azcsc-plan.pdf>).

¹⁴² Data Dashboard, Ariz. Dep't of Health Serv.'s, <https://www.azdhs.gov/preparedness/epidemiology-disease-control/infectious-disease-epidemiology/covid-19/dashboards/index.php> (last visited Aug. 13, 2020) (see "Hospital Bed Usage & Availability" tab, subtabs for "ICU Bed Usage and Availability" and "Inpatient Bed Usage and Availability").

¹⁴³ See Benchmarks for Businesses by County, Ariz. Dep't of Health Serv.'s, (available at: <https://www.azdhs.gov/documents/preparedness/epidemiology-disease-control/infectious-disease-epidemiology/novel-coronavirus/business-benchmarks.pdf>) (last updated Aug. 27, 2020).

¹⁴⁴ *Id.*

¹³⁴ Press Release, Governor of Arizona Announces Further Action to Reverse COVID-19 Spread in the State (June 29, 2020) (available at: <https://azgovernor.gov/governor/news/2020/06/further-action-reverse-covid-19-spread-arizona>).

¹³⁵ Jessica Boehm, Ariz. Cent., *Feds downplay Phoenix mayor's COVID-19 testing concerns, but commit to new mass test site in west Phoenix* (July 8, 2020), <https://www.azcentral.com/story/news/local/phoenix/2020/07/08/feds-discount-gallego-concerns-but-commit-covid-19-testing-site/5400030002/>.

¹³⁶ Will Stone, *Health Experts Link Rise in Arizona Coronavirus Cases to End of Stay-At-Home Order*, Nat'l Pub. Radio (June 14, 2020), <https://www.npr.org/2020/06/14/876786952/health-experts-link-rise-in-arizona-coronavirus-cases-to-end-of-stay-at-home-ord>.

¹³⁷ *Arizona's surge in coronavirus cases has been "the worst in the entire country," health experts say*, CBS News (July 13, 2020), <https://www.cbsnews.com/news/arizona-coronavirus-cases-worst-in-united-states>.

¹³⁸ *State Reports*, White House Coronavirus Task Force, *17–23 (July 26, 2020) (on file with HHS).

¹³⁹ *Id.* See Data Dashboard, Ariz. Dep't of Health Serv.'s, <https://www.azdhs.gov/preparedness/epidemiology-disease-control/infectious-disease-epidemiology/covid-19/dashboards/index.php> (last visited Aug. 31, 2020) (see "Hospital Bed Usage & Availability" tab).

¹²⁹ *California Coronavirus Map and Case Count*, N.Y. Times, <https://www.nytimes.com/interactive/2020/us/california-coronavirus-cases.html> (last visited Aug. 31, 2020).

¹³⁰ *Blueprint for a Safer Economy*, Cal. All, <https://covid19.ca.gov/safer-economy/#top> (last visited Aug. 31, 2020).

¹³¹ *Id.*

¹³² *See id.*

¹³³ *State Officials Announce Latest COVID-19 Facts*, Cal. Dep't. of Pub. Health, <https://www.cdph.ca.gov/Programs/OPA/Pages/NR20-213.aspx> (last updated Aug. 30, 2020).

are experiencing substantial transmission, during which all businesses must remain closed.¹⁴⁵

The Director assesses that the IFR and CDC Order have helped protect the overtaxed Arizona healthcare system from additional strain and conserve health care resources for the domestic population. The Director further assesses that absent the IFR and CDC Order, covered aliens moving through congregate settings in CBP facilities in Arizona could have been capable of transmitting the virus that causes COVID-19, thereby increasing the already serious danger of the introduction of COVID-19 into Arizona and, by extension, community transmission in Arizona. The additional strain on the system would have been problematic because the situation in Arizona has been serious, with hospital occupancy rates nearing limits, critical staff shortages, and the activation of State plans for allocating health care.

As with California, the Director assesses that increased community transmission in Arizona would likely result in increased numbers of cases, as well as increased case and positivity rates, and ultimately increased numbers of individuals who have serious outcomes. Increases in case and positivity rates would, in turn, frustrate efforts by Arizona counties to meet benchmarks for the reopening of businesses. The Director assesses that the introduction of covered aliens into Arizona through congregate settings in CBP facilities would likely have a negative impact on case and positivity rates in Arizona, which would not be in the interest of U.S. public health.

The Director's concerns are driven partly by the public health situation in Mexico. As of August 31, 2020, Mexico has 591,712 confirmed cases, and 63,819 reported deaths.¹⁴⁶ Some observers believe the actual COVID infections and deaths are multiples (likely between 10 to 20 times) of what is reported, as Mexico has the lowest diagnostic testing per capita of any country in the Organization for Economic Co-operation and Development (OECD).¹⁴⁷

While the data on Mexico is limited, there are signs that the epicenter of the COVID-19 pandemic in Mexico is shifting from Mexico City to the

Mexican border states as the overall public health situation improves somewhat. As of August 28, 2020, under SALUD's "stoplight" designation system, only one of Mexico's 32 states, Colima, is red, 21 are orange, and 10 are yellow. Five states advanced to orange from red. According to SALUD, Mexico City's cases are stabilizing and hospital occupancy in the city decreased to 47 percent, from a high of approximately 80 percent in mid-June. Although hospital occupancy rates have improved in recent weeks—the national hospital occupancy rate is 36 percent—hospital occupancy rates remain elevated in Mexican border states such as Nuevo Leon (61 percent) and Coahuila (48 percent). As of August 26, 2020, several Mexican border states report relatively high numbers of active COVID-19 infections: Tamaulipas (3,566 active cases), Nuevo Leon (6,028 active cases) and Baja California (1,440 active cases). On August 2, 2020, the health minister of the Mexican border State of Chihuahua died from COVID-19 after nearly two weeks of inpatient hospitalization.¹⁴⁸

A shift in the epicenter of the COVID-19 pandemic in Mexico to the U.S.-Mexico border region would present increased concerns for U.S. public health because all covered aliens crossing the U.S.-Mexico border necessarily travel through that region. If community transmission in the Mexican border region increases, then the numbers of COVID-19 cases in that region are likely to increase, as are the numbers of infected covered aliens who seek to introduce themselves into the United States. The introduction of more infected covered aliens would probably have a negative impact on community transmission in the United States, and ultimately U.S. public health.

III. 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. Congress enacted section 362 in 1944, and modeled it on Section 7 of the Quarantine Act of 1893, which was informed by U.S. public health laws from the early days of the Republic. The history of the U.S. public health laws is a helpful backdrop when analyzing the congressional intent behind section 362. Below we discuss the history of such laws, followed by a discussion of section 362 and other relevant statutory authorities.

A. History of the U.S. Public Health Laws

Congress has long recognized the danger posed by communicable disease and granted broad powers to the Executive Branch to address the danger during times of emergency. In 1796, Congress passed an Act Relative to Quarantine, which authorized the President to direct U.S. officers to "aid in the execution of quarantine, and also in the execution of the health laws of the states, respectively, in such manner as may to him appear necessary."¹⁴⁹

After a yellow fever outbreak in New York in 1798, Congress enacted "An Act Respecting Quarantine and Health Laws."¹⁵⁰ This statute replaced the Act of May 1796 and created a more robust Federal public health regime. It authorized and required certain officers to aid in the execution of State quarantine and health laws, including those with respect to vessels arriving in or bound to any U.S. port. It also authorized the Secretary of the Treasury to vary or dispense with regulations concerning the entry of vessels and cargoes when required for consistency with quarantine and other health laws. Just as the Director has recognized the threat that the introduction of COVID-19 presents to CBP personnel, the Act recognized that the "prevalence of any contagious or epidemical disease" at a port could present a danger to Federal officials. Therefore, it authorized measures to protect Federal officials during an outbreak. Specifically, it authorized the Secretary of the Treasury and the President to order the relocation of revenue officers and public offices, respectively, from a dangerous port to a safe location.¹⁵¹ Almost 100 years later, the U.S. experienced a severe cholera outbreak caused by persons arriving from Europe.¹⁵² In response, Congress passed the Quarantine Act of 1893, ch. 114, 27 Stat. 449. Several provisions of that Act addressed the Federal authority to quarantine persons arriving in the United States. Section 7 of the Act of 1893, which used terms nearly identical to the current section 362, expanded Federal authority beyond the authority to quarantine persons. Specifically, it authorized the President to "prohibit" the "introduction" of persons into the United States if "the quarantine defense" was insufficient to address a

¹⁴⁵ *Id.*

¹⁴⁶ WHO Coronavirus Disease (COVID-19) Dashboard, WHO, <https://covid19.who.int/table> (last visited Aug. 31, 2020).

¹⁴⁷ Azam Ahmed, *Hidden Toll: Mexico Ignores Wave of Coronavirus Death in Capital*, The N.Y. Times (May 8, 2020, updated May 28, 2020), <https://www.nytimes.com/2020/05/08/world/americas/mexico-coronavirus-count.html>.

¹⁴⁸ Laura Gottesdieer, *Mexican State health minister dies after being hospitalized for COVID-19*, Reuters (July 26, 2020, 11:57 a.m.), <https://www.reuters.com/article/us-health-coronavirus-mexico-idUSKCN24R0K5>.

¹⁴⁹ An Act relative to Quarantine, ch. 31, 1 Stat. 474 (May 27, 1796).

¹⁵⁰ An Act respecting Quarantine and Health Laws, ch 12, 1 Stat. 619 (Feb. 25, 1799).

¹⁵¹ *Id.*

¹⁵² *History of Quarantine*, Ctrs. for Disease Control & Prevention, <https://www.cdc.gov/quarantine/historyquarantine.html> (last updated July 20, 2020).

“serious danger of the introduction of the [disease] into the United States”, and a “suspension of the right to introduce” persons or property was demanded in the interest of public health: [W]henver it shall be shown to the satisfaction of the President that by reason of the existence of cholera or other infectious or contagious diseases in a foreign country there is serious danger of the introduction of the same into the United States, and that notwithstanding the quarantine defense this danger is so increased by the introduction of persons or property from such country that a suspension of the right to introduce the same is demanded in the interest of the public health, the President shall have power to prohibit, in whole or in part, the introduction of persons and property from such countries or places as he shall designate and for such period of time as he may deem necessary. 27 Stat. 449, 452 (Feb. 15, 1893).

Section 7 was broader than some of the other sections of the Act of 1893 because it applied to the act of introducing a person into the United States, and not simply to ships or vessels carrying passengers.¹⁵³ Section 7 prevented individuals traveling aboard vessels from circumventing vessel-specific prohibitions that focused solely on disembarkations in American harbors. By allowing the President to broadly prohibit the “introduction” of persons, it ensured that travelers could not evade the prohibition by swimming or walking to shore.¹⁵⁴ Congress also

¹⁵³ Congress repeatedly used “ship” or “vessel” in other sections of the 1893 Act, but conspicuously referred more broadly to “persons or property” in section 7. Compare The Quarantine Act of 1893, ch. 114, 27 Stat. 449 section 7 with section 1 (unlawful for ships to enter U.S. ports from abroad except in accordance with public health regulations); section 2 (requiring ships abroad to obtain a bill of health); section 3 (authorizing, *inter alia*, regulation of “vessels sail[ing] from any foreign port or place”); section 5 (issuance of regulations for, *inter alia*, “vessels in foreign ports,” and prohibition on vessels arriving without a bill of health); and section 6 (providing for “an infected vessel” to be “remand[ed]” to quarantine station). The fact that Congress did not mention “ship” or “vessel” in section 7, as it does in the other sections of the Act, indicates that Congress did not intend to limit section 7’s application to ships.

¹⁵⁴ Consistent with contemporaneous dictionaries and the ordinary meaning and usage of “introduce,” a person could “introduce” him or herself. Introduction of a person was an action that could be taken by individuals as well as third parties. See *Universal English Dictionary* 1067 (John Craig ed. 1861) (defining “introduction” to include, *inter alia*, “the act of bringing into a country” and “the ushering of a person into presence”); *American Dictionary of the English Language* 113 (Noah Webster ed., 1828) (similar definitions); cf. *Ashley v. Bd. of Sup’rs of Presque Isle Cty.*, 83 F. 534, 540 (6th Cir. 1897) (referring to a “party [who] introduces himself as a witness in his own behalf”) (emphasis added); *Olds Wagon Works v. Benedict*,

sought to give the Executive Branch the power to prevent asymptomatic persons infected with a communicable disease from moving into the country before the asymptomatic persons and the customs or public health officials could detect the disease. Such persons, if allowed into the country, would “disseminate the poison that has been slumbering in their midst and imperil the lives of any community in which they happen to locate.” H.R. 9757, 52nd Cong., 2d Sess., Report No. 2210 at 4 (Jan. 9, 1893). The risk of asymptomatic transmission arose from persons moving into the United States by vessel, by foot, or by any other any means, and increased once the person was on U.S. soil and poised to move further into the country.

Section 7 also was noteworthy because it granted the authority to “suspend” the “right to introduce” persons or property. In 1893, as now, “suspend” was a term of art for temporarily ceasing the operation or effect of laws. See, e.g., U.S. Const. art. I, sec. 9, cl. 2 (“The Privilege of the Writ of Habeas Corpus shall not be suspended, unless when in Cases of Rebellion or Invasion the public Safety may require it.”); see also *Universal English Dictionary* 815 (John Craig ed. 1869) (defining “suspend,” in part, as “to cause to cease for a time from operation or effect, as, to *suspend* the habeas corpus act”) (emphasis in original). Unlike the other sections of the Act of 1893, section 7 used the phrase “*suspension* of the right to introduce,” which by its plain meaning demonstrates that Congress intended for section 7 to authorize the President to cease temporarily the effect of any laws conferring a right to introduce persons.¹⁵⁵

Furthermore, the Congressional record reflects a clear and consistent theme that section 7 is intended to give the President the authority to suspend any right to introduce persons that any immigration laws confer on the Executive Branch. As one Senator explained:

[I]f section 7 be adopted, then I think it will be quite clear that . . . the power to suspend immigration altogether, either temporarily or permanently as a health device, is intended to be lodged solely in the President of the United States, where it certainly should be lodged. In other words, if it be true that the quarantine power

67 F. 1, 4 (8th Cir. 1895) (discussing an “intervener who *introduces himself* into a pending action in a state court”) (emphasis added).

¹⁵⁵ See *Universal English Dictionary* 815 (John Craig ed. 1869) (defining “suspension,” in part, as “[t]he act of suspending; the state of being suspended; in special senses, a keeping in doubt; postponement of legal execution”).

involves in it the power of total suspension of immigration, if we leave the bill without the proposed section 7, every petty quarantine officer, or certainly the Secretary of the Treasury, will have it, to which I do not agree. I think it is quite clear that this section should be added, declaring in terms whenever the health or protection of the country from infection requires the total suspension of immigration, that power is to belong to the President[.]

24 Cong. Rec. 393 (Jan. 7, 1893) (statement of Sen. Hoar); see also *id.* at 393–94 (statement of Sen. Chandler) (recognizing that section 7 would give the President the power to suspend immigration in his discretion, whenever there is danger of infection); 24 Cong. Rec. 470 (Jan. 10, 1893) (statement of Sen. Gray) (stating that the exigency posed by “apprehension of the invasion of contagious disease [] is sufficient . . . to justify this extraordinary power of the entire suspension of immigration”).¹⁵⁶ The exigency of the cholera outbreak taught that it was necessary to convey a broad power to the Executive Branch to use in rare times of emergency to protect public health. As one Senator put it, “I believe that our duty is to provide, *as far as our constitutional authority can possibly go*, for the prevention of the introduction of these epidemics. It is a peculiarly binding and obligatory duty at this time.” 2 Cong. Rec. 472 (Jan. 10, 1893) (statement of Sen. Morgan) (emphasis added).

Congress enacted the Act of 1893 two years after enacting the Immigration Act of 1891 (“Immigration Act”), which authorized the Treasury Department to regulate immigration, and excluded from admission into the United States aliens “suffering from a loathsome or a dangerous contagious disease.” Act of Mar. 3, 1891, ch. 551, section 1, 26 Stat. 1084. Section 8 of the Immigration Act authorized inspection officers from the Treasury Department to board any arriving vessel, inspect the aliens on the vessel, and have surgeons conduct medical examinations of the aliens. Section 9 imposed a penalty on any person or transportation company bringing to the United States any alien “suffering from a loathsome or dangerous contagious disease.”

When Congress enacted section 7 of the Act of 1893, Congress was fully

¹⁵⁶ The Act of 1893 passed overwhelmingly with broad bipartisan support, but even those opposed to the law recognized it granted the President the authority to suspend immigration. See, e.g., 24 Cong. Rec. 370–71 (Jan. 6, 1893) (statement of Sen. Mills) (“I shall vote very cheerfully against placing in the hands of the President of the United States, whether he be a Republican or a Democrat, any such extraordinary power as that, to suspend immigration to this country at his pleasure.”).

aware of the Immigration Act that it had enacted just two years earlier. The Act of 1893 was not a redundant immigration law. It was a broad public health statute that gave the President a sweeping but temporary power to combat larger, global threats to public health. Congress intended for the power to prohibit the introduction of persons to be a categorical one that operates separately and independently of the immigration power that applies against individual aliens suffering from a contagious disease. Congress recognized that this separate public health authority was needed to address, among other things, situations where an infected but asymptomatic person was seeking introduction into the United States, or government resources were overtaxed.

In June 1929, President Herbert Hoover issued an Executive Order invoking section 7 of the Act of 1893 to restrict the “Transportation of Passengers” from China and the Philippines because of a meningitis outbreak.¹⁵⁷ Since November 1928, 17 trans-Pacific passenger-carrying vessels with epidemic cerebrospinal meningitis infections on board had arrived at U.S. Pacific coast ports. The continued arrival of passengers with cerebrospinal meningitis infection had “overtaxed” Federal and state quarantine facilities, and “notwithstanding the quarantine defense, there exist[ed] danger of introducing this disease into the United States[.]”¹⁵⁸ Therefore, “in order to prevent the further introduction” of cerebrospinal meningitis into the United States, the Executive Order provided that no persons may be introduced directly or indirectly by transshipment or otherwise into the United States or any of its possessions or dependencies from any port in China (including Hong Kong) or the Philippine Islands for such period of time as may be deemed necessary, except under such conditions as may be prescribed by the Secretary of the Treasury.¹⁵⁹

Although the Executive Order focused on vessels, it was not limited to them; it clearly stated that “no persons may be introduced directly or indirectly by transshipment or otherwise into the United States,” except as permitted by the Treasury Secretary (emphasis added). The regulations accompanying the Executive Order did not purport to narrow the Executive Order or foreclose the Executive Branch from enforcing section 7 of the Act of 1893 against symptomatic or asymptomatic persons

from China or the Philippines who introduced themselves into the United States by swimming or walking ashore.¹⁶⁰ The Executive Order tailored the Federal response to a discrete problem: The arrival at Pacific Coast ports of trans-Pacific passenger-carrying vessels with epidemic cerebrospinal meningitis infection existing on board. Neither the Executive Order nor the accompanying regulations purported to set forth a comprehensive or final interpretation or framework for the implementation of section 7 of the Act of 1893. President Hoover’s Executive Order was consistent with the statutory text, which communicates clearly that the authority to prohibit the introduction of persons is not limited to any one communicable disease, setting, mode of introduction, or geographic location.

In 1944, Congress enacted section 362 of the PHS Act, 42 U.S.C. 265. Section 362 is nearly identical to section 7 of the 1893 Act. Whenever the Surgeon General 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, the Surgeon General, in accordance with regulations approved by the President, shall have the power 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.

The legislative history of section 362 indicates that it was largely intended to reenact section 7 of the 1893 Act. As explained in a house report, “Section 362 would reenact a provision of present law (42 U.S.C. 111) authorizing the suspension of travel of persons and shipment of goods from any foreign country where a communicable disease exists, if there is found to be serious danger of introduction of the disease into the United States. Consistently with the general administrative pattern in the bill, the authority now lodged in the

President would be placed in the Surgeon General, to be exercised under Presidential regulations.” H.R. Rep. No. 78–1364, at 25 (1944).

The differences between section 7 and section 362 are few. First, section 362 grants authority to the Surgeon General (not the President). Second, it applies to any “communicable disease” (not “cholera or other infectious or contagious diseases”). Third, it omits the phrase “notwithstanding the quarantine defense.” Fourth, it authorizes the Surgeon General to suspend the right to introduce when it is “required” (not “demanded”) in the interest of public health.

Congress’s omission of the phrase “notwithstanding the quarantine defense” reinforced Congress’s intent that the Executive Branch have the flexibility to prohibit the introduction of persons in situations both where quarantine is available as a public health measure, and where it is not. Originally, section 7 of the Act of 1893 linked the authority to prohibit the introduction of persons to the inadequacy of quarantine as a national defense against disease transmission. By decoupling the prohibition of the introduction of persons from the inadequacy of quarantine, Congress gave the Surgeon General even greater flexibility to prohibit the introduction of persons into the United States in the interest of public health, by allowing that power to be exercised regardless of whether the government is exercising its quarantine powers, and regardless of the adequacy of any quarantine measures. This statutory change followed the meningitis outbreak of 1929, during which President Hoover prohibited the introduction of persons arriving from Asia when Federal and local quarantine facilities were operational but overtaxed.¹⁶¹

The current statutory text therefore expressly gives the Director the authority to “prohibit, in whole or in part, the introduction of persons” from foreign countries whenever he determines there is a serious danger of the introduction of a communicable disease into the United States and that this danger is so increased by the introduction of persons from those countries that a “suspension of the right to introduce persons” is required in the interest of public health. The statute is not limited to any particular communicable disease, setting, mode of introduction, or geographic location.

¹⁵⁷ Exec. Order No. 5143 (June 21, 1929).

¹⁵⁸ *Id.*

¹⁵⁹ *Id.*

¹⁶⁰ See Regulations Governing Embarkation of Passengers and Crew at Ports in China and the Philippine Islands and Their Transportation to the United States Ports Prescribed in Accordance with Executive Order Approved June 21, 1929 (July 11, 1929), included in Conn. Dep’t of Health, Connecticut Health Bulletin, vol. 43, No. 9, 324–326 (Sep. 1929).

¹⁶¹ Exec. Order No. 5143 (June 21, 1929).

B. Other Statutory Authorities Relevant to This Rulemaking

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; section 367, 42 U.S.C. 270, and section 368, 42 U.S.C. 271.

Section 311 authorizes the Secretary to accept State and local assistance in the enforcement of quarantine rules and regulations and to assist the States and their political subdivisions in the control of communicable diseases. 42 U.S.C. 243(a).

As previously discussed, 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. 42 U.S.C. 264(a). 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. 42 U.S.C. 264(b).

Section 365 provides that it shall be the duty of customs officers and of Coast Guard officers to aid in the enforcement of quarantine rules and regulations.¹⁶² 42 U.S.C. 268(b). Under Section 365, Coast Guard officers have aided in the apprehension and detention of individuals for purposes of quarantine and isolation, particularly at U.S. ports of entry. They have also enforced CDC's No Sail Order with respect to certain cruise ships.¹⁶³ Additionally, the

¹⁶² 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. Sec. 1401(j). 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. Sec. 203(1), such that reference to the Secretary of the Treasury should be read to reference the Secretary of Homeland Security.

¹⁶³ See No Sail Order and Suspension of Further Embarkation, 85 FR 16628, 16631 (Mar. 24, 2020); No Sail Order and Suspension of Further Embarkation; Notice of Modification and Extension and Other Measures Related to Operations, 85 FR 21004, 21007 (Apr. 15, 2020).

customs officers from DHS have assisted CDC in implementing the CDC Order on covered aliens.

The vesting in DHS of a duty to aid HHS/CDC in the enforcement of rules and regulations promulgated under section 362 is critical to the functioning of the PHS Act because DHS has personnel and resources at the operational level that HHS/CDC may require to execute a prohibition on the introduction of persons into the United States. HHS/CDC, for example, does not have officers at POEs who can avert dangers to public health by taking into Federal custody and expelling persons who seek to introduce themselves into the United States in violation of a CDC Order. Nor does HHS/CDC have the operational capability to avert dangers to public health by interdicting vessels that seek to introduce persons into the United States or people who attempt to enter into the United States between ports of entry in violation of a CDC Order. HHS/CDC, like its predecessor agencies and public health agencies at the state level, depends partly on law enforcement agencies with operational capabilities to avert dangers to public health by enforcing HHS/CDC's public health orders against those who seek to violate them.

Section 368 provides that any person who violates regulations implementing sections 361 or 362 will be subjected to a fine or imprisonment for not more than one year, or both. Pursuant to 18 U.S.C. 3559 and 3571, an individual may face a fine of up to \$100,000 for a violation not resulting in death, and up to \$250,000 for a violation resulting in death. Under section 368, HHS/CDC may refer violators to the U.S. Department of Justice for criminal prosecution. HHS/CDC does not have independent authority under section 368 to impose criminal fines or imprison violators.

IV. Provisions of New Section 71.40 and Changes From Interim Final Rule

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

There are a few notable changes between this final rule and the IFR. First, this final rule has a slightly different name from the IFR, which was titled "*Control of Communicable Diseases; Foreign Quarantine: Suspension of Introduction of Persons Into the United States From Designated Foreign Countries or Places for Public Health Purposes*." HHS/CDC decided to

change the name of the final rule to "*Control of Communicable Diseases; Foreign Quarantine: Suspension of the Right to Introduce and Prohibition of Introduction of Persons into United States from Designated Foreign Countries or Places for Public Health Purposes*" to better align with the text of section 362, which uses the phrase "suspension of the right to introduce" and states that the Director shall have "the power to prohibit . . . the introduction of persons."

Second, the final rule uses the term "quarantinable communicable disease" instead of "communicable disease." The purpose of this change is to clarify that these procedures do not apply to all communicable diseases. Instead, these procedures are limited to preventing the introduction of *quarantinable* communicable diseases, which are included in the "Revised List of Quarantinable Communicable Diseases" found in Executive Order 13295, as amended by Executive Order 13375 and Executive Order 13674.¹⁶⁴ The current list of diseases includes cholera, diphtheria, infectious tuberculosis, plague, smallpox, yellow fever, viral hemorrhagic fevers (including Lassa, Marburg, Ebola, Crimean-Congo, South American, and others not yet isolated or named), severe acute respiratory syndromes (including Middle East Respiratory Syndrome and COVID-19), and influenza caused by novel or reemergent influenza viruses that are causing, or have the potential to cause a pandemic.

Third, the final rule adds in section 71.40(c) the requirement that the Director include in his or her Order a statement of "the serious danger posed by the introduction of the quarantinable communicable disease in the foreign country or countries (or one or more designated political subdivisions or regions thereof) or places from which the introduction of persons is being prohibited." After considering comments (*infra* section V.), HHS/CDC decided to add this requirement because HHS/CDC agrees that the Director ought to provide the public with a short and concise factual statement on the serious danger of the introduction of the quarantinable communicable disease that justifies the exercise of those powers. For similar reasons, this final rule also adds that any order issued pursuant to it shall state the means by which the prohibition on introduction shall be implemented.

¹⁶⁴ Exec. Order 13295 (Apr. 4, 2003), as amended by Exec. Order 13375 (Apr. 1, 2005) and Exec. Order 13674 (July 31, 2014).

Finally, HHS/CDC is changing the use of the word “vector” in the definition of “suspension of the right to introduce.” While the term “vector” may technically include humans in some definitions, it is generally accepted in the scientific community that vectors are living organisms that can transmit infectious diseases between humans or to humans from animals, such as mosquitoes, ticks, flies, and fleas, among others. There is not an equivalent term that applies specifically to humans.

A. Section 71.40(a)

As discussed previously, Section 362 of the PHS Act requires that the Director first “determine [] that by reason of the existence of any communicable disease in a foreign country there is a serious danger of the introduction of such disease into the United States, and that this danger is so increased by the introduction of such persons . . . from such country that a suspension of the right to introduce such persons . . . is required in the interest of the public health” Only then “shall [the Director] have the power to prohibit, in whole or in part, the introduction of persons . . . 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.”

Section 71.40(a) interprets and implements the requirements in section 362 that the Director must fulfill in order to prohibit the introduction of persons into the United States. Specifically, section 71.40(a) establishes that the Director may prohibit, in whole or in part, the introduction into the United States of persons from designated foreign countries (or one or more political subdivisions or regions thereof) or places, only for such period of time that the Director deems necessary to avert the serious danger of the introduction of a quarantinable communicable disease by issuing an order in which the Director determines that:

(1) By reason of the existence of any quarantinable 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 quarantinable 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 right to introduce such persons into the United

States is required in the interest of public health.

In this final rule, HHS/CDC adds to section 71.40(a) that the prohibition on the introduction into the United States of persons from designated foreign countries (or one or more political subdivisions or regions thereof) or places may be done “in whole or in part.” The phrase “in whole or in part” appears in section 362, so HHS/CDC believes it is appropriate to include it in the final rule. The authority to prohibit the introduction of persons into the United States is a broad one, and HHS/CDC will tailor its use of the authority to what is required in the interest of public health. If HHS/CDC concludes that public health requires only a prohibition on the introduction of certain persons from foreign countries (or one or more political subdivisions or regions thereof) or places, then HHS/CDC will not prohibit the introduction of all persons from such countries or places.

HHS/CDC may, in its discretion, consider a wide array of facts and circumstances when determining what is required in the interest of public health in a particular situation. Those facts and circumstances may include the same ones that HHS/CDC considers when issuing travel health notices: The overall number of cases of disease; any large increase in the number of cases over a short period of time; the geographic distribution of cases; any sustained (generational) transmission; the method of disease transmission; morbidity and mortality associated with the disease; the effectiveness of contact tracing; the adequacy of state and local health care systems; and the effectiveness of state and local public health systems and control measures.

Additionally, this final rule states that the Director may prohibit the introduction of persons into the United States for such period of time as he or she “deems necessary to avert the serious danger of the introduction of a quarantinable communicable disease.” The IFR stated that the Director may prohibit the introduction into the United States of persons for such period of time that he or she “deems necessary for the public health.” HHS/CDC makes this change so that the final rule more closely tracks the statutory text.

Finally, in section 71.40(a)(2), HHS/CDC includes the phrase “suspension of the right to introduce,” instead of “suspension of the introduction” of persons. The final rule language tracks the statute verbatim. HHS/CDC interprets the statutory phrase “suspension of the right to introduce” in section 71.40(b)(5). As discussed

more fully below, HHS/CDC clarifies that the “suspension of the right to introduce” means to cause the temporary cessation of the effect of any law, rule, decree, or order pursuant to which a person might otherwise have the right to be introduced or seek introduction into the United States.

B. Section 71.40(b)

Section 71.40(b) of this final rule defines some of the statutory language that HHS/CDC has incorporated into section 71.40(a) of this final rule.

1. 71.40(b)(1): “Introduction into the United States”

As explained above, section 71.40(a) of this final rule tracks the language of section 362 of the PHS Act, stating that the Director “may prohibit, in whole or in part, the introduction into the United States of persons” Section 71.40(b)(1) of this final rule defines “introduction into the United States” as 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 or property in the United States, in a manner that the Director determines to present a risk of transmission of a quarantinable communicable disease to persons, or a risk of contamination of property with a quarantinable communicable disease, even if the quarantinable communicable disease has already been introduced, transmitted, or is spreading within the United States.

This definition is consistent with dictionary definitions of “introduction,” Congress’ and courts’ use of the phrase, and the interest of public health.

The word “introduction” is the noun form of “introduce,” which “is a flexible and broad term.” *U.S. v. Trek Leather, Inc.*, 767 F.3d 1288, 1298 (Fed. Cir. 2014). Dictionaries from around the eras when both the Act of 1893 and section 362 were enacted contain similarly broad definitions of “introduction.”¹⁶⁵ The definitions support HHS/CDC’s view that the

¹⁶⁵ See *Universal English Dictionary* 1067 (John Craig ed. 1861) (defining “introduction” to include, *inter alia*, “the act of bringing into a country” as well as “the ushering of a person into presence”); *American Dictionary of the English Language* 113 (Noah Webster ed., 1st ed. 1828) (similar definitions); *Funk and Wagnall’s New Standard Dictionary of the English Language* (1946) (defining “introduce” as to “bring, lead, or put in; conduct inward; usher in; insert” and “introduction” as the “act of introducing, in any sense, as of inserting, bringing into notice or use, making acquainted; as, the introduction of a key into a door, or of one person to another”).

“introduction” of a person into the United States can include a person’s bringing of himself or herself into the United States, or a third party’s bringing of the person into the United States.

Congress has used the words “introduce” and “introduction” elsewhere in Title 42 of the U.S. Code when referring to the movement into commerce of goods that cause pollution. 42 U.S.C. 7545(c) (“The Administrator may . . . control or prohibit the . . . introduction into commerce . . . of any fuel or fuel additive . . .”), 7522(a)(1) (prohibiting “the introduction, or delivery for introduction, into commerce,” of certain motor vehicles). Courts have explained that “introduction into commerce commences upon the arrival of imported goods upon United States soil, but introduction does not necessarily end there.” *United States v. Steinfelds*, 753 F.2d 373, 377 (5th Cir. 1985). Once goods are on U.S. soil and clear customs, the seller of the goods may continually introduce them into commerce through his or her conduct. *Id.* at 378. Thus, “introduction” may be a continuing process, as opposed to a single event that occurs at a fixed point in time.

The dictionaries, other statutes within Title 42, and case law are all helpful to the interpretation of the phrase “introduction into the United States.” None of those authorities, however, squarely address how closely a person must interact with the United States and for how long to constitute an “introduction” in the context of transmitting disease. The interpretation of “introduction” is within CDC’s delegated statutory authority. *City of Arlington, Tex. v. F.C.C.*, 569 U.S. 290, 296 (2013) (“Congress knows to speak . . . in capacious terms when,” as here, “it wishes to enlarge [] agency discretion”). It is also squarely within the expertise of HHS/CDC: It involves scientific and technical knowledge and experience regarding communicable diseases generally, and the application of such knowledge and experience to the unique facts and circumstances of the specific quarantinable communicable disease that threatens public health.¹⁶⁶

¹⁶⁶ The courts frequently defer to the CDC’s judgment on such issues. *In re Approval of Judicial Emergency Declared in Eastern District of California*, 956 F.3d 1175, 1181 (9th Cir. 2020) (determining that it would not be safe to resume normal court operations until “the CDC lifts its guidance regarding travel-associated risks and congregate settings and physical distancing”); *Valentine v. Collier*, 956 F.3d 797, 801 (5th Cir. 2020) (staying preliminary injunction that required prison officials to immediately implement measures in excess of those suggested by CDC guidelines);

HHS/CDC’s regulatory definition in section 71.40(b)(1) resolves the ambiguity by making clear that the introduction of a person into the United States can occur, for example, when a person on U.S. soil moves further into the United States, and comes into contact with new persons or property in ways that increase the risk of spreading the quarantinable communicable disease. “Introduction” does not necessarily conclude the instant that the person first steps onto U.S. soil. If the person has been on U.S. soil, and HHS/CDC (through CBP) stops the person’s movement before he or she comes into contact with new persons or property in a way that risks spreading a quarantinable communicable disease, then HHS/CDC has prevented the introduction of the person under section 362. For example, if a person walked from Canada to Vermont, walked 15 miles into the United States, and was intercepted by DHS before coming into contact with new persons or property, and returned to Canada without entering a congregate setting, then HHS/CDC would have prevented the “introduction” of the person into the U.S.

A person who has been in the United States for longer than the incubation period of the quarantinable communicable disease, and has not yet exhibited symptoms or tested positive for the quarantinable communicable disease, may have finished introducing himself or herself into the United States. That determination, however, will be based on HHS/CDC’s application of its scientific and technical expertise to the specific facts and circumstances.

2. 71.40(b)(2): “Prohibit, in whole or in part, the introduction into the United States of persons”

In section 362, Congress gave the Secretary “the power to prohibit, in whole or in part, the introduction [into the United States] of persons . . . from such countries or places as he shall designate in order to avert” an increase in the “serious danger of the introduction of [any communicable disease in a foreign country] into the United States.” Congress’ grant of authority is general in scope. When Congress enacted section 362, the power to “prohibit” meant the power “to forbid; to interdict by authority; to hinder; to debar; to prevent; [or] to

Elim Romanian Pentecostal Church v. Pritzker, 962 F.3d 341 (7th Cir. 2020) (upholding against constitutional challenge an executive order that was grounded in CDC guidelines); *Hickox v. Christie*, 205 F.Supp.3d 579, 598–99 (D.N.J. 2016) (relying on CDC recommendations to determine the appropriate way to assess the risk from Ebola).

preclude.”¹⁶⁷ Congress did not specify how the Secretary should go about debarring, preventing, or precluding the introduction of persons “in order to avert” the increased danger to public health. Nor did Congress specify how prohibitions of persons “in whole” differ from prohibitions of persons “in part.”

It has long been recognized that “where a general power is conferred or duty enjoined, every particular power necessary for the exercise of the one, or the performance of the other, is also conferred.”¹⁶⁸ Here, HHS/CDC identifies particular powers that it may exercise under section 362 by defining the phrase to “[p]rohibit, in whole or in part, the introduction into the United States of persons” to mean “to prevent the introduction of persons into the United States by suspending any right to introduce into the United States, physically stopping or restricting movement into the United States, or physically expelling from the United States some or all of the persons.” The definition clarifies that prohibitions on introduction could include not only CDC orders suspending rights to introduce persons, but also actions by HHS/CDC or its Federal or state partners to physically expel persons from, or stop or restrict the movement of persons into, the United States. The definition further explains that the Director may apply different prohibitions against some or all of the persons from the foreign country who seek introduction into the United States. The Director may, for example, suspend all rights to introduce all persons from the foreign country, request that DHS physically expel the cohort of persons from the foreign country who are already on U.S. soil, and further request that DHS stop the movement into the United States of any other persons from the foreign country who are not on U.S. soil.

These particular powers are necessary because the introduction into the United States of persons from a foreign country may continue after they have crossed a U.S. land border and moved onto U.S. soil. If such persons are coming into

¹⁶⁷ Prohibit, *Universal English Dictionary* 458 (John Craig ed. 1869); see also Prohibit, *Funk and Wagnall’s New Standard Dictionary of the English Language* 1980 (1946) (“to forbid, especially by authority or legal enactment . . .”); Prohibit, *Oxford English Dictionary* 1441 (1933) (“to forbid (an action or thing) by or as by a command or statute; to interdict”).

¹⁶⁸ *Luis v. United States*, 136 S. Ct. 1083, 1097 (2016) (Thomas, J., concurring) (quoting Thomas Cooley, *Constitutional Limitations* 63 (1868)); see also 1 J. Kent, *Commentaries on American Law* 464 (13th ed. 1884) (“whenever a power is given by a statute, everything necessary to the making of it effectual or requisite to attain the end is implied”).

contact with others in the United States in a manner that the Director determines to present a risk of transmission of a quarantinable communicable disease, or a risk of contamination of property, then the Director must have the power to stop the further movement of these persons into the United States or else the Director's power to prohibit the introduction of persons would be rendered meaningless. Specifically, the Director must have the power to prevent the further movement of such persons into the United States through quarantine, isolation, or expulsion. As discussed previously, quarantine and isolation may be unworkable under certain circumstances or for certain populations. In such instances, expulsion may be the only means by which the Director can fulfill the purpose of the statute.

To the extent section 362 is silent or ambiguous as to the particular powers available to HHS/CDC, the resolution of that interpretive issue is within HHS/CDC's delegated statutory rulemaking authority. *City of Arlington, Tex.*, 569 U.S. at 296. It is also within the expertise of HHS/CDC. HHS/CDC has scientific and technical knowledge and experience with public health tools for slowing the introduction into the United States of quarantinable communicable diseases from abroad. HHS/CDC knows what public health tools HHS/CDC must have readily available in order to avert the increased danger to public health presented by a communicable disease from abroad. Here, HHS/CDC interprets section 362 as conferring the power to expel persons from the United States because HHS/CDC cannot otherwise fulfill the purpose of section 362.

3. 71.40(b)(3): "Serious danger of the introduction of such quarantinable communicable disease into the United States"

As discussed above, section 362 of the PHS Act requires that the Director determine that the existence of a communicable disease in a foreign country presents "a serious danger of the introduction of such disease into the United States" before he or she prohibits the introduction of persons from the foreign country into the United States. At the time Congress enacted section 362, "serious" meant "[g]rave in manner or disposition; solemn; not light or volatile,"¹⁶⁹ "[g]rave and earnest in quality, manner, feeling or disposition; not inclined to joke or trifle," or "[o]f great or relating to a matter of importance, or having important or

dangerous possible consequences."¹⁷⁰ Congress, however, did not explain when the danger of the introduction of a communicable disease becomes "grave in manner" or "of great weight and importance." In the public health context, the term "serious danger" is ambiguous.

The resolution of the ambiguity is within HHS's delegated statutory rulemaking authority. *City of Arlington, Tex.*, 569 U.S. at 296. It is also within HHS/CDC's scientific and technical expertise. HHS/CDC is best equipped to make judgments about the dangers presented by quarantinable communicable diseases abroad and the measures that should be taken to mitigate those dangers.

To resolve the ambiguity, HHS defines "serious danger of the introduction of such quarantinable communicable disease into the United States" in 71.40(b)(3) as "the probable introduction of one or more persons capable of transmitting the quarantinable communicable disease into the United States, even if persons or property in the United States are already infected or contaminated with the quarantinable communicable disease." This regulatory definition clarifies that, even if persons or property in the United States are already infected or contaminated with a quarantinable communicable disease, the introduction of one or more additional persons capable of disease transmission in the same or different localities can nevertheless present a serious danger of the introduction of the disease into the United States. Additionally, this regulatory definition clarifies that the danger of introduction becomes serious when one or more additional persons capable of disease transmission would more likely than not be introduced into the United States. To be clear, this regulatory definition does not require the Director to make a numerical finding or a quantitative or empirical showing of probability in order to prohibit the introduction of persons. The Director may make a qualitative determination, based on the known facts and circumstances, that the introduction of one or more persons capable of transmitting the quarantinable communicable disease is probable.

HHS/CDC's experience during the COVID-19 pandemic informs its interpretation of the statutory language.

¹⁷⁰ *Serious*, Funk and Wagnall's New Standard Dictionary of the English Language 2233 (1946). A contemporary dictionary defines "serious" as "excessive or impressive in quality, quantity, extent, or degree." *Serious*, Merriam-Webster Dictionary, <https://www.merriam-webster.com/dictionary/serious> (last visited Aug. 28, 2020).

The initial epicenters of the disease in the United States included two large urban areas: Seattle and New York City. At that time, the danger of the introduction of COVID-19 into other border states from Canada and Mexico, without regard to the outbreaks in Seattle and New York City, was manifest. The issuance of the CDC Order prohibiting the introduction of covered aliens into the United States was in the interest of public health because it mitigated the serious danger of cross-border introduction of COVID-19 in the other border states.

4. 71.40(b)(4): "Place"

HHS/CDC defines the term "place" to include any location specified by the Director, including any carrier, whatever the carrier's flag, registry, or country of origin. This clarifies that when HHS/CDC refers to "place" in this final rule, it refers not just to territory within or outside of a country, but also to carriers, as that term is defined in 42 CFR 71.1,¹⁷¹ regardless of the carrier's flag, registry, or country of origin.

5. 71.40(b)(5): "Suspension of the right to introduce"

In section 71.40(b)(5), this final rule defines "suspension of the right to introduce," a phrase used in section 362, to mean "to cause the temporary cessation of the effect of any law, rule, decree, or order, pursuant to which a person might otherwise have the right to be introduced or seek introduction into the United States."

The regulatory definition tracks the definition of the word "suspend" from the late 19th century. *Universal English Dictionary* 815 (John Craig ed. 1869) (defining "suspend" in part as "to cause to cease for a time from operation or effect, as, to *suspend* the habeas corpus act") (emphasis in original). The definition of "suspend" in the early 20th century was substantially the same. *See Funk and Wagnall's New Standard Dictionary of the English Language* 2432 (1946) (defining "suspend" as "to cause to cease for a time; hold back temporarily from operation; interrupt; intermit; stay; as, to *suspend* the rules; to *suspend* business; *suspend* sentence"); *Oxford English Dictionary* 255 (1933) (defining "suspend" as to "cause (of a law or the like) to be for the time no longer in force; to abrogate or make inoperative temporarily").

The regulatory definition is also consistent with the long-standing use of the word "suspend" to describe the

¹⁷¹ 42 CFR Sec. 71.1 defines "carrier" to mean "a ship, aircraft, train, road vehicle, or other means of transport, including military."

¹⁶⁹ *Serious*, *Universal English Dictionary* 661 (John Craig ed. 1869).

temporary cessation of the effect of other U.S. laws. The Suspension Clause of the Constitution, which authorizes the temporary suspension of the privilege of the writ of habeas corpus in times of rebellion or invasion, is a prime example. U.S. Const. art. I, sec. 9, cl. 2. Additional examples of such suspensions are found in the U.S. Code.¹⁷²

Finally, the regulatory definition is consistent with the legislative history of section 362, as reflected in the debates concerning its immediate (and substantially similar) statutory predecessor, section 7 of the Act of 1893. The debates surrounding that provision show that members of Congress understood they were granting the President the authority to suspend immigration. *See* 24 Cong. Rec. 393 (1893) (statement of Sen. Hoar) (the statute would grant the “power to suspend immigration altogether, either temporarily or permanently as a health device”); *see also id.* at 393–94 (statement of Sen. Chandler) (recognizing that section 7 would give the President the power to suspend immigration in his discretion, whenever there is danger of infection); 24 Cong. Rec. 470 (Jan. 10, 1893) (statement of Sen. Gray) (stating that the exigency posed by “invasion of contagious disease is sufficient . . . to justify this extraordinary power of the entire suspension of immigration.”). It is reasonable to conclude that Congress in 1944 had the same understanding, because it re-enacted the same phrase and there is no legislative history to the contrary.

A “right to introduce” persons may conceivably arise under the Federal laws, rules, decrees, or orders governing aviation, shipping, trade, immigration, law enforcement, or correctional facilities, among others. The Director is not obligated to identify each specific “right to introduce” an individual person that the Director suspends when

issuing an order under section 362 and this final rule. An order under section 362 suspends the effect of “any law, rule, decree, or order” under which an individual person would “otherwise have the right to be introduced or seek introduction into the United States.”

C. Section 71.40(c)

HHS/CDC may suspend the introduction of persons into the United States from certain places, and for certain periods, through an administrative order executed by the Director. In section 71.40(c), HHS/CDC describes the required contents of such order. Any order issued by the Director under section 71.40 shall include a statement of the following:

(1) The foreign countries (or one or more political subdivisions or regions thereof) or places from which the introduction of persons is being prohibited.

(2) The period of time or circumstances under which the introduction of any persons or class of persons into the United States is being prohibited.

(3) The conditions under which that prohibition on introduction will be effective in whole or in part, including any exceptions that the Director determines are appropriate.

(4) The means by which the prohibition will be implemented.

(5) The serious danger posed by the introduction of the quarantinable communicable disease in the foreign country or countries (or one or more political subdivisions or regions thereof) or places from which the introduction of persons is being prohibited.

This last requirement was not included in the IFR. However, after considering comments, HHS/CDC decided to add it. The agency has broad powers under section 362, and the exercise of those powers pursuant to this final rule could have significant consequences. HHS/CDC agrees that the Director ought to provide the public with a short and concise factual statement on the serious danger of the introduction of the quarantinable communicable disease that justifies the exercise of those powers. For similar reasons, this final rule also adds that any order issued pursuant to it shall state the means by which the prohibition on introduction shall be implemented.

Any “class of persons” identified by the Director pursuant to the second requirement would be defined based on public health criteria, which may include the epidemiology of the quarantinable communicable disease, as well as the geographic area and specific

locations of the persons.

Implementation of any order would also take into account any international obligations of the United States.

Accordingly, the Director may make exceptions for certain persons in an order, including: Aliens whose travel falls within the scope of section 11 of the United Nations Headquarters Agreement or who would otherwise be allowed entry into the United States pursuant to United States obligations under applicable international agreements; diplomatic travelers; U.S. government employees; and those travelling for humanitarian purposes.

D. Section 71.40(d)

This final rule adds a requirement in Section 71.40(d) that the Director shall, when issuing any order under this section, and as practicable under the circumstances, consult with all Federal departments or agencies that would be impacted by the order. The Director shall, as practicable, provide the Federal departments or agencies with a copy of the order before issuing it. The purpose of this requirement is to ensure that HHS/CDC accounts for the interests of the other departments or agencies in the order, includes appropriate exceptions in the order, and promotes a coordinated and transparent Federal response to the quarantinable communicable disease. It may sometimes be impracticable to engage in such consultation before taking action to protect the public health. In those circumstances, the Director shall consult with Federal departments and agencies as soon as practicable after issuing his or her order, and may then modify the order as appropriate.

HHS/CDC might at times rely on (1) state and local authorities who agree to help implement orders issued pursuant to section 71.40, or (2) other Federal agencies to implement and execute the orders issued under this section. 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 shall 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 or the United States Coast Guard under 42 U.S.C. 268(b), or another Federal department or agency, then the 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, officers, or agents are expected to aid in the enforcement of

¹⁷² *See, e.g.*, 10 U.S.C. Sec. 123(a) (“In time of war, or of national emergency . . . the President may suspend the operation of any provision of law relating to the promotion, involuntary retirement, or separation of commissioned officers . . .”); 22 U.S.C. Sec. 289 (stating that congressional authorization to accept membership in the International Refugee Organization does not constitute action “which will have the effect of . . . suspending . . . any of the immigration laws or other laws of the United States”); 22 U.S.C. Sec. 5722(a) (authorizing the President to issue an order suspending the application of United States law to Hong Kong “whenever the President determines that Hong Kong is not sufficiently autonomous”); 46 U.S.C. Sec. 3101 (“When the President decides that the needs of foreign commerce require, the President may suspend a provision of this part for a foreign-built vessel registered as a vessel of the United States on conditions the President may specify”).

the order, to the extent that they are permitted to do so under their existing legal authorities.

E. Section 71.40(e)

Section 71.40(e)(1) provides that this final rule 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 has taken or will take measures such as quarantine or isolation, or other measures maintaining control over such individuals, to prevent the risk of transmission of the quarantinable communicable disease into the United States. HHS/CDC includes this exception because the Secretary of Defense has the authority and means to prevent the introduction of a quarantinable communicable disease into the United States from his or her personnel returning from foreign countries. Therefore, this final rule need not apply to Department of Defense personnel.

In addition, section 71.40(e)(2) provides that this final rule does not apply to United States government employees, contractors, or assets on orders abroad, or their accompanying family members who are on their orders or are members of their household if the Director receives assurances from the relevant head of agency and determines that the head of the agency or department has taken or will take, measures such as quarantine or isolation to prevent the risk of transmission of a quarantinable communicable disease into the United States.

F. Section 71.40(f)

Section 71.40(f) of the IFR provided that the IFR did not apply to U.S. citizens or LPRs. The IFR stated that determining the appropriate protections for U.S. citizens and LPRs would benefit from additional consideration and public comments.¹⁷³ HHS/CDC received comments on the potential application of section 362 of the PHS Act to U.S. citizens and LPRs. Given the complex and important legal and policy questions presented by the potential application of section 362 to U.S. citizens, U.S. nationals, and LPRs, HHS/CDC has determined that it would be in the public interest to provide notice of, and accept comments on, any regulatory text that HHS/CDC would propose to apply to U.S. citizens, U.S. nationals, and LPRs. Further notice and comment would enable HHS/CDC to provide the public with a more fulsome explanation of the potential public health threats

and policy rationales that support the regulatory text and seek further input from the public. For now, HHS/CDC finalizes 71.40(f) to state: “This section shall not apply to U.S. citizens, U.S. nationals, and lawful permanent residents.”

G. Section 71.40(g)

In section 71.40(g), HHS/CDC adds a severability clause. HHS/CDC believes this final rule complies with all applicable law, and that the invalidation of this final rule in its entirety would ultimately harm U.S. public health. In the event that any provision of this final rule should be held invalid or unenforceable, either facially or as applied, the remaining provisions shall remain valid with the maximum effect as permitted by law.

V. Responses to Public Comments

The Department provided a 30-day comment period, which closed on April 24, 2020. The Department received 218 public comments to the IFR, and every comment was read and considered. HHS/CDC’s responses to public comments in this section of this final rule respond directly to comments regarding the procedures established by the IFR and finalized in this final rule. In the interest of public transparency, HHS/CDC also responds to some comments about the CDC Order on covered aliens (as opposed to the procedures established by the IFR and finalized in this final rule). In some instances, the prior sections of this final rule address the issues raised by commenters. Additionally, HHS/CDC does not respond to comments that are directed at other departments or agencies or that are otherwise beyond the scope of this final rule. Commenters included professional organizations, industry representatives, religious organizations, and the general public. After considering the comments, the Department finalizes the IFR with the changes described in Section III.

General Comments

Comment: Some commenters stated 30 days was not sufficient time to comment on the proposed rule and asked the Department to extend the comment period.

Response: HHS/CDC respectfully disagrees that the 30-day comment period was insufficient. HHS/CDC notes that the Administrative Procedure Act (APA) does not have a minimum time period for comments. Further, E.O. 13563 recommends a 60-day comment period, when feasible. Considering the current public health emergency, HHS/CDC determined that a 30-day comment

period was sufficient for this rulemaking. The comment period closed 30 days after publication of the IFR in the **Federal Register** on March 24, 2020.

Comment: Other commenters stated that the rule should have been issued pursuant to the agency rulemaking process governed by section 553(b) of the APA, 5 U.S.C. 553. These commenters noted that although the agency’s justification for applying the “good cause” emergency exception in section 553(b)(3)(B) is understandable in the context of the COVID–19 pandemic, the rule is intended to last beyond the current public health crisis, so the “good cause” exception should not apply.

Response: HHS/CDC respectfully disagrees. 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 are “impracticable, unnecessary, or contrary to the public interest.” Allowing for prior notice and opportunity for public comment on the interim final rule was impracticable and contrary to the public interest because it would have prevented HHS from establishing procedures to allow it to quickly address the COVID–19 pandemic through the issuance of orders such as the one suspending the introduction of covered aliens into the United States. COVID–19 has spread rapidly, and taking prompt measures to slow the spread of the disease was necessary to protect public health.

Comment: Commenters stated that the IFR grants new public health powers to the Executive Branch that did not already exist, or shifts political accountability for the exercise of public health powers from the President (who is elected) to the CDC Director (who is a principal officer appointed by the President and confirmed by the U.S. Senate).

Response: Since 1944, section 362 of the PHS Act has provided that whenever the Surgeon General (now the CDC Director, by delegation from the HHS 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, the Surgeon General (now the CDC Director), in accordance with regulations approved by the President,

¹⁷³ 85 FR 16559, 16564 (Mar. 24, 2020).

shall have the power 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. A predecessor statute dating back to 1893 granted the President similar authority. The IFR and this final rule implement the long-standing statutory authority of the Executive Branch, consistent with the design of Congress in 1944.

Comment: A number of commenters provided comments about the CDC Order on covered aliens, not the IFR or this final rule. These included comments about the particular facts underlying the CDC Order, particular language used in the Order, such as the meaning of “covered aliens,” and the public health analysis in the CDC Order. Other commenters seemed to misunderstand the differences between the CDC Order and the IFR and this final rule, or disagreed with the Director’s determination to apply the CDC Order only to CBP facilities at land borders.

Response: We believe these comments confuse the IFR, the final rule, and the CDC Order on covered aliens. The CDC Order relates exclusively to the COVID-19 pandemic, defines “covered aliens,” and prohibits the introduction of “covered aliens” into the United States through congregate settings in CBP facilities at land borders. This final rule does not define “covered aliens.” Nor does this final rule prohibit the introduction of any persons into the United States without an administrative order issued by the Director. Rather, this final rule finalizes the procedures for the Director to use when he or she determines that a temporary prohibition on the introduction of persons from a foreign country into the United States is necessary in the interest of U.S. public health. The procedures in this final rule are general in nature; they are not limited to a specific quarantinable communicable disease or person or category of persons.

Comment: A number of commenters stated that the period of preventing introduction of COVID-19 to U.S. populations has now passed and that our highest priority as a nation must be to reduce community spread through the current tools we have available such as self-isolation.

Response: HHS/CDC disagrees with the proposition that HHS/CDC should limit its response to the COVID-19 pandemic to the use of conditional release orders or recommendations to self-quarantine or self-isolate or similar public health tools. HHS/CDC and its

state and local partners are using public health tools such as quarantine, isolation, and conditional release to mitigate the spread of COVID-19. But the use of those public health tools does not and should not foreclose the appropriate use of other public health tools—including the statutory authority to prohibit the introduction of persons—to combat the disease. HHS/CDC needs the flexibility to deploy the full array of available public health tools in response to the COVID-19 pandemic, which continues to evolve within the United States and abroad.

Even now, the introduction into the United States of persons from foreign countries with COVID-19 would increase the serious danger of further introduction of COVID-19 into different areas of the United States. The section 362 authority and this final rule remain critical to mitigating the further introduction of COVID-19 into those areas.

Moreover, this final rule seeks to implement a permanent procedure which the Director may use to issue an order suspending the right to introduce persons into the United States when there is a serious danger of the introduction of a quarantinable communicable disease into the United States. This final rule is needed to address not only the COVID-19 pandemic, but also future public health threats.

Comments: A commenter stated that the IFR is arbitrary and capricious because the agency has failed to consider important factors, such as the impact that the CDC Order on covered aliens will have on individuals who seek to enter the United States and on those in the United States who are awaiting their arrival; reliance interests; and alternatives to suspending migration, such as quarantine or isolation of persons.

Response: This final rule explains why the benefits to U.S. public health that flow from mitigating the introduction of quarantinable communicable diseases into the United States may outweigh any impact on family well-being that may result from deferred visitation of family members in the United States. The same reasoning applies to non-family members who await the arrival of persons in the U.S. This final rule also discusses reasonable alternatives that were considered, and why prohibitions on the introduction of persons may sometimes be more appropriate public health measures than quarantine and isolation.

Comment: Some commenters stated that the final rule would have a negative effect on the economy because

immigrants from Mexico or Canada would be unable to come to the United States to participate in the labor market.

Response: This final rule provides that when issuing any Order, the Director shall, as practicable under the circumstances, consult with all Federal departments or agencies whose interests would be impacted by the Order, which may include the U.S. Departments of Agriculture, Commerce, and the Treasury. Any potential economic consequences of an Order would be considered by the Director as part of the consultation process.

Comment: A number of commenters opined that expulsions of aliens to Central America and Mexico may exacerbate public health challenges during the COVID-19 pandemic.

Response: These comments appear to be directed at the CDC Order on covered aliens issued pursuant to the IFR, and not this final rule. This final rule provides a mechanism for the CDC Director to prohibit the introduction of persons when he or she 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 from such country that a suspension of the right to introduce such persons is required in the interest of public health. If the CDC Director determines, in the exercise of his or her scientific and technical expertise, that these conditions are met and expulsion is in the interest of the public health, he or she may issue an administrative order pursuant to this final rule that requires expulsion. This final rule, standing alone, does not require expulsion.

Comments: Some commenters stated that there could be particular vulnerability or hardship to “LGBTIQ” persons, women, or children.

Response: HHS/CDC works to protect the United States from health, safety and security threats, both foreign and in the United States. Whether diseases start at home or abroad, are chronic or acute, curable or preventable, human error or deliberate attack, HHS/CDC fights disease and supports communities and citizens to do the same. HHS/CDC believes this final rule will help HHS/CDC accomplish its mission. Under this final rule, the Director would consult with other Federal departments and agencies whose interests would be impacted by any Order, including the U.S. Department of Homeland Security, and would have the discretion to include exceptions for persons in the Order when appropriate.

Comments: A number of commenters stated that expelling an alien under section 362 of the PHS Act violates the United States' obligations under the 1967 Protocol relating to the Status of Refugees (1967 Refugee Protocol) and the Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (CAT) and violates statutory protections, including the William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008 (TVPRA), the CAT regulations implemented pursuant to the Foreign Affairs Reform and Restructuring Act of 1998 (FARRA) (8 U.S.C. 1231 note), the asylum and withholding provisions at 8 U.S.C. 1158 and 1231(b)(3), and the American Declaration on the Rights and Duties of Man. Some commenters said the IFR fails to provide legal process to individuals subject to the rule, including asylum-seekers, even though U.S. law guarantees aliens an opportunity to request protection at POEs after crossing into the United States. Commenters also stated that expelling an alien who is a minor violates the Stipulated Settlement Agreement in *Flores v. Barr*, 934 F.3d 910 (C.D. Cal. 2019) (the "Flores Settlement Agreement," or the "FSA").

Responses: These comments are directed to the CDC Order on covered aliens issued pursuant to the IFR, and not this final rule. To the extent these comments are directed to both the CDC Order and this final rule, HHS/CDC respectfully disagrees with them. In section 362 of the PHS Act, Congress authorized the suspension of the introduction of persons into the United States when a suspension of the right to introduce persons is required in the interest of U.S. public health. Congress did not exempt from the scope of section 362 any category of persons or any rights of introduction under specific laws, including any found in Title 8 of the U.S. Code.

The TVPRA and the FSA

The requirements of the TVPRA and FSA do not generally apply to situations where the Director has determined that a suspension of the right to introduce persons is required in the interest of public health. The *Flores* settlement agreement and the statutory provisions providing that unaccompanied alien children (UACs)¹⁷⁴ are to be transferred

to the care and custody of HHS's Office of Refugee Resettlement (ORR) are directed towards the continuing custody and the conditions of confinement in which minors are held in custody within the United States. *See, e.g.*, 6 U.S.C. 279 (defining "UAC" in subsection 279(g) and referring to "the care of unaccompanied alien children" in subsection 279(a)); *Flores* Settlement Agreement at 7 (defining the relevant class as "[a]ll minors who are detained in the legal custody of the INS").

The TVPRA provides specific processes governing the custody and removal of UACs under Title 8. But the CDC has prohibited the introduction of aliens under section 362 of the PHS Act for public health reasons without regard to the age of the alien (or the persons accompanying him), and actions to enforce the CDC prohibition necessarily involve the prohibition on entering or return of an alien outside of Title 8's procedures.

Therefore, suspension of introduction, and the derivative expulsion authority under section 362 of the PHS Act generally operates independently from Title 8 with respect to minors and other persons. The custody requirement under 8 U.S.C. 1232(b)(3) within the TVPRA is not a rule governing the procedures by which an alien is removed or expelled. Rather, it is a statutory obligation that applies to all departments and agencies in the U.S. government, whether or not the government is removing UACs pursuant to Title 8 (or expelling minors under Title 42). This subsection requires only that UACs in the custody of a Federal department or agency be transferred to the custody of HHS within 72 hours unless "exceptional circumstances" apply. 8 U.S.C. 1232(b)(3). The current public health emergency plainly would qualify as an "exceptional circumstance[]" permitting an exception from the 72-hour transfer requirement.

The FSA governs the conditions under which minors may be held in government custody in connection with their arrest or detention under immigration laws. FSA ¶ 10 (defining the class as "All minors who are detained in the legal custody of the INS."), ¶ 12, ¶ 14 ("Where the INS determines that the detention of the minor is not required either to secure his or her timely appearance before the INS or the immigration court, or to ensure the minor's safety or that of others, the INS shall release a minor

from its custody without unnecessary delay . . ."). Minors who are subject to a prohibition on introduction under section 362 of the PHS Act would not be arrested or detained under the immigration laws and they are expelled from the United States as expeditiously as possible. Minors who comply with a public health order under section 362 would not be arrested for violating the PHS Act or the order either. The FSA therefore does not apply to minors who are quarantined, isolated, or expelled under a public health order.

Indeed, "the [FSA] is a binding contract and a consent decree. . . . It is a creature of the parties' own contractual agreements and is analyzed as a contract for purposes of enforcement." *Flores v. Barr*, 407 F. Supp. 3d 909, 931 (C.D. Cal. 2019); *see also City of Las Vegas v. Clark Cty.*, 755 F.2d 697, 702 (9th Cir. 1985) ("A consent decree, which has attributes of a contract and a judicial act, is construed with reference to ordinary contract principles."). The FSA applies only to those minors in the "legal custody" of the former Immigration and Naturalization Service (INS) as the term was intended by the parties when the Agreement was signed in 1997. FSA ¶¶ 4, 10. That means it applies to minors who are in immigration custody under Title 8. The Agreement does not encompass, was not intended to encompass, and did not anticipate custody incident to a public health order issued pursuant to the PHS Act. If a minor were expelled under section 362, that minor would not be in the "legal custody" of any legal successor to any party to the FSA. Although the FSA does not explicitly define "legal custody," it recognizes a critical distinction between *legal custody* and *physical custody*. The FSA provides for the INS in some instances to place a minor in the *physical custody* of a licensed program, but the FSA specifies that the minor remains in the *legal custody* of the INS. FSA ¶ 19; *see also Gao v. Jenifer*, 185 F.3d 548, 551 (6th Cir. 1999) (explaining that the INS's contracts with these third-party programs explicitly state that the INS retains legal custody while the programs have physical custody). While a minor is in the physical custody of a licensed program, the INS retains the sole authority to transfer and release the minor (except that the licensed program can transfer *physical custody* in emergencies). FSA ¶ 19. Thus, paragraph 19 makes clear that under the Agreement, the "legal custody of the INS" means custody at the direction of the INS under relevant immigration

¹⁷⁴ "[T]he term 'unaccompanied alien child' [UAC] means a child who—(A) has no lawful immigration status in the United States; (B) has not attained 18 years of age; and (C) with respect to whom—(i) there is no parent or legal guardian in the United States; or (ii) no parent or legal guardian in the United States is available to provide care and custody." 6 U.S.C. 279(g). The Director of the Office

of Refugee Resettlement (ORR) of HHS is responsible, among other things, for "coordinating and implementing the care and placement of [UAC] who are in Federal custody by reason of their immigration status." 6 U.S.C. Sec. 279(b)(1)(A).

laws, which grant the INS authority over the detention or release of the minor. *Id.*

The original class certified in the *Flores* litigation included only individuals under the age of eighteen who “are, or will be arrested and detained pursuant to 8 U.S.C. 1252.” In 1986, when the class was certified, 8 U.S.C. 1252 governed discretionary detention during deportation proceedings. At the time the FSA was signed in 1997, the INS’s legal authority to detain minors remained within Title 8 of the U.S. Code. 8 U.S.C. 1225(b), 1252(a); see also *Reno v. Flores*, 507 U.S. 292, 294–95 n.1 (1993). Such detention was incident to immigration removal proceedings, the authority for which was also detailed in Title 8. 8 U.S.C. 1225(a), 1226, 1231, 1252(b). The authority for immigration proceedings, as well as the authority to hold minors in immigration custody, is still found in Title 8 today. See 8 U.S.C. 1225, 1226, 1231, and 1232. The successors of the INS who carry out these immigration functions today are CBP, ICE, and U.S. Citizenship and Immigration Services, all of which are part of DHS, as well as the ORR in HHS with respect to UACs. See Homeland Security Act of 2002, 402, 462, 1512, Public Law 107–296, 116 Stat. 2135 (November 25, 2002) (codified at 6 U.S.C. 202, 279, 552); TVPRA, 8 U.S.C. 1232.

CDC, though part of HHS along with ORR, is not a successor to the INS with respect to the detention addressed in the FSA. Custody incident to the government’s implementation of order issued by the Director under its section 362 authority is different from the Title 8 immigration custody that the Agreement covers.¹⁷⁵ Section 362 provides the Director with “the power 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.” Custody incident to implementation of this provision is not pursuant to immigration laws. The Director, not DHS, has the legal authority for these processes.¹⁷⁶ Individuals processed

under Title 42 are not processed for immigration enforcement actions.

At the time the FSA was signed in 1997, the parties could not have anticipated the COVID–19 pandemic in 2020, and that some of the legal-successor agencies to the INS would be charged with implementing emergency procedures on behalf of the Director under section 362. The “basic goal of contract interpretation” is to give effect to the parties’ mutual intent “at the time of contracting.” *Founding Members of the Newport Beach Country Club v. Newport Beach Country Club, Inc.*, 109 Cal. App. 4th 944, 955 (Cal. Ct. App. 2003) (citing Cal. Civ. Code § 1636). The sections of Title 42 being implemented in this final rule are not immigration statutes or even custody statutes, and their purview is not limited to aliens. Rather, they provide broad authority to CDC to respond to public health threats. Further, the FSA makes clear that the parties were addressing and settling specific issues related to custody by the INS incident to immigration proceedings, under the applicable law governing that custody. See, e.g., FSA §§ 9, 11, 12.A, 14, 24.A (providing for bond hearings before an immigration judge). Nothing in the FSA suggests that the parties intended it to govern—or anticipated that it would govern—any emergency procedures implemented by the HHS/CDC under section 362 of the PHS Act.

The CAT and the 1967 Refugee Protocol

The final rule implements authority under section 362 of the PHS Act, which authorizes a prohibition on the introduction of persons in the interest of public health. Although HHS/CDC believes that the final rule is entirely consistent with the international obligations of the United States under the CAT and the 1967 Refugee Protocol, those international treaties are non-self-executing. See *Khan v. Holder*, 584 F.3d 773, 783 (9th Cir. 2009) (“[T]he [Refugee] Protocol is not self-executing.”); *Auguste v. Ridge*, 395 F.3d 123, 132 (3d Cir. 2005) (the CAT “was not self-executing”); *Trinidad y Garcia v. Thomas*, 683 F.3d 952, 955 (9th Cir. 2012) (en banc) (per curiam) (“The CAT is a treaty signed and ratified by the United States, but is non-self-executing. 136 Cong. Rec. 36, 198 (1990).”); Therefore, the domestic statutes that implement these obligations and their corresponding regulations would control as a matter of domestic law in

DHS with the Homeland Security Act. 6 U.S.C. Sec. 203. DHS’s role in enforcing the HHS/CDC Order arises from the PHS Act, not any immigration statute. The Agreement did not cover the Treasury Department.

the event of any potential conflict. See *Medellin v. Texas*, 552 U.S. 491, 504 n.2 (2008) (“A ‘non-self-executing’ treaty does not by itself give rise to domestically enforceable federal law. Whether such a treaty has domestic effect depends upon implementing legislation passed by Congress.”).

Congress implemented certain aspects of CAT into domestic law by statute as part of the Foreign Affairs Reform and Restructuring Act of 1998 (FARRA). 8 U.S.C. 1231 note. That statute declares it to be “the policy of the United States not to expel, extradite, or otherwise effect the involuntary return of any person to a country in which there are substantial grounds for believing the person would be in danger of being subjected to torture” and to prescribe regulations to implement U.S. obligations under Article 3 of the Conventions. See Public Law 105–277, div. G, subdiv. B, title XXII, § 2242(a)–(b) (1998), codified at 8 U.S.C. 1231 note. In its ratification statement accompanying the treaty, the U.S. Senate observed that the “substantial grounds” requirement would be interpreted as requiring an alien to establish that it would be “more likely than not that he would be tortured” in the prospective country of removal. Resolution of Ratification, Convention Against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, Senate Consideration of Treaty Document 100–20, II.(2), 136 Cong. Rec. S17904 (Oct. 27, 1990).

Under 42 U.S.C. 268, customs officers have an obligation to aid in enforcement of HHS/CDC’s administrative Orders issued under section 362 of the PHS Act. HHS/CDC therefore expects that DHS will take the lead role in enforcing any CDC Order prohibiting the introduction of persons into the United States. In connection with existing enforcement of the current CDC Order on covered aliens, HHS/CDC understands that DHS provides aliens with the opportunity to express a fear that they will suffer torture in the country to which they are being returned. So long as border officials apply a process for assessing non-refoulement concerns, as appropriate, the government satisfies its treaty obligations, as reflected in the FARRA. See *Trinidad y Garcia*, 683 F.3d at 956–57 (concluding, in a challenge to extradition on non-refoulement grounds, that if the agency found it “more likely than not” that an extradited person would not face torture abroad, then “the court’s inquiry shall have reached its end”).

In addition to implementing its CAT obligations through the FARRA, the

¹⁷⁵ See, e.g., Order Suspending Introduction of Certain Persons from Countries Where a Communicable Disease Exists, 85 FR 17060 (Mar. 26, 2020).

¹⁷⁶ The INS could not have implemented CDC’s section 362 orders. The role of DHS in public health enforcement is pursuant to section 365 of the PHS Act, which provides, “It shall be the duty of the customs officers and of Coast Guard officers to aid in the enforcement of quarantine rules and regulations” Neither the Coast Guard, nor any customs officers, were part of the INS. The customs officer authorities now within DHS were transferred from the Department of the Treasury to

United States has implemented the non-refoulement obligation under the 1967 Protocol by enacting the withholding-of-removal provisions in section 241(b)(3) of the INA (8 U.S.C. 1231(b)(3)). These statutory provisions prohibit the removal of an individual to a country where he or she would face persecution or torture, subject to several statutory exceptions. One such exception excludes any alien from statutory withholding-of-removal protection where “there are reasonable grounds to believe that the alien is a danger to the security of the United States.” *Id.* 1231(b)(3)(B)(iv). This statutory exception is derived from Article 33 of the 1967 Protocol, which contains an exception for a refugee for “whom there are reasonable grounds for regarding as a danger to the security of the country in which he is.” See 1967 Protocol, Article 33.2.

In *Matter of A-H-*, 23 I&N Dec. 774 (2005), the Attorney General interpreted the phrase “danger to the security of the United States” in an analogous provision of the INA (the former section 243(h)(2)(D) of the INA) to mean “a risk to the Nation’s defense, foreign relations, or economic interests.” In *re Matter of A-H-*, 23 I&N Dec. 774, 788 (AG 2005); see also *Yusupov v. Attorney General of U.S.*, 518 F.3d 185, 204 (3d Cir. 2008) (upholding in relevant part the Attorney General’s interpretation in *Matter of A-H-*); cf. 8 U.S.C. 1189(d)(2) (defining “national security” in a separate provision of the INA as encompassing “the national defense, foreign relations, or economic interests of the United States”). Because enforcement of a CDC Order would occur pursuant to section 362 of the PHS Act, this provision of the INA does not directly apply to orders issued under the final rule. Nonetheless, where the Director has determined that there is a reasonable ground to believe that the introduction of an alien, or class of aliens, would pose a danger of introducing a quarantinable communicable disease into the United States, then there would be a reasonable ground for regarding those aliens to be as “a danger to the security of the United States” as construed by *Matter of A-H*. See Notice of Proposed Rulemaking, *Security Bars and Processing*, 85 FR 41,201, 41,208–41,210 (July 9, 2020). As the ongoing COVID–19 pandemic has shown, the entry and spread of communicable disease from abroad can threaten the lives of the U.S. population and inflict grievous harm on the national economy.

In addition, this final rule would allow for the Director to address any additional humanitarian concerns, if

appropriate, in connection with implementing the Order. As explained in this final rule, the Director may provide that certain persons are excepted in an Order, and that could include exceptions for persons traveling for humanitarian purposes. The Director expects to consult with relevant federal departments and agencies when issuing any order under section 71.40(d). For the same reasons, the American Declaration on the Rights and Duties of Man does not bar this final rule.

Comments: One commenter stated that the IFR applies only to land borders, even though, as the IFR itself notes, transportation hubs, like airports and cruise ship terminals, are congregate settings “conducive to disease transmission.” The IFR does not bar travel by tourists arriving by plane or ship, even though these modes of transportation are explicitly listed as congregate settings with a risk of disease transmission.

Response: These comments appear to be directed to the CDC Order on covered aliens issued pursuant to the IFR, and not the IFR or this final rule. The CDC Director may use the procedures in the IFR and this final rule to issue an administrative order that applies to persons who seek to introduce themselves into the United States through airports or cruise ship terminals. There are, however, additional tools available to address public health risks in transportation hubs. Such tools include proclamations under section 212(f) of the INA and No Sail Orders.

Section 71.40(a), Statutory Requirements for the CDC Director To Suspend the Introduction of Persons Into the United States

Comments: Several commenters stated that, taken together, the IFR and CDC Order on covered aliens incorrectly assume that persons from a foreign country cannot self-quarantine or self-isolate in the United States as an alternative to expulsion. These commenters noted that many persons trying to cross the U.S.-Mexico border know people in the United States who could presumably provide a place to self-quarantine or self-isolate. Some commenters also suggested that DHS could parole asylum-seekers into the United States to await their asylum proceedings in U.S. immigration courts.

Response: To the extent the commenters maintain that HHS/CDC can never lawfully prohibit the introduction of persons into the United States through the expulsion of persons, HHS/CDC respectfully disagrees with the comments. As previously discussed,

the specific power to expel persons is a corollary to the general power to prohibit the introduction of persons. HHS/CDC cannot effectuate the authority granted by section 362 unless HHS/CDC can expel persons, particularly in cases where quarantine and isolation are inadequate due to epidemiological factors, resource limitations, geography, location, or other considerations.

In the case of the CDC Order issued pursuant to the IFR, it is not reasonable to assume that all covered aliens subject to the Order can or will comply with conditional release orders or safely self-quarantine or self-isolate after introduction into the country. That has not been HHS/CDC’s experience with foreign nationals arriving in the United States on commercial flights, which require valid travel documents and clearance of customs. Even some foreign nationals who produce valid travel documents, fly internationally, and clear customs do not comply with self-quarantine or self-isolation protocols, or provide contact information to HHS/CDC for use in public health monitoring and contract tracing investigations.

Covered aliens under the CDC Order seek to introduce themselves into the United States under circumstances and in ways that suggest to HHS/CDC that they are less likely to adhere to a conditional release order or self-quarantine or self-isolation protocol. For starters, all covered aliens lack valid travel documents, which suggests that they are not coming prepared to comply with U.S. legal processes. Many walk into the United States from Mexico or Canada, which suggests that they do not have access to transportation. DHS informs HHS/CDC that under normal circumstances—when the introduction of persons is not suspended—many covered aliens would be asylum-seekers, who by definition lack permanent U.S. residences. DHS and DOJ also inform HHS/CDC that under normal circumstances, many would be removed from the United States *in absentia* for failure to appear for immigration proceedings.¹⁷⁷ Persons who are unprepared to comply with U.S. legal processes and lack transportation and a permanent U.S. residence would likely encounter difficulties complying with conditional release orders or self-quarantine or self-isolation protocols. For such orders or

¹⁷⁷ In fiscal year 2019, out of 181,876 initial case completions for aliens who are not UACs, 82,753 aliens (45%) were ordered removed *in absentia*. In the first two quarters of fiscal year 2020, out of 154,744 initial case completions for aliens who are not UACs, 81,330 aliens (53%) were ordered removed *in absentia*.

protocols to be effective, persons who HHS/CDC temporarily apprehends and then conditionally releases with orders—or, alternatively, persons to whom HHS/CDC recommends self-quarantine or self-isolation—must be able to travel to suitable quarantine or isolation locations, and then quarantine or isolate for the time period prescribed or recommended by HHS/CDC. Many covered aliens subject to the CDC Order on covered aliens would have to overcome significant hurdles to meet those basic requirements.

Moreover, implementation of conditional release orders for covered aliens would divert substantial HHS/CDC resources away from existing public health operations during the COVID-19 pandemic. HHS/CDC presently operates quarantine stations at 20 ports of entry and land-border crossings, only four of which are at a border with Canada or Mexico.¹⁷⁸ To implement conditional release orders for covered aliens, HHS/CDC would have to open and operate new quarantine stations at numerous Border Patrol stations and POEs, surge technical support to CBP at the same locations, or do some combination of both. HHS/CDC would also have to monitor the health of tens of thousands of covered aliens introduced into the United States, and alert public health departments about any health issues that need follow-up.¹⁷⁹ HHS/CDC does not have resources and personnel available to execute those additional functions; HHS/CDC would have to reallocate personnel from existing quarantine operations, which would jeopardize the effectiveness of those operations, endanger public health, and impose additional costs on U.S. taxpayers.

Several commenters asserted that HHS/CDC should nevertheless allow covered aliens to self-quarantine or self-isolate because the U.S. Immigration Policy Center (USIPC) interviewed 607 asylum seekers in 2019, and 91.9% of them reported having family or close friends living in the United States. Tom K. Wong, *Seeking Asylum: Part 2* (Oct. 29, 2019). USIPC, however, is not a public health agency,¹⁸⁰ and its study

predated the COVID-19 pandemic. The study focused on the condition of aliens subject to “the Migrant Protection Protocols (MPP), also known as the ‘Remain in Mexico’ policy.” *Id.* at 3. USIPC did not look at whether the family or close friends had personal residences and, if so, whether they would make them available as self-quarantine or self-isolation locations. Nor did USIPC look at whether residences were suitable for self-quarantine or self-isolation in compliance with HHS/CDC guidelines.¹⁸¹

Even if HHS/CDC were to assume that many covered aliens have family or close friends in the United States, that fact alone would not control HHS/CDC’s public health analysis. HHS/CDC has weighed many considerations—including the epidemiology of COVID-19, the structural and operational limitations of CBP facilities, the available HHS/CDC and CBP resources, the requirements of other public health

Immigration Policy Ctr., UC San Diego, <https://usipc.ucsd.edu/> (last visited Sep. 1, 2020). The USIPC website encourages readers to “[v]isit UC San Diego’s Coronavirus portal for the latest information on the campus community.” *Id.* On the portal, UC San Diego informs students, faculty, and staff that for Fall 2020, in-person class size “is limited to fewer than 50 students per class, or 25% of classroom capacity, whichever is smaller.” *Return to Learn: Fall 2020 Plan*, UC San Diego, <https://returntolearn.ucsd.edu/return-to-campus/fall-2020-Jan/index.html> (last visited Sep. 1, 2020). UC San Diego further states that “[i]f a student is coming to campus from an international location, CDC guidelines recommend a 14-day quarantine period. Students with a housing contract can complete the quarantine period in specially designated on-campus housing” *Id.* (emphasis added). The USIPC website suggests that USIPC defers to UC San Diego on public health issues, and that UC San Diego generally follows CDC guidance when addressing such issues.

¹⁸¹ Persons who self-isolate should stay home except to get medical care. When at home, they should stay in a separate room from other household members, if possible; use a separate bathroom, if possible; avoid contact with other members of the household and pets; and avoid sharing personal household items, like cups, towels and utensils. *Coronavirus Disease 2019 (COVID-19), What to Do If You Are Sick*, Ctrs. for Disease Control & Prevention, <https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/steps-when-sick.html> (last updated May 8, 2020). Persons who self-quarantine should stay at home for 14 days after their last contact with a person who has COVID-19, watch for symptoms of COVID-19, and, if possible, stay away from others, especially people who are at higher risk for getting very sick from COVID-19. *Coronavirus Disease 2019 (COVID-19), When to Quarantine*, Ctrs. for Disease Control & Prevention, <https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html> (last updated Aug. 16, 2020). When at home, persons in self-quarantine should stay at least 6 feet from other people, and clean and disinfect frequently touched objects and surfaces, among other things. *Coronavirus Disease 2019 (COVID-19), Household Checklist*, Ctrs. for Disease Control & Prevention, <https://www.cdc.gov/coronavirus/2019-ncov/daily-life-coping/checklist-household-ready.html> (last updated June 13, 2020).

operations during the COVID-19 pandemic, and the needs of the domestic population—when issuing and continuing its Order on covered aliens pursuant to the IFR. HHS/CDC maintains that its implementation of a self-quarantine or self-isolation protocol for covered aliens would consume undue HHS/CDC and CBP resources without averting the serious danger of the introduction of COVID-19 into CBP facilities. Expulsion is a more effective public health measure for CBP facilities that preserves finite HHS/CDC resources for other public health operations.

Section 71.40(b), Definitions Used in This Section

Comment: Some commenters stated that section 362 of the PHS Act authorizes the Secretary to stop the risk of introduction of a disease into the United States, and the IFR unlawfully extends the Secretary’s authority to situations where a disease is already in the United States.

Response: HHS/CDC respectfully disagrees for the reasons stated in Section IV.B of this final rule.

Comment: Some commenters stated that HHS/CDC’s inclusion of aircraft in its definition of “place” exceeds the CDC’s limited statutory authority and would allow the Director to suspend the introduction of persons, not because of the serious danger of the introduction of a quarantinable communicable disease from a foreign country into the United States, but because of the existence of a quarantinable communicable disease onboard an aircraft.

Response: HHS/CDC respectfully disagrees with this comment. To prevent the introduction of a quarantinable communicable disease, the Director must have the authority to prohibit the introduction of persons from a foreign country or place, as well as any carriers carrying those persons.

Comment: A number of commenters expressed the view that the IFR fails to give meaning to the phrase “serious danger” from section 362 of the PHS Act, as the IFR 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.”

Response: The final rule defines “serious danger of the introduction of such quarantinable communicable disease into the United States” to mean the *probable* introduction of one or more persons capable of transmitting the quarantinable communicable disease into the United States, even if persons or property in the United States

¹⁷⁸ *Quarantine and Isolation: U.S. Quarantine Stations*, Ctrs. for Disease Control & Prevention, <https://www.cdc.gov/quarantine/quarantine-stations-us.html> (last updated July 24, 2020) (Those quarantine stations are in Detroit, MI; El Paso, TX; San Diego, CA; and Seattle, WA).

¹⁷⁹ *Id.*

¹⁸⁰ USIPC is a part of the University of California San Diego (UC San Diego) that “brings together leading academics, policy analysts, immigrant-rights leaders, and policymakers across all levels of government to conceptualize, debate, and design a new U.S. immigration policy agenda” U.S.

are already infected or contaminated with the quarantinable communicable disease. This regulatory definition clarifies that, even if persons or property in the United States are already infected or contaminated with a quarantinable communicable disease, the introduction of one or more additional persons capable of disease transmission in the same or different localities can nevertheless present a serious danger of the introduction of the disease into the United States. Additionally, this regulatory definition clarifies that the danger of introduction becomes serious when one or more additional persons capable of disease transmission would more likely than not be introduced into the United States. Section IV.B.3 further explains why this definition comports with the statute.

Section 71.40(c), Director's Terms of the Suspension

Comment: A number of commenters recommended that the CDC self-impose a required expiration for each order, or alternatively a short-interval and recurrent review of the Director's determinations and orders under the IFR, with such objective review conducted by an agency inspector general or Federal third-party agency.

Response: HHS/CDC agrees that recurrent HHS/CDC review of CDC Orders is good policy. The CDC Order on covered aliens issued and continued pursuant to the IFR have undergone recurrent review. Section 71.40(c) of this final rule provides that any order issued pursuant to this final rule shall designate the "period of time or circumstances under which the introduction of any persons or class of persons into the United States shall be suspended." It would be unwise to state a specific time period in this final rule because the epidemiology of quarantinable communicable diseases varies.

HHS/CDC respectfully disagrees with the comment calling for "objective review conducted by an agency inspector general or Federal third-party agency." The Secretary delegated his or her statutory authority under section 362 to the CDC Director, which was proper. HHS/CDC is best positioned to review the necessity of its own orders. Moreover, HHS/CDC's core mission is to develop and apply disease prevention and control strategies to improve the health of all Americans while it also works to ensure domestic preparedness, eliminate disease, and end epidemics.¹⁸² HHS/CDC has the

scientific and technical expertise required to determine whether the existence of a quarantinable communicable disease in a foreign country or place poses a serious danger to the United States, whether that serious danger is increased by the introduction of persons from such country, and whether a prohibition on the introduction of such persons should be imposed or continued.

By contrast, the mission of the HHS Office of the Inspector General (OIG) "is to provide objective oversight to promote the economy, efficiency, effectiveness, and integrity of HHS programs, as well as the health and welfare of the people they serve."¹⁸³ OIG conducts and supervises audits and investigations relating to certain programs and operations and provides a means for keeping the Secretary and Congress informed of problems and deficiencies relating to the administration of HHS programs. See 5 U.S.C. 2, 4. OIG does not have the statutory authority or scientific or technical expertise required to make public health judgments about the imposing or continuing of prohibitions on the introduction of persons.

Additionally, the Director may not subdelegate statutory authority under section 362 to another Federal department. Federal officials may subdelegate their authority to subordinates absent evidence of contrary Congressional intent, but they may not subdelegate to other departments absent express statutory authority to do so. See *U.S. Telecom Ass'n v. FCC*, 359 F.3d 554, 566 (D.C. Cir. 2004); *Gentiva Healthcare Corp. v. Sebelius*, 857 F. Supp. 2d 1, 7 (D.D.C. 2012). The Director does not have express statutory authority to subdelegate statutory authority under section 362 to another Federal department.

Comment: A number of commenters recommended that the Department add a fourth requirement to the components of a CDC Order: A statement of the evidence of the quarantinable communicable disease threat in the foreign countries (or one or more designated political subdivisions or regions thereof) or places from which the introduction of persons is being suspended, on which the CDC Director relies in issuing such order.

Response: HHS/CDC has considered this comment and decided, for the

organization/cio-orgcharts/pdfs/CDCfs-508.pdf (last visited Sep. 1, 2020).

¹⁸³ *About OIG*, U.S. Dep't. of Health & Human Serv.'s Off. of the Inspector Gen., <https://oig.hhs.gov/about-oig/about-us/index.asp> (last visited Sep. 1, 2020).

reasons explained in the section of this final rule entitled "Provisions of New Section 71.40," to incorporate a modified version of this requirement in the final rule. Accordingly, section 71.40(c) of the final rule requires that, in any order issued pursuant to this final rule, the Director shall include a statement describing the danger posed by the quarantinable communicable disease in the foreign country or countries (or one or more designated political subdivisions or regions thereof) or places from which the introduction of persons is being suspended. Also, this final rule applies to quarantinable communicable diseases broadly, not just to COVID-19. So section 71.40(c) requires that the statement describe the danger posed by the quarantinable communicable disease that led the Director to invoke the section 362 authority.

Section 71.40(d), Persons To Whom This Section Applies

Comment: A number of commenters stated that previous efforts to prevent the introduction of persons with active contagious diseases from entering the U.S. have been based on an examination of the person, not on the person's membership in a particular group.

Response: These comments are directed to the CDC Order on covered aliens issued pursuant to the IFR, and not to the IFR or this final rule. No action can or will be taken under this final rule absent an order issued by the Director. To the extent these comments are directed to this final rule, HHS/CDC respectfully disagrees with them. Like the IFR, this final rule sets forth facially neutral procedures for the exercise of the 362 authority by the Director. The procedures do not turn on whether a person is a member of a particular group.

Moreover, the CDC Order on covered aliens issued pursuant to the IFR prohibits introduction of covered aliens traveling from Canada or Mexico, regardless of their national origin, who would otherwise be introduced into the United States. Covered aliens are those who lack valid travel documents and would otherwise spend material amounts of time in congregate areas. The CDC Order on covered aliens does not prohibit the introduction of persons into the United States based on factors such as race, color, religion, national origin, sex, age, or disability. Also, the CDC Order on covered aliens, as implemented by DHS, provides for discretionary, individualized exceptions from the prohibition on introduction.

Comment: Some commenters stated that HHS/CDC should clarify that the

¹⁸² *Mission Statement*, Ctrs. for Disease Control & Prevention, <https://www.cdc.gov/about/>

rule applies to persons, regardless of nationality, if they have travelled from designated countries.

Response: HHS/CDC believes that the final rule's language that it applies to those "from designated foreign countries" states in plain language that the prohibition of introduction of persons is based on the country a person is travelling from, and not their nationality.

Section 71.40(f), Exception for U.S. Citizens, U.S. Nationals, and Lawful Permanent Residents

Comment: Some commenters indicated that this final rule should also apply to U.S. citizens and LPRs who may be introduced into the United States during the COVID-19 pandemic. Some commenters further asserted that the issuance of a rule that applies to some aliens, but not all persons, may be unconstitutional.

Response: The Director has no present intention to apply the section 362 authority to U.S. citizens, U.S. nationals, or LPRs in connection with the COVID-19 pandemic (indeed, the Director has never intended to do so). This is partly because U.S. citizens, U.S. nationals, and LPRs generally present to POEs with valid travel documents, and do not spend material amounts of time in congregate settings in such facilities. Because U.S. citizens, U.S. nationals, and LPRs spend less time in congregate settings than covered aliens subject to the CDC Order on covered aliens issued pursuant to the IFR, they present lower public health risks in those settings.

Given the complex and important legal and policy questions presented by the potential application of section 362 to U.S. citizens, U.S. nationals, and LPRs, HHS/CDC has determined that it would be in the public interest to provide notice of, and accept comments on, any regulatory text that HHS/CDC would propose to apply to U.S. citizens, U.S. nationals, and LPRs in other contexts. Further notice and comment would enable HHS/CDC to provide the public with a more fulsome explanation of the potential public health threats and policy rationales that support the regulatory text without jeopardizing the ability of HHS/CDC to protect U.S. public health from COVID-19 in the immediate future.

HHS/CDC maintains that its approach in this final rule is rational and constitutional.

Comment: Some commenters stated that mariners and airline crews should be excluded from this rule because prohibiting them from being introduced into the U.S. could cause serious logistical and safety issues.

Response: HHS/CDC has considered this comment and appreciates the concerns raised. Nevertheless, HHS/CDC does not believe it is necessary to create express regulatory exclusions for mariners and airline crews. Any order issued pursuant to this final rule would be tailored by the Director to what public health requires and, to the greatest extent possible, adhere to U.S. federal policy of facilitating the critical work of mariners and aircrew. If public health measures such as quarantine, isolation, conditional release, or social distancing are adequate to protect public health, then HHS/CDC would take those measures and not suspend the introduction of such persons.

VI. Alternatives Considered

HHS/CDC has considered a number of alternatives to the final rule. One alternative that HHS/CDC has considered is rescinding the IFR and the CDC Order on covered aliens issued pursuant to the IFR, and foregoing the issuance of this final rule. HHS/CDC has ruled out that alternative because there is still a serious danger of introduction of COVID-19 into the United States from Canada and Mexico, and the public health situation in Mexico remains tenuous. As noted above, quarantine, isolation, and conditional release are still not workable options on the scale that would be needed for protecting U.S. public health from the introduction of COVID-19; Federal quarantine and isolation of covered aliens would be impracticable, and covered aliens as a population are not a good fit for public health measures such as conditional release and recommendations to self-quarantine or self-isolate. The rescission of the IFR would result in tens of thousands of covered aliens entering congregate settings each month, which would put the health of the DHS workforce and the domestic U.S. population at greater risk, likely increase community transmission of COVID-19 and new COVID-19 cases in the States in the U.S.-Mexico border region, and strain the capacity of U.S. health-care systems. There are good reasons to issue this final rule, especially when the efforts of the domestic population to avoid congregate settings are considered. The rescission of the IFR and CDC Order would undercut those efforts, which the domestic population has undertaken at great personal sacrifice.

HHS/CDC also considered and declined to include procedures in this final rule that apply to U.S. citizens, U.S. nationals, and LPRs. Such procedures present complex and important legal and policy issues, and

the Director has no present intention of prohibiting the introduction of U.S. citizens, U.S. nationals or LPRs into the United States as part of the response to the COVID-19 pandemic. Further notice and comment rulemaking on any proposed regulatory text that would apply outside the COVID-19 context would be in the public interest.

VII. Regulatory Impact Analysis

A. 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 \$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/CDC has determined that this 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 primarily against persons and not state, local, or tribal governments. Accordingly, HHS/CDC has not prepared a budgetary impact statement or specifically addressed the regulatory alternatives considered.

B. National Environmental Policy Act (NEPA)

HHS has determined that the amendments to 42 CFR part 71 will not have a significant impact on the environment.

C. Executive Order 12988: Civil Justice Reform

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

D. Executive Order 13132: Federalism

This 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/CDC believes that the final rule does not warrant additional analysis under Executive Order 13132.

E. Plain Language Act of 2010

Under the Plain Language Act of 2010 (Pub. L. 111–274, October 13, 2010, 124 Stat. 2861), 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 final rule, consistent with the Federal Plain Writing Act guidelines.

F. Congressional Review Act and Administrative Procedure Act

The Congressional Review Act (CRA) 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).

OIRA has determined that this final rule is not a “major rule” for purposes of the CRA. The actual experience of HHS/CDC with the IFR and the CDC Order on covered aliens informs the CRA analysis. The IFR, like this final rule, establishes procedures by which the Director can issue an administrative order implementing section 362 of the PHS Act. Neither the IFR nor this final rule can have any economic effect absent an administrative order.

So far, the only administrative order that the Director has determined is necessary in the interest of public health is the CDC Order on covered aliens. That Order is unlikely to have an

annualized effect on the economy of \$100,000,000 or more for two reasons. First, the CDC Order on covered aliens has no direct economic effect. It applies only to individual persons, and not to commercial entities such as carriers; restrictions on commercial and passenger carriers have been imposed by DHS and HHS/CDC under different authorities. Second, any indirect economic effect is unlikely to equal or exceed \$100,000,000 annualized. The only potential indirect economic effect identified by HHS/CDC is a reduction in the utilization of the U.S. health care system by covered aliens. While that reduction helps protect U.S. public health by lessening the strain on the U.S. health care system, and preserving finite health care resources for the domestic population, HHS/CDC’s analysis has determined that the dollar value of the reduced utilization of the U.S. health care system is unlikely to equal or exceed \$100,000,000 annualized.

This year should serve as a benchmark for any future years in which the Director might find it necessary in the interest of public health to prohibit the introduction of persons from foreign countries into the United States. The COVID–19 pandemic is a once-in-a-generation public health emergency and, as discussed previously, the Federal government has mitigated the serious danger of the introduction of COVID–19 into the United States through a wide array of measures. The Director’s exercise of his authority under section 362 of the PHS Act through issuance of the CDC Order on covered aliens is just one of those measures. Others include the INA section 212(f) proclamations; quarantine, isolation, and conditional release; the CDC No Sail Order for cruise ships; and travel restrictions at land POEs along the U.S.-Canada and U.S.-Mexico borders. If the Director’s exercise of his authority under section 362 of the PHS Act is unlikely to have an annual economic effect of \$100,000,000 during the COVID–19 pandemic, then it follows that any future exercise of the section 362 authority pursuant to this final rule is unlikely to have an annual effect on the economy of \$100,000,000 or more.

The other tests for a “major rule” are not met. This final rule is procedural in nature. It does not impose any cost or price increases, or have any 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.

Because this final rule is not a “major rule” under the CRA, only the APA governs the effective date of this final rule. The APA provides that the publication of a substantive rule shall be made not less than 30 days before its effective date, except “as otherwise provided by the agency for good cause found and published with the rule.” 5 U.S.C. 553(d)(3). This final rule shall become effective 30 days from its publication in the **Federal Register** unless the IFR ceases to be in effect (for example, if it is vacated or enjoined by a court) before that time, in which case this final rule shall become effective immediately for good cause. There would be good cause because, as discussed in earlier sections of this final rule, the procedures established by the IFR and this final rule are critical to HHS/CDC’s ability to mitigate the serious danger of the introduction of COVID–19 into the United States, and thereby protect U.S. public health.

As discussed previously in this final rule, the Director assesses that the CDC Order on covered aliens is benefitting U.S. public health in several ways. The Director assesses that the CDC Order is: Reducing the danger of the introduction of COVID–19 into CBP facilities, which protects both the DHS workforce and migrants from COVID–19; reducing the strain on the health-care system in the U.S.-Mexico border region by decreasing utilization by covered aliens, which conserves health-care resources for the domestic population; and helping to slow the community transmission of COVID–19 and the number of new COVID–19 cases in the States in the U.S.-Mexico border region, which helps protect the domestic population from COVID–19. These benefits to U.S. public health would be lost immediately if the IFR and, by extension, the CDC Order on covered aliens ceased to be effective.

Of course, there would probably be secondary effects on U.S. public health and safety. As previously discussed in this final rule, the Director has assessed that the numbers of CBP employees who test positive for COVID–19 or enter quarantine would probably be larger absent the CDC Order, and CBP has informed HHS/CDC that further degradation of its workforce in the Laredo Sector due to COVID–19 would jeopardize CBP’s ability to execute its public safety mission. Thus, one likely secondary effect would be further degradation of the CBP workforce due to COVID–19 and, according to CBP, a corresponding reduction in public safety in the Laredo Sector. Similar effects would be possible in other sectors.

States in the U.S.-Mexico border region would probably also experience secondary effects. As previously discussed in this final rule, the Director has assessed that increased community transmission in California and Arizona would likely result in increased numbers of cases, as well as increased case and positivity rates, and ultimately increased numbers of individuals who have serious outcomes. Increases in case and positivity rates would, in turn, frustrate efforts in those States to step down to lower tiers in the reopening guidelines. The Director has further assessed that the introduction of covered aliens into California and Arizona through congregate settings in CBP facilities would likely have a negative impact on case and positivity rates in California and Arizona, which would not be in the interest of U.S. public health. Similar secondary effects would be possible in other States in the U.S.-Mexico border region such as Texas.

It is also foreseeable that the Federal government might have to address secondary effects in ICE facilities or ORR shelters for migrants. If, for example, the numbers of migrants entering those facilities were to increase, then the Federal government would have to attempt to manage the intake of the new migrants consistent with HHS/CDC infection control guidelines in order to help protect the health of the migrants, the facility workforces, and the U.S. domestic population. DHS and ORR report that the operationalizing of such guidelines is more complex than their ordinary operations. It is possible that facility censuses could reach or exceed levels that are workable under HHS/CDC infection control guidelines, in which case HHC/CDC may be left with no workable options for protecting U.S. public health.

HHS/CDC does not reasonably anticipate factual changes in the next 30 days that would materially affect HHS/CDC's good cause analysis.¹⁸⁴ While HHS/CDC modeling predicts that the total new deaths from COVID-19 will continue to decrease in September 2020, HHS/CDC reasonably anticipates that community transmission and the rates of new COVID-19 cases will remain serious concerns with respect to DHS, ORR, and the States in the U.S.-Mexico border region. For the next 30 days, any temporary loss of the procedures established by the IFR would jeopardize

HHS/CDC's ability to protect U.S. public health from COVID-19 and other quarantinable communicable diseases. As a result, there would be good cause for this final rule to become effective immediately in the event that the IFR ceases to be in effect.

There would be no prejudice to the public if the final rule became effective immediately. The final rule, like the IFR, permits the Director to prohibit the introduction into the United States of persons from designated foreign countries (or one or more political subdivisions or regions thereof) or places, only for such period of time that the Director deems necessary to avert the serious danger of the introduction of a communicable disease, by issuing an order in which the Director determines that:

(1) By reason of the existence of any quarantinable 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 quarantinable 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 right to introduce such persons into the United States is required in the interest of public health.

While the final rule mirrors the IFR at its core, the final rule is narrower than the IFR, clarifies aspects of the regulatory procedures, and enhances public transparency. Notably, the final rule applies only to quarantinable communicable diseases, which are a subset of communicable diseases specified by the President in Executive Orders. The final rule also: aligns the regulatory text with section 362 of the PHS Act; defines additional terms; and requires the Director, when issuing an administrative order, to state both the means by which the prohibition on introduction shall be implemented, and the serious danger posed by the introduction of the quarantinable communicable disease. These changes would be beneficial, not prejudicial, to the public.

G. 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 final rule is not economically significant for the purposes of Executive Orders 12866 and 13563 for the same reasons that it is not a major rule for purposes of the CRA. The Office of Management and Budget (OMB) has reviewed this rule.

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, 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,

¹⁸⁴ COVID-19 Forecasts: Deaths, Ctrs. for Disease Control & Prevention, <https://www.cdc.gov/coronavirus/2019-ncov/covid-data/forecasting-us.html> (last updated Sep. 2, 2020).

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).

HHS/CDC certifies that this final rule will not have a significant economic impact on a substantial number of small entities. This final rule establishes a regulatory procedure by which the Director may exercise the section 362 authority through issuance of an administrative order. Without an administrative order, this final rule can have no economic impact.

HHS/CDC may use the procedures created by this final rule to issue administrative orders against individual persons. In addition, HHS/CDC may use the procedures created by this final rule to issue administrative orders against carriers of persons, such as cruise ships or airlines. HHS/CDC, however, does not reasonably contemplate issuing administrative orders against carriers of persons that are small entities for two reasons. First, small entities are by their nature less likely than large entities to transport large numbers of persons in congregate settings. Second, based on experience, HHS/CDC reasonably contemplates mitigating the public health risks presented by carriers that are small entities through less sweeping public health measures, such as quarantine, isolation, and conditional release, or no-sail orders issued under other procedures, or no-fly lists of passengers. HHS/CDC reasonably contemplates that any administrative orders against carriers would be rare, and would be limited to large entities transporting large numbers of persons in congregate settings. Accordingly, HHS/CDC certifies that this final rule will not have a significant economic impact on a substantial number of small entities when considered together with any administrative order that HHS/CDC could conceivably issue in the future.

H. Assessment of Federal Regulation and Policies on Families

Section 654 of the Treasury and General Government Appropriations Act of 1999, Public Law 105–277, sec. 654, 112 Stat. 2681 (1998) requires Federal departments and agencies to determine whether a policy or regulation could affect family well-being. HHS/CDC conducts such an analysis below and certifies the same. Section 601 (note) required agencies to assess whether a regulatory action (1) impacted the stability or safety of the family, particularly in terms of marital commitment; (2) impacted the authority of parents in the education, nurturing, and supervision of their children; (3) helped the family perform its functions; (4) affected disposable income or poverty of families and children; (5) was justified if it financially impacted families; (6) was carried out by State or local government or by the family; and (7) established a policy concerning the relationship between the behavior and personal responsibility of youth and the norms of society.

This final rule establishes the process by which the Director may issue administrative orders suspending the introduction of persons. Standing alone, without an administrative order from the Director, it has no direct impact on family well-being based on any of the factors listed above. If the family well-being determination requirement were still in force, an assessment of the impact of this final rule on family well-being would not be required.

The current CDC Order on covered aliens does not implicate factors (2) through (7) listed above. HHS/CDC, however, recognizes that the current CDC Order on covered aliens, and future orders by the Director, could potentially impact family stability under factor (1). This is because such orders temporarily prevent persons from introducing themselves into the United States and, as a consequence, may prevent the persons from seeing family members in the United States. Any such impact on family well-being would last for the duration of the order.

In the judgment of HHS/CDC, the benefits to U.S. public health that flow from preventing the introduction of quarantinable communicable diseases into the United States far outweigh any impact on family well-being that might result from deferred visitation of family members in the United States. Families benefit greatly when family members—particularly seniors and other members of vulnerable populations—are healthy and safe from quarantinable communicable diseases. The suffering

and loss of family members due to disease is tragic, and the burden of caring for family members with serious disease may be emotionally and financially significant. The better approach overall for protecting family well-being is to reduce the danger of quarantinable communicable diseases, notwithstanding any temporary deferral of visitation.

I. Paperwork Reduction Act of 1995

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

J. Regulatory Reform Analysis Under Executive Order 13771

Executive Order 13771, titled “Reducing Regulation and Controlling Regulatory Costs,” was issued on January 30, 2017, and requires that the costs associated with significant new regulations “shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.” OMB’s *Guidance Implementing Executive Order 13771, Titled “Reducing Regulation and Controlling Regulatory Costs,”* issued on April 5, 2017, (<https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2017/M-17-21-OMB.pdf>), explains that “E.O. 13771 deregulatory actions are not limited to those defined as significant under E.O. 12866 or OMB’s Final Bulletin on Good Guidance Practices.” It has been determined that this proposed rule imposes no more than de minimis costs, and therefore is not considered a regulatory action under Executive Order 13771.

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, 42 CFR part 71 is amended 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. Revise § 71.40 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.

(a) The Director may prohibit, in whole or in part, the introduction into the United States of persons from designated foreign countries (or one or more political subdivisions or regions thereof) or places, only for such period of time that the Director deems necessary to avert the serious danger of the introduction of a quarantinable communicable disease, by issuing an order in which the Director determines that:

(1) By reason of the existence of any quarantinable 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 quarantinable 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 right to introduce such persons into the United States is required in the interest of public health.

(b) For purposes of this section:

(1) *Introduction into the United States* 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 or property in the United States, in a manner that the Director determines to present a risk of transmission of a quarantinable communicable disease to persons, or a risk of contamination of property with a quarantinable communicable disease, even if the quarantinable communicable disease has already been introduced, transmitted, or is spreading within the United States;

(2) *Prohibit, in whole or in part, the introduction into the United States of persons* means to prevent the introduction of persons into the United States by suspending any right to introduce into the United States, physically stopping or restricting movement into the United States, or physically expelling from the United States some or all of the persons;

(3) *Serious danger of the introduction of such quarantinable communicable*

disease into the United States means the probable introduction of one or more persons capable of transmitting the quarantinable communicable disease into the United States, even if persons or property in the United States are already infected or contaminated with the quarantinable communicable disease;

(4) 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 flag, registry, or country of origin; and

(5) *Suspension of the right to introduce* means to cause the temporary cessation of the effect of any law, rule, decree, or order pursuant to which a person might otherwise have the right to be introduced or seek introduction into the United States.

(c) Any order issued by the Director under this section shall include a statement of the following:

(1) The foreign countries (or one or more political subdivisions or regions thereof) or places from which the introduction of persons shall be prohibited;

(2) The period of time or circumstances under which the introduction of any persons or class of persons into the United States shall be prohibited;

(3) The conditions under which that prohibition on introduction shall be effective in whole or in part, including any relevant exceptions that the Director determines are appropriate;

(4) The means by which the prohibition shall be implemented; and

(5) The serious danger posed by the introduction of the quarantinable communicable disease in the foreign country or countries (or one or more political subdivisions or regions thereof) or places from which the introduction of persons is being prohibited.

(d) When issuing any order under this section, the Director shall, as practicable under the circumstances, consult with all Federal departments or agencies whose interests would be impacted by the order. The Director shall, as practicable under the circumstances, provide the Federal departments or agencies with a copy of the order before issuing it. In circumstances when it is impracticable to engage in such consultation before taking action to protect the public health, the Director shall consult with the Federal departments or agencies as soon as

practicable after issuing his or her order, and may then modify the order as he or she determines appropriate. In addition, the Director may, as practicable under the circumstances, consult with any State or local authorities that he or she deems appropriate in his or her 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 shall 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 any individual designated by the Department of Homeland Security to perform the duties of a customs officer) 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:

(1) Members of the armed forces of the United States and associated personnel if the Secretary of Defense provides assurance to the Director that the Secretary of Defense has taken or will take measures such as quarantine or isolation, or other measures maintaining control over such individuals, to prevent the risk of transmission of the quarantinable communicable disease into the United States; or

(2) Other United States government employees or contractors on orders abroad, or their accompanying family members who are on their orders or are members of their household, if the Director receives assurances from the relevant head of agency and determines that the head of the agency or department has taken or will take, measures such as quarantine or isolation, to prevent the risk of transmission of a quarantinable communicable disease into the United States.

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

(g) Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of utter

invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

Dated: September 4, 2020.
Alex M. Azar II,
Secretary, Department of Health and Human Services.
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