DEPARTMENT OF HEALTH & HUMAN SERVICES

The Honorable John O'Connor
Attorney General
313 N.E. 21st Street
Oklahoma City, Oklahoma 73105

Dear Attorney General O'Connor:

I am responding on behalf of Health and Human Services (HHS) Secretary Xavier Becerra to your petition submitted on behalf of the Attorney Generals of 15 U.S. States[1] (hereinafter, "the petitioners") to amend the definition of "public health emergency" in 42 CFR 70.1. Under the Administrative Procedure Act, each agency must "give an interested person the right to petition for the issuance, amendment, or repeal of a rule." 5 U.S.C. § 553(e).

Your petition raises the following concerns:

- Definitions 3, 4, and 5 of "public health emergency" as used in 42 CFR 70.1 exceeds the HHS and the Centers for Disease Control and Prevention (CDC) statutory authority because it constitutes an unlawful delegation of authority to either the World Health Organization (WHO) (in the case of definitions 4 and 5) or to a foreign nation's decision to report a disease event to WHO (in the case of definition 3).
- HHS should repeal definitions in 42 CFR 70.1 that reference WHO because WHO ostensibly allows political influence from China to manipulate its health decisions.
- HHS/CDC would not be harmed by repealing definitions 3, 4, and 5 because it previously stated as part of its 2017 final rulemaking that it would exercise its independent judgment in assessing whether a public health emergency existed under 42 CFR part 70.

Section 361(a) of the Public Health Service Act authorizes the HHS Secretary to "make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession." 42 U.S.C. § 264(a). Section 361(b) provides that regulations authorizing the apprehension, detention, or conditional release of individuals shall be specified in Executive orders of the President[2] upon

[1] These States are Oklahoma, Alabama, Arizona, Arkansas, Florida, Georgia, Indiana, Louisiana, Mississippi, Missouri, Montana, Nebraska, South Carolina, Texas, and Utah.

[2] The current list of "quarantinable" communicable diseases includes Cholera, Diphtheria, infectious Tuberculosis, Measles, Plague, Smallpox, Yellow Fever, Viral Hemorrhagic Fevers, Severe acute respiratory syndromes, and Flu that can cause a pandemic. Executive Order 13295 (April 4, 2003), as modified by Executive Orders 13375 (April 1, 2005), 13674 (July 31, 2014), and 14047 (Sept. 17, 2021). Coronavirus disease 2019 is subject to federal quarantine and isolation because it meets the definition for Severe acute respiratory syndromes.

the recommendation of the Secretary, in consultation with the Surgeon General.[3] 42 U.S.C. § 264(b). Section 361(c) provides that regulations authorizing apprehension, detention, examination, or conditional release of individuals shall be applicable only to individuals coming into a State or possession from a foreign country or a possession. 42 U.S.C. § 264(c).

Section 361(d)(1) authorizes the apprehension and examination of individuals who are in the "qualifying stage" of a communicable disease if such individuals are (A) "moving or about to move from a State to another State;" or (B) "a probable source of infection to individuals who, while infected with such disease in a qualifying stage, will be moving from a State to another State." 42 U.S.C. § 264(d)(1). A "qualifying stage" is further defined in section 361(d)(2) as "a communicable stage;" or "a precommunicable stage if the disease would be likely to cause a public health emergency if transmitted to other individuals." 42 U.S.C. § 264(d)(2).

On August 15, 2016, HHS published a Notice of Proposed Rulemaking (81 FR 53240) in which we proposed a new definition of "public health emergency." HHS/CDC felt it was important to define ''public health emergency'' as used under section 361(d)(2) to provide the public with a clear understanding of HHS/CDC's authority for interstate quarantine, isolation, or conditional release. We requested public comment on this definition.

As defined under 42 CFR 70.1, HHS proposed that "public health emergency" mean:

> (1) Any communicable disease event as determined by the CDC Director with either documented or significant potential for regional, national, or international communicable disease spread or that is highly likely to cause death or serious illness if not properly controlled; or
> (2) Any communicable disease event described in a declaration by the Secretary pursuant to 319(a) of the Public Health Service Act (42 U.S.C. 247d (a)); or
> (3) Any communicable disease event the occurrence of which is notified to the World Health Organization, in accordance with Articles 6 and 7 of the International Health Regulations (IHR), as one that may constitute a Public Health Emergency of International Concern; or
> (4) Any communicable disease event the occurrence of which is determined by the Director-General of the World Health Organization, in accordance with Article 12 of the IHR, to constitute a Public Health Emergency of International Concern; or
> (5) Any communicable disease event for which the Director-General of the World Health Organization, in accordance with Articles 15 or 16 of the IHR, has issued temporary or standing recommendations for purposes of preventing or promptly detecting the occurrence or reoccurrence of the communicable disease.

In the Final Rule published on January 19, 2017, HHS discussed the public comments received on this proposed definition (82 FR 6905-6910). HHS explained that "public health emergency" as used in § 361(d) differed from how the term is used in other provisions of the Public Health Service Act because it authorizes specific public health measures (apprehension and

---

[3] Although statute originally assigned authority to the Surgeon General, these statutory powers and functions were later transferred to the Secretary of Health, Education, and Welfare, now the Department of Health and Human Services Secretary. *See* Reorganization Plan No. 3 of 1966, 31 Fed. Reg. 8855 (June 25, 1966), reprinted in 80 Stat. 1610 (1966); *see also* 20 U.S.C. § 3508(b).

examination) to specific individuals (those in the precommunicable stage of a quarantinable communicable disease), but only if the disease would be likely to cause a public health emergency (82 Fed. Reg. 6905 Jan. 19, 2017). HHS/CDC therefore considered it essential to define the term because the existence of such an emergency is a statutory prerequisite to the apprehension and examination of individuals in the precommunicable stage of a quarantinable communicable disease.

We note that the term "public health emergency" is only referenced in the definitions section of 42 CFR part 70, as its own definition and under the definition of "qualifying stage" which quotes from § 361(d) verbatim. Apprehension and detention of individuals with quarantinable communicable diseases is then authorized under 42 CFR 70.6 if the CDC Director reasonably believes the individual to be in the "qualifying stage" of the disease. Any exercise of authority under § 70.6 is further governed by other substantive provisions under part 70, including § 70.14 setting forth additional requirements relating to the issuance of federal quarantine orders. Among other things, such orders must identify the individuals or groups to be quarantined, the location of the quarantine, explain the factual basis for the Director's reasonable belief that the individual is in the qualifying stage of the disease, explain the factual basis for the Director's reasonable belief that the individual is moving or about to move from one U.S. State into another or otherwise constitutes a probable source of infection to other individuals moving between U.S. States, explain that the order will be reassessed within 72 hours, and notify the individual of the opportunity for an agency medical review, as well as the potential for criminal penalties if non-compliant.

In the 2017 Final Rule, HHS also addressed comments that incorporating references to WHO in the definition of public health emergency implicated U.S. sovereignty and rejected these concerns. Specifically, HHS found:

> By including references to a [Public Health Emergency of International Concern (PHEIC)], HHS/CDC is not constraining its actions or makings [sic] its actions subject to the dictates of the WHO. Rather, the declaration or notification of a PHEIC is only one way for HHS/CDC to define when the precommunicable stage of a quarantinable communicable disease may be likely to cause a public health emergency if transmitted to other individuals. While HHS/CDC will give consideration to the WHO's declaration of a PHEIC or the circumstances under which a PHEIC may be notified to the WHO, HHS/CDC will continue to make its own independent decisions regarding when a quarantinable communicable disease may be likely to cause a public health emergency if transmitted to other individuals. Thus, HHS/CDC disagrees that referencing the WHO determination of a PHEIC results in any relinquishment of U.S. sovereignty.[4]

Agency practice since 2017 accords with the understanding that CDC would only consider WHO's determinations when exercising its own independent judgment regarding apprehension and detention of individuals. Between January and March 2020, HHS/CDC, in conjunction with other federal agencies, repatriated approximately 1,100 individuals from Wuhan, China, and the *Diamond Princess* cruise ship in Yokohama, Japan, in response to the coronavirus disease 2019 (COVID-19) pandemic. HHS/CDC quarantined these individuals for 14 days at five U.S.

---

[4] 82 FR 6905-6906

Department of Defense (DOD) facilities. HHS/CDC, in conjunction with other federal agencies, later quarantined approximately 2,000 individuals from the *Grand Princess* cruise ship in San Francisco, California. These individuals were similarly quarantined at a variety of DOD and other facilities for the incubation period of the disease until CDC determined that such practices were no longer warranted based on the evolution of the pandemic.

Although HHS/CDC, in the case of the Wuhan and *Diamond Princess* evacuees relied on complementary quarantine authorities at 42 CFR 71.32(a), 71.33, pertaining to foreign arrivals, the agency also referenced 42 CFR 70.6. Specifically, CDC found that these individuals met the standards for quarantine under 42 CFR 70.6 because they were reasonably believed to be in a qualifying stage of the disease and, if released from quarantine, would be moving or are about to move from one U.S. State into another or constitute a probable source of infection to others who may be moving from one U.S. State into another.

In the case of the *Grand Princess*, HHS/CDC relied solely on 42 CFR 70.6 because these individuals were already in the United States and not in the process of arriving from a foreign country when placed under quarantine. Both quarantine orders noted that the WHO Director General, pursuant to the IHR, had declared that the outbreak of COVID-19 constituted a Public Health Emergency of International Concern. The quarantine orders also referenced the Secretary's determination that COVID-19 constituted a public health emergency under the Public Health Service Act. Additionally, these quarantine orders (consistent with agency practice) were supported by medical declarations signed under penalty of perjury setting forth additional pertinent facts and circumstances as to what was known about COVID-19 at the time and the agency's determination as to the necessity for apprehension and detention.

In conclusion, the petition does not raise any significant concerns that were not previously raised and considered by HHS/CDC when finalizing the proposed regulations in 2017. The language and structure of the regulations, as well as agency practice in implementation, furthermore, belie the contention that an unlawful delegation has occurred because apprehension and quarantine determinations are only carried out subject to the CDC Director's independent judgment.

Although we acknowledge the concerns noted in the petition regarding purported political influence on WHO decision-making, they do not support removing references to that organization in 42 CFR 70.1. Rather, HHS/CDC considers it important to include references to WHO in the definition of "public health emergency" to inform the public of the circumstances that HHS/CDC may consider when determining whether a public health emergency exists using its own independent judgment. Furthermore, we are committed to strengthening WHO so that it can be more effective, transparent, and agile, including the organization's ability to prepare for and respond to COVID-19 and the next pandemic.

These efforts include strengthening the IHR (2005). We believe in the need for strong global relationships to combat COVID-19 and prepare for future pandemics. Since the 2005 revision of the IHR, the world has benefited from an increased level of transparency, improved rapid pathogen information sharing and stronger response coordination. However, the COVID-19 pandemic and other recent public health emergencies have revealed gaps and shortcomings. The U.S. is seeking targeted amendments to increase rapid and timely sharing of data and information

related to outbreaks and pathogens between countries and to enhance early warning triggers so that countries can take actions to prepare for and respond to emergencies such as COVID-19.

The IHR's origins date back to 1851, when international efforts sought to address the spread of infectious diseases entering Europe from Asia; this was codified in the 1892 International Sanitary Convention (ISC), which sought to protect countries from infectious disease threats. When the WHO was created in 1948, oversight of the ISC became part of its mandate. In 1951, the World Health Assembly (WHA) replaced the ISC with the International Sanitary Regulations, which covered six diseases; in 1969, these were further revised and renamed as the International Health Regulations (IHR). With the increase in international travel and trade, and the emergence, re-emergence and international spread of emerging infectious diseases, in 1995, WHO Member States recognized a need for a substantial revision to extend the scope of diseases and related health events covered by the IHR to take into account almost all public health risks (biological, chemical, radiological, or nuclear in origin) that might affect human health, irrespective of the source. The revised IHR (2005) entered into force in 2007, have 196 States Parties, and require States Parties to notify a wide range of events to the WHO.

The IHR (2005) constitutes a legally binding global health security framework to prevent, detect, and respond to acute public health risks that have the potential to cross borders and threaten the health of populations worldwide, while minimizing interference with world travel and trade. However, the IHR has not been fully implemented by States Parties, and COVID-19 stressed health systems, further exposing existing gaps and weaknesses. Criticisms from numerous reviews over the last 15 years include: a lack of country core capacities in pandemic preparedness, insufficient implementation of requirements by national governments, weaknesses in WHO´s emergency response systems and programs, and other gaps and challenges in pandemic preparedness and response at national and international levels, including fundamental weaknesses in health systems and lack of indicators to detect and respond to new infectious disease threats (e.g., unknown viruses). Although there have been numerous proposals to improve the IHR (2005) through amendment, none have been taken up yet.

At this year's WHA, the United States proposed targeted IHR amendments that were developed and refined over the last year in consultation with fellow WHO Member States. Strengthening the global health infrastructure as quickly and effectively as possible is critically important as we begin the third year in our battle against COVID-19. The United States discussed these proposed amendments with other WHO Member States as part of the Working Group on Strengthening WHO Preparedness and Response, whose report was considered by the Health Assembly during this year's meeting.

In resolution WHA75.12 of May 28, 2022, the Seventy-fifth World Health Assembly adopted amendments to Articles 55, 59, 61, 62 and 63 of the IHR, as proposed by the United States. These amendments strengthen requirements for reporting emergencies to the WHO. These and other amendments the United States is proposing, however, do not provide the WHO with enforcement powers and do not authorize WHO to interfere in the United States' internal decision-making processes. Strengthening the existing IHR does not diminish U.S. sovereignty or the ability of Americans to make their own healthcare decisions and claims in that regard are false. The effort to strengthen the IHR is about improving transparency and speeding action, so

nations have the information and the recommendations they can use. Finally, strengthening the IHR also helps to ensure that other countries do their part on global health, something we should all embrace.

Lastly, your assertion that HHS/CDC would not be harmed by deleting definitions 3, 4, and 5 of "public health emergency" as used in 42 CFR 70.1, even if accurate, does not justify the expenditure of agency resources to amend the regulations. Also, as explained in the 2017 Final Rule, HHS/CDC considered it important to include references to WHO in the definition of "public health emergency" to inform the public of the circumstances that HHS/CDC may consider when making such a determination using its own independent judgment. Accordingly, we decline the petitioners' request to amend 42 CFR 70.1 by deleting definitions 3, 4, and 5 of "public health emergency" at this time.

Sincerely,

Marvin Figueroa
Director, Intergovernmental and External Affairs