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IN FOCUS

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U.S. Proposals to Amend the International Health Regulations

Background

Since 1980, outbreaks of new and long-standing infectious diseases have been occurring with greater frequency and causing higher numbers of human infections. The World Health Assembly (WHA), the governing body of the World Health Organization (WHO), has occasionally amended a long-standing set of rules called the International Health Regulations (IHR) to address this growing global threat. In January 2022, the United States introduced amendments to the Regulations that sought to broaden the ways in which WHO could respond to public health threats and increase the pace of such responses. Congressional deliberations of these amendments focused on the potential implications of implementation and whether adoption of the amendments would require congressional consent since the United States consented to be legally bound by the Regulations through an executive agreement. This In Focus addresses common questions regarding the IHR, including the role of Congress and the status of U.S.-proposed amendments to the Regulations.

International Health Regulations

In 1969, WHA adopted the IHR to stop the spread of six diseases (cholera, plague, yellow fever, smallpox, relapsing fever, and typhus) through quarantine and other infectious disease control measures. The WHA amended the IHR several times, most comprehensively in 2005. The 2005 edition, known as IHR (2005), expanded methods for controlling infectious disease outbreaks beyond quarantine and broadened the type of public health events that would require international coordination. The Regulations provide an overarching legal framework that defines the rights and obligations of parties to the agreement (which includes the United States and all other WHO Member States) in handling public health events and emergencies that have the potential to cross borders. They also outline criteria for declaring a public health emergency of international concern (PHEIC) and requirements for Member States to

- report public health events;
- designate National IHR Focal Points for communication with WHO; and
- establish and maintain core capacities for surveillance and response.

IHR (2005) compliance is measured through a self-assessment questionnaire that WHO sends to Member States.

Public Health Emergency of International Concern

Following the emergence of an event that might be deemed a PHEIC, the WHO Director-General convenes an international team of independent experts to analyze available information on the event and consider the views of the State Party where the event is occurring. The team, called the Emergency Committee, makes recommendations to the Director-General on how to control the event and whether to declare a PHEIC. The composition of each Emergency Committee varies per outbreak. The *IHR Emergency Committee for Pneumonia Due to the Novel Coronavirus 2019-nCoV*, for example, was composed of 15 scientists from around the world, including an official from the U.S. Centers for Disease Control and Prevention (CDC). Though the Director-General usually follows the advice of Emergency Committees, the Director-General makes final determinations on the event.

A PHEIC declaration alerts countries to implement public health emergency responses, as outlined in IHR (2005). The Regulations provide the framework for the response and Member States develop their own implementation plans. In upholding IHR (2005), the Regulations specify that Member States have "the sovereign right to legislate and to implement legislation in pursuance of their health policies." As such, a PHEIC declaration does not automatically restrict travel or impose specific quarantine requirements, for example.

Following a PHEIC declaration, countries may take a number of actions, including heightening surveillance, reporting incidence of the relevant disease to the WHO, and allocating resources for domestic or international responses. On behalf of the United States, former U.S. Department of Health and Human Services (HHS) Secretary Alex Azar, for example, "declared a public health emergency for the entire United States to aid the nation's healthcare community in responding to 2019 novel coronavirus" following the WHO PHEIC declaration for Coronavirus Disease 2019 (COVID-19). A declaration can also enable WHO to access certain emergency funding during an outbreak, such as that provided through the United Nations (U.N.) Central Emergency Response Fund and the World Bank Pandemic Emergency Financing Facility.

Frequently Asked Questions

How were the IHR adopted and amended?

Articles 21 and 22 of the WHO Constitution authorize WHA to adopt regulations to prevent the spread of infectious diseases, among other things. WHA developed and amended the IHR pursuant to this authority.

Article 55 of IHR (2005) specifies that any WHO Member or the WHO Director-General may submit amendments to be considered by WHA. If WHA adopts any amendments, Article 59 of IHR (2005), as amended, specifies that WHO Member States have 10 months to notify their intent to reject all or some of the regulations or to accept them subject to reservations. A "reservation" functions as a

partial adoption of the Regulations. For states accepting IHR amendments, the amendments take effect 12 months after their initial adoption.

When did the United States become a party to the IHR, and are the Regulations a treaty?

In 1948, Congress passed a joint resolution authorizing the President to accept membership for the United States in WHO. Through an "executive agreement," the United States accepted to be legally bound by the IHR. An executive agreement is an international agreement based on constitutional authority conferred on the executive branch (e.g., executive authority over foreign affairs). Although an executive agreement is a type of treaty from an international law perspective, it does not qualify as a treaty for purposes of the U.S. Constitution's Treaty Clause, which requires Senate advice and consent.

How does WHO monitor IHR (2005) implementation?

IHR (2005) requires all Member States to have developed minimum public health capacities to detect acute public health events in a timely manner, assess and report to WHO through their National IHR Focal Point health events that may constitute a PHEIC, and respond to public health risks and emergencies. WHO monitors State Party progress in these areas through the issuance and analysis of self-assessment questionnaires.

How does WHO enforce IHR?

As noted, IHR (2005) does not provide WHO with enforcement authority; instead, IHR (2005) specifies that implementation must follow national decisionmaking processes. If a WHO Member State asserts another is not adhering to IHR obligations, that Member State may raise the issue with the other Member State, privately or during WHA sessions. A WHO Member State could also initiate dispute settlement procedures set out in Article 56 of IHR (2005). To date, no WHO Member State has ever invoked the Article 56 process against another Member State.

Why did the United States propose amendments to IHR (2005)?

In the first year of the COVID-19 pandemic, the Trump Administration criticized what it called WHO's delayed acknowledgement that COVID-19 was spreading via human-to-human transmission and WHO's inability to investigate fully the origins of the pandemic. Several Members of Congress also criticized the WHO response and called for a range of actions, including withdrawing from WHO, holding China accountable for failing to comply with IHR (2005) in a timely fashion, strengthening WHO, and boosting global disease surveillance capacity within and outside of WHO. The Trump Administration, after announcing in 2020 the intent to withdraw the United States from WHO, released a "WHO Roadmap" to "strengthen the WHO by increasing accountability and its ability to be impartial and objective, [and] improve transparency and its overall effectiveness, by providing it with a more comprehensive set of tools that are fit-for-purpose to address new and emerging threats." At the 150th Session of the WHO Executive Board in January 2022, the United States introduced amendments to IHR (2005) that were expected to be considered at the 75th WHA in May 2022. The amendments introduced by the Biden Administration built on the aforementioned Roadmap, congressional calls for strengthening IHR (2005) compliance, and feedback from the WHO Working Group on Strengthening WHO Preparedness and Response to Health Emergencies.

What did the amendments propose?

The amendments were primarily aimed at expanding the capacity of WHO to respond to public health events, including to

- permit WHO to develop an early warning system and to issue a public health alert for events that are not deemed a PHEIC;
- enable WHO to issue a PHEIC and other alerts should a Member State where the event is occurring decline to cooperate;
- require the Member State that rejected WHO consultation to provide a rationale for its decision;
- permit a WHO Regional Director to declare a public health emergency of regional concern;
- direct countries to provide WHO-convened experts investigating a possible PHEIC "short term access to relevant sites ... in compliance with national law"; and
- establish a Compliance Committee to oversee and report on global IHR (2005) compliance.

What is the status of the U.S.-proposed amendments?

The 75th WHA did not consider the U.S.-proposed amendments. Instead, it adopted amendments to shorten the period of time in which countries could implement and object to any IHR amendments. The WHA also decided to establish a Working Group on IHR amendments "to discuss targeted amendments to address specific and clearly identified issues, challenges, including equity, technological or other developments, or gaps that could not effectively be addressed otherwise but are critical to supporting effective implementation and compliance of the International Health Regulations …" The Working Group is to propose a package of targeted amendments for consideration no later than the 77th Health Assembly in 2024.

Does the Administration require congressional approval to propose or adopt IHR amendments?

The executive branch retains authority to introduce IHR amendments without congressional consent. If Congress wishes to exercise greater control over U.S. proposals for or positions on IHR amendments, it could consider requiring the Administration to notify and consult with Congress about such proposals. Congress could also consider placing conditions on the use of appropriated funds or enact a Sense of Congress expressing support for or concern about particular amendments.

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