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IN FOCUS

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International Health Regulations Amendments

Background

Since 1980, outbreaks of new and long-standing infectious diseases have been occurring with increasing frequency and intensity. In response, the World Health Assembly (WHA), the governing body of the World Health Organization (WHO), has been amending the International Health Regulations (IHR)—a set of rules on global responses to public health emergencies. The IHR was most recently amended in June 2024. In January 2022, the United States and several other States Parties proposed amendments to the regulations. The 75th WHA agreed to establish a working group that would consolidate the proposals into a revised IHR. The working group presented the proposals to the 77th WHA, which debated and adopted agreed-upon amendments on June 1, 2024, as summarized below. Several Members of Congress expressed concern that some of the proposed amendments might encroach upon U.S. sovereignty. The State Department issued a press release in June 2024 asserting that the amendments would "make the global health security architecture stronger overall while maintaining full respect for sovereignty of individual states." This In Focus addresses common questions regarding the IHR, including the role of Congress.

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 has since amended the IHR several times. 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 States Parties, including the United 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, described below) and requirements for States Parties to

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

2024 Amendments to IHR (2005)

In the first year of the COVID-19 pandemic, States Parties debated whether WHO had sufficient authority to investigate the origins of a potential PHEIC, particularly when a State Party slowed the process (as China had). The United States and several other countries proposed amendments to the IHR to address this and several other related concerns. The proposal prompted broader discussions regarding IHR implementation, including the absence of financing mechanisms and distribution networks for procuring and disseminating countermeasures in low- and middle-income countries (LMIC) and ensuring sovereign rights of States Parties. These and other issues were addressed in the amendments, as summarized below.

Sovereignty. While IHR amendments were being deliberated, several Members expressed concern that broadening the IHR might threaten U.S. sovereignty while numerous observers challenged that idea. Per Article 3, States Parties have "the sovereign right to legislate and to implement legislation in pursuance of their health policies." As such, a PHEIC declaration would not automatically restrict travel or impose specific quarantine requirements, for example. Article 4, as amended, instructed States Parties to designate or establish a National IHR Authority, "in accordance with its national law and context," to coordinate the implementation of the regulations.

Equity. Early in the COVID-19 pandemic, LMIC struggled to gain access to novel therapeutics and vaccines to combat the disease. This phenomenon prompted intense debate about the equitable distribution of pandemic countermeasures. Article 3, as amended, added the promotion of "equity and solidarity" among the IHR (2005) principles. Article 13, as amended, authorized WHO to "facilitate, and work to remove barriers to, timely and equitable access by States Parties to relevant health products." The article also directed the DG to support States Parties in expanding and diversifying production of relevant health products, including by promoting research and development and strengthening local production of relevant health products. Per Article 13, the DG is permitted to "share with a State Party, upon its request, the product dossier related to a specific relevant health product, as provided to WHO by the manufacturer for approval and where the manufacturer has consented."

Financing. For many years, IHR proponents argued that a funding mechanism was needed to support IHR implementation in LMICs. (For more information on this issue, see CRS In Focus IF10022, *The Global Health Security Agenda (2014-2019) and International Health Regulations (2005)*). The Global Health Security and International Pandemic Prevention, Preparedness and Response Act of 2022 authorized U.S. participation in a Financial Intermediary Fund—later called the Pandemic Fund—to support countries in IHR implementation, among other things. Article 44, as amended, established a Coordinating Financial Mechanism (CFM) to, inter alia, use or conduct needs and funding gap analyses, and promote sustainable financing for IHR implementation, including harmonizing existing funding streams and mobilizing new ones.

Transparency and Accountability. Article 44, as amended, specified that the DG shall report all its work on expanding access to and funding for relevant products to the WHA, including through the CFM. Article 49, as amended, instructed the DG to share with all States Parties supporting evidence for determining and terminating a PHEIC and the composition of the Emergency Committee tasked with recommending whether the DG should declare a PHEIC.

Implementation. Discussions about IHR shortcomings also centered around its lack of any implementation mechanism. Article 54, as amended, established the IHR States Parties Committee to facilitate IHR implementation. The language specifies that the committee shall be "non-adversarial," "non-punitive," and consultative in nature with the aim of promoting and supporting learning and cooperation among States Parties, among other things.

Public Health Emergency of International Concern

IHR amendments require the DG to determine whether a PHEIC constitutes a pandemic emergency (Article 12) and describe actions to be taken by States Parties in the event of a pandemic emergency. Following the emergence of an event that might be deemed a PHEIC, including a pandemic emergency, the DG convenes an international team of independent experts (Article 48) to analyze available information on the event and consider the views of the State Party where the event is occurring (Article 49). The team, called the Emergency Committee, makes recommendations to the DG on how to control the event and whether to declare a PHEIC. The composition of each Emergency Committee varies per outbreak, though it is expected to include at least one expert nominated by the State Party where the event is occurring. The IHR Emergency Committee for COVID-19, for example, was composed of 15 scientists from around the world, including China and the United States. Though the DG usually follows the advice of Emergency Committees, the Director-General makes final determinations on the event.

A PHEIC declaration alerts countries to implement national public health emergency plans. The regulations provide the framework for the plans, which States Parties develop according to their national laws and policies. Should a PHEIC be declared, countries may take a number of steps, including heightening surveillance, reporting incidence of the relevant disease to WHO, and allocating resources for responses. Following the WHO PHEIC declaration for COVID-19, for example, then U.S. Department of Health and Human Services (HHS) Secretary Alex Azar "declared a public health emergency for the entire United States to aid the nation's healthcare community in responding to 2019 novel coronavirus." A declaration can also enable WHO to access funding from sources like the United Nations (U.N.) Central Emergency Response Fund and the Pandemic Fund administered by the World Bank.

Frequently Asked Questions

How were the IHR adopted and amended?

Article 21 of the WHO Constitution authorized the WHA to adopt regulations for preventing the spread of infectious diseases, including sanitary and quarantine requirements, disease and other nomenclatures, diagnostic procedure standards, and safety, advertising, and labeling standards for pharmaceutical and other products. The WHA developed the IHR pursuant to this authority. Article 55 of IHR (2005) authorized WHA to consider and adopt IHR amendments proposed by WHO States Parties.

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

In 1948, President Harry Truman signed into law a joint resolution authorizing the President to accept U.S. membership in WHO, and to become party to the WHO Constitution. Under the WHO Constitution, States Parties can adopt new conventions, agreements, and regulations through a vote at WHA. New conventions and agreements require a Member State to become party via signature and ratification "in accordance with its constitutional processes" as a standalone treaty. In contrast, regulations adopted by WHA, and amendments thereto, enter into force for all States Parties automatically following a notice period after WHA adoption, unless an individual Member State notifies the DG that it wishes to reject or modify its obligations under such regulations. The United States agreed to be bound by the obligations of IHR (2005) with the reservation that aspects of IHR implementation might be left to U.S. state governments rather than the federal government.

How does WHO monitor IHR (2005) implementation?

WHO monitors State Party progress through the issuance and analysis of self-assessment questionnaires known as Joint External Evaluations. Article 50 also established a Review Committee, which among other things, was tasked with periodically reviewing IHR functions.

How does WHO enforce IHR?

IHR (2005) does not provide WHO with enforcement authority. Instead, the regulations specify that implementation must follow national decisionmaking processes. If a WHO Member State asserts another is not adhering to IHR obligations, Article 43, as amended, instructs the concerned Member State to raise the issue with the other Member State directly or through the DG. Unless otherwise agreed to by the States Parties involved, information shared during the consultation shall be kept confidential. A WHO Member State could also initiate dispute settlement procedures set out in Article 56. To date, no WHO Member State has ever invoked the Article 56 process against another Member State.

Does the executive branch 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 executive branch to notify and consult with Congress about such proposals. Congress could also consider placing conditions on the use of appropriated funds or adopt a sense of Congress provision expressing support for or concern about particular amendments.

Tiaji Salaam-Blyther, Specialist in Global Health

IF12139

Matthew C. Weed, Specialist in Foreign Policy Legislation

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