

The United States Endorses Amendments to the International Health Regulations
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The United States has endorsed¹ the World Health Assembly's (WHA) adoption of amendments to the International Health Regulations (IHR).² Based on lessons learned from the COVID-19 epidemic, the amendments are the most significant changes to global health rules in two decades.³ Their approval comes more than two years after the United States, joined by forty other World Health Organization (WHO) member states, first proposed revisions to the IHR.⁴ Congratulating the WHA delegates, WHO Director-General Tedros Adhanom Ghebreyesus said: "You have strengthened the cornerstone of international health law. And in doing so, you have made the world safer."⁵ Commending too the "giant step [made] toward protecting the health of humanity," Secretary of Health and Human Services Xavier Becerra emphasized that the U.S. government's "first responsibility has always been to protect the lives and livelihood of the American people and the security of our country."⁶ "With this agreement," he continued, "we take steps to hold countries accountable and strengthen measures to stop outbreaks before they threaten Americans and our security."⁷

¹ See U.S. Mission to International Organizations in Geneva, U.S. National Statement for Agenda Items 13.3 and 13.4 (IHR and INB) (June 2, 2024), at <https://geneva.usmission.gov/2024/06/02/u-s-national-statement-for-agenda-items-13-3-and-13-4-ih-and-inb> [<https://perma.cc/2BUJ-6EZ8>] [hereinafter U.S. National Statement]; U.S. Dep't of State Press Release, Amendments to International Health Regulations Strengthen Global Pandemic Preparedness (June 3, 2024), at <https://www.state.gov/amendments-to-international-health-regulations-strengthen-global-pandemic-preparedness> [<https://perma.cc/XGS7-LBMA>].

² WHO Press Release, World Health Assembly Agreement Reached on Wide-Ranging, Decisive Package of Amendments to Improve the International Health Regulations (June 1, 2024), at <https://www.who.int/news/item/01-06-2024-world-health-assembly-agreement-reached-on-wide-ranging-decisive-package-of-amendments-to-improve-the-international-health-regulations-and-sets-date-for-finalizing-negotiations-on-a-proposed-pandemic-agreement> [<https://perma.cc/LDJ9-5JVP>] [hereinafter WHO Press Release]; Strengthening Preparedness for and Response to Public Health Emergencies Through Targeted Amendments to the International Health Regulations (2005), Annex, WHO Doc. WHA77.17 (June 1, 2024), at https://apps.who.int/gb/ebwha/pdf_files/WHA77/A77_R17-en.pdf [<https://perma.cc/FC8W-T3JA>] [hereinafter Amended IHR].

³ Important amendments were made to the IHR in 2005 following the outbreak of Severe Acute Respiratory Syndrome (SARS) two years before.

⁴ See Proposal [from the United States] for Amendments to the International Health Regulations (2005), WHO Doc. A75/18 (Apr. 12, 2022), at https://apps.who.int/gb/ebwha/pdf_files/WHA75/A75_18-en.pdf [<https://perma.cc/8MCS-5LBQ>]; U.S. Mission to International Organizations in Geneva, Strengthening WHO Preparedness for and Response to Health Emergencies (Jan. 26, 2022), at <https://geneva.usmission.gov/2022/01/26/strengthening-who-preparedness-for-and-response-to-health-emergencies> [<https://perma.cc/H4QD-BY3Q>].

⁵ WHO Press Release, WHO Director-General's Closing Remarks on the INB and IHR Discussions at the Seventy-Seventh World Health Assembly (June 1, 2024), at <https://www.who.int/director-general/speeches/detail/who-director-general-s-closing-remarks-on-the-inb-and-ih-discussions-at-the-seventy-seventh-world-health-assembly-1-june-2024> [<https://perma.cc/3PBR-QF5P>].

⁶ U.S. Dep't of Health and Human Services Press Release, Statement from Secretary Xavier Becerra on Amended International Health Regulations (June 1, 2024), at <https://www.hhs.gov/about/news/2024/06/01/statement-secretary-xavier-becerra-amended-international-health-regulations.html> [<https://perma.cc/RA7E-UTKM>] [hereinafter Becerra Statement]; see also U.S. Dep't of State Press Release, Amendments to International Health Regulations Strengthen Global Pandemic Preparedness (June 3, 2024), at <https://www.state.gov/amendments-to-international-health-regulations-strengthen-global-pandemic-preparedness> [<https://perma.cc/E3HX-HBSU>].

⁷ Becerra Statement, *supra* note 6.

The amendments align with the Biden administration's new Global Health Security Strategy, which prioritizes global health security in U.S. global health policy and focuses on bilateral partnerships to curtail disease at its source.⁸ Negotiations at the WHO to conclude a Pandemic Agreement, which will focus on pandemic prevention, preparedness, and response, are ongoing.⁹

As revised in 2005, the IHR establishes binding rules for controlling the international spread of disease.¹⁰ It obligates states to “develop, strengthen and maintain” capacity to “prevent, detect, assess, notify and report” disease or the potential for disease;¹¹ to notify the WHO of “all events which may constitute a public health emergency of international concern [PHEIC] within its territory” within twenty-four hours;¹² and to “develop, strengthen and maintain” capacity to “respond promptly and effectively to public health risks and [PHEICs].”¹³ It requires states to collaborate and assist one another, including in the detection of disease, the development of capacities, and the garnering of financial resources for the implementation of IHR obligations.¹⁴ It includes rules that regulate public health measures, such as those pertaining to conveyances and travelers.¹⁵ It provides rules for the determination of PHEICs by the WHO director-general, and upon the issuance of such a determination, it gives the WHO director-general authority to issue temporary recommendations.¹⁶ And it permits the WHO to collect and assess information from member states and other sources (including nongovernmental organizations), seek verification from states regarding disease events, coordinate and assist member states in investigations and responses to PHEICs, and help states build their IHR capacities.¹⁷

The COVID-19 epidemic revealed shortcomings in the IHR's ability to provide an effective and coordinated pandemic response. States had not fully implemented the IHR's obligations, lacked capacity to do so, and failed to report the COVID-19 threat with sufficient speed.¹⁸ And the WHO had not determined quickly enough the health emergency presented by the COVID-19 outbreak or taken the steps needed to coordinate a response.¹⁹

To reform the IHR, the WHA in 2022 established a Working Group on Amendments to the International Health Regulations (2005) (WGIHR).²⁰ The WGIHR considered more than three hundred proposals, and after eight negotiating sessions, it submitted the IHR

⁸ See White House, U.S. Government Global Health Security Strategy 2024 (Apr. 2024), at <https://www.whitehouse.gov/wp-content/uploads/2024/04/Global-Health-Security-Strategy-2024-1.pdf> [<https://perma.cc/8YKQ-KUV3>]; U.S. Dep't of State, United States Global Health Security Partnerships, at <https://www.state.gov/united-states-global-health-security-partnerships> [<https://perma.cc/5MF6-UAEY>].

⁹ See Apoorva Mandavilli, *Countries Fail to Agree on Treaty to Prepare the World for the Next Pandemic*, N.Y. TIMES (May 24, 2024), at <https://www.nytimes.com/2024/05/24/health/pandemic-treaty-vaccines.html>; Revised Draft of the Negotiating Text of the WHO Pandemic Agreement, WHO Doc. A/INB/9/3 (2024).

¹⁰ On the 2005 revision, see David P. Fidler, *From International Sanitary Conventions to Global Health Security: The New International Health Regulations*, 4 CHINESE J. INT'L L. 325 (2005).

¹¹ Amended IHR, *supra* note 2, Art. 5(1).

¹² See *id.* Art. 6(1), Annex 2 (providing a “decision instrument for the assessment and notification of events”).

¹³ See *id.* Art. 13(1).

¹⁴ See *id.* Art. 44(1).

¹⁵ See *id.*, pt. V.

¹⁶ See *id.* Art. 12.

¹⁷ See, e.g., *id.* Arts. 5(3), 9(1), 10, 11.

¹⁸ See Editorial, *The Future of the International Health Regulations*, 10 LANCET GLOB. HEALTH E927 (July 2022).

¹⁹ See *id.*

²⁰ See WHO Doc. WHA75(9), para. 2(a) (2022). The prior year, the Executive Board of the WHO urged “Member States to take all appropriate measures to consider potential amendments to the International Health Regulations (2005).” WHO Doc. EB150(3) (2021).

amendments that were agreed to by the WHA on June 1.²¹ The U.S. delegation was active in the negotiations, proposing specific amendments that were designed to “clarify early-warning triggers for international response to widespread health emergencies, enhance biosafety and biosecurity, ensure rapid information sharing, improve WHO’s ability to use publicly available information to assess global health threats, and create a mechanism to improve implementation and compliance with the IHR.”²²

Delays in concluding the Pandemic Agreement and interest, mainly from developing countries, in creating a new fund to support IHR implementation nearly prevented the amendments’ adoption by the WHA.²³ Though supporting the negotiation of a Pandemic Agreement,²⁴ the United States sought to delink the two negotiating processes.²⁵ It also demurred on the creation of a new fund.²⁶ Separating out a decision on the IHR amendments from the Pandemic Agreement negotiations, Ambassador Pamela Hamamoto, the U.S. Chief Negotiator for the Pandemic Accord Negotiations, said that the agreement would require “one to two [more] years” of negotiations, as “fundamental differences remain on core issues central to the agreement.”²⁷ The WHA moved forward without establishing a new fund and approved the IHR amendments. At the same time, the WHA decided to extend the mandate of the Pandemic Agreement negotiations, with a direction “to finish . . . work [on the agreement] as soon as possible, and submit its outcome for consideration by the [next meeting of the WHA in] 2025, or earlier . . . if possible in 2024.”²⁸

The IHR amendments seek to enhance implementation of the regulations and promote equity. Negotiators designed three new bodies as ways to facilitate and improve performance. At the state level, each party is required to establish a National IHR Authority to “coordinate the implementation of the[] Regulations within the jurisdiction of the State Party.”²⁹ At the

²¹ See World Health Organization Press Release, Ground-Breaking Progress Made in Member State Negotiations on Amendments to the International Health Regulations (IHR) (May 18, 2024), at [https://www.who.int/news/item/18-05-2024-ground-breaking-progress-made-in-member-state-negotiations-on-amendments-to-the-international-health-regulations-\(ihr\)](https://www.who.int/news/item/18-05-2024-ground-breaking-progress-made-in-member-state-negotiations-on-amendments-to-the-international-health-regulations-(ihr)) [<https://perma.cc/JJ2Q-G3GM>]; WHO, Proposed Amendments to the International Health Regulations (2005) Submitted in Accordance with Decision WHA75(9) (2022) (updated Mar. 2024), at https://apps.who.int/gb/wgihrr/pdf_files/wgihrr1/WGIHR_Submissions_Original_Languages.pdf [<https://perma.cc/94UL-RJTX>].

²² Testimony of Loyce Pace, MPH Assistant Secretary for Global Affairs U.S. Department of Health and Human Services Before the Select Subcommittee on the Coronavirus Pandemic Committee on Oversight and Accountability United States House of Representatives (Dec. 13, 2023), at <https://oversight.house.gov/wp-content/uploads/2023/12/SSCP-HHS-Testimony-for-231213-Hearing.pdf> [<https://perma.cc/2YZG-DB2K>].

²³ Jenny Lei Ravelo, *The Holdouts on Negotiating Amendments to the IHR at WHA77*, DEVEX (May 30, 2024), at <https://www.devex.com/news/the-holdouts-on-negotiating-amendments-to-the-ihr-at-wha77-107709>.

²⁴ See U.S. Dep’t of State Press Release, Joint Statement by Secretary of State Antony J. Blinken and Secretary of Health and Human Services Xavier Becerra (Mar. 29, 2024), at <https://www.state.gov/joint-statement-by-secretary-of-state-antony-j-blinken-and-secretary-of-health-and-human-services-xavier-becerra> [<https://perma.cc/8CZF-3KMD>].

²⁵ See Ravelo, *supra* note 23.

²⁶ See *id.*

²⁷ Kerry Cullinan, *Push for International Health Regulation Changes to Be Passed This Week – But Disagreement About Future of Pandemic Agreement Talks*, HEALTH POL’Y WATCH (May 28, 2024), at <https://healthpolicy-watch.news/strong-push-for-international-health-regulations-changes-to-be-passed-this-week> [<https://perma.cc/P9PG-2JCT>].

²⁸ WHO Doc. WHA77(20) (2024), para. 1.

²⁹ Amended IHR, *supra* note 2, Art. 4(1*bis*). The National IHR Authority is different from the National IHR Focal Point, which is a state-level communications liaison with the WHO.

WHO level, the new rules establish a States Parties Committee “to facilitate the effective implementation of [the] Regulations . . . [through] promoting and supporting learning, exchange of best practices, and cooperation among States Parties.”³⁰ Also at the WHO level, the rules now create a Coordinating Financial Mechanism to “promote the provision of timely, predictable, and sustainable financing for the implementation of the[] Regulations,” “seek to maximize the availability of financing,” and “work to mobilize new and additional financial resources.”³¹ How successful these implementation techniques will be is unclear. They are all facilitative; none requires a specific outcome, such as the contribution of financial resources, or establishes a compulsory procedure, such as a compliance mechanism.³²

The IHR amendments also provide the WHO with some new authorities. One is the ability of the WHO director-general to determine the existence of a “pandemic emergency” to denote a higher level of emergency than a PHEIC.³³ Such a designation, however, is merely a signaling device. Identification of a “pandemic emergency” creates no additional requirements upon states in the IHR, and it also has no specific implications for the WHO. Any additional consequences, rights, and obligations that might stem from the existence of a “pandemic emergency” will need to be agreed upon in the context of the negotiations of a Pandemic Agreement.

The IHR amendments also task the WHO with “facilitat[ing], and work[ing] to remove barriers to, timely and equitable access by States Parties to relevant health products after the determination of and during” a PHEIC.³⁴ “Relevant health products” are health products needed to respond to a PHEIC, such as “medicines, vaccines, diagnostics, medical devices” (among others).³⁵ To this end, the WHO director-general is given the authority to “conduct, and periodically review and update, assessments of the public health needs,” “publish such assessments,” “facilitate timely and equitable access to relevant health products,” support states in “scaling up and geographically diversifying the production of relevant health products,” and support states “to promote research and development and strengthen local

³⁰ *Id.* Art. 54*bis*(1)(a).

³¹ *Id.* Art. 44*bis*(1). Relatedly, states, “subject to applicable law and available resources,” are to “maintain or increase domestic funding, as necessary, and collaborate, . . . as appropriate, to strengthen sustainable financing to support the implementation” of the regulations. *Id.* Art. 44(2*bis*).

³² Upon the adoption of the amendments, the United States made clear with regard to the new financing provisions that “we are limited to what we can do under our national laws and retain discretion on how we carry out the financing provisions In the United States, our Congress maintains discretion on funding.” U.S. National Statement, *supra* note 1.

³³ *Id.* Art. 12(1), 4*bis*. A “pandemic emergency” is defined as a PHEIC:

that is caused by a communicable disease and:

- (i) has, or is at high risk of having, wide geographical spread to and within multiple States; and
- (ii) is exceeding, or is at high risk of exceeding, the capacity of health systems to respond in those States; and
- (iii) is causing, or is at high risk of causing, substantial social and/or economic disruption, including disruption to international traffic and trade; and
- (iv) requires rapid, equitable and enhanced coordinated international action, with whole-of-government and whole-of-society approaches.

Amended IHR, *supra* note 2, Art. 1(1).

³⁴ *Id.* Art. 13(8); *see also id.* Art. 3(1) (adding that the implementation of the regulations “shall promote equity and solidarity”).

³⁵ *Id.* Art. 1(1).

production of quality, safe and effective relevant health products.”³⁶ The United States said of these provisions that they “improve[] access to critical health products so we can more equitably prevent, prepare and respond to pandemic emergencies regardless of where they arise.”³⁷

While the IHR amendments are not as strong on implementation as the proposals made by the United States, they elaborate positions that the United States endorses while at the same time not creating substantive obligations that it opposes, such those pertaining to financing and equity. The United States has not yet made public any reservation it might submit regarding the new amendments. In 2006, the United States announced its acceptance of the 2005 IHR amendments³⁸ and submitted one reservation—relating to federalism—and three understandings.³⁹ While an announcement of acceptance is not required for the IHR amendments to take effect, any reservations must be submitted within eighteen months.⁴⁰ The Senate Republican caucus objected to the IHR amendments and anticipatorily argued that a Pandemic Agreement must be submitted to the Senate for its advice and consent to ratification in accordance with Article II of the U.S. constitution.⁴¹ The WHO constitution was approved by a joint resolution of Congress.^{42*}

INTERNATIONAL ECONOMIC LAW

President Biden Adds, Increases, and Maintains Tariffs on Chinese Goods Levied by President Trump

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Following a review of tariffs on Chinese goods levied by President Donald J. Trump pursuant to Section 301 of the Trade Act of 1974,¹ President Joseph R. Biden, Jr. has decided to add some, increase others, and maintain the remainder.² The new and augmented tariffs—on

³⁶ *Id.* Art. 13(8)(a)–(e).

³⁷ U.S. National Statement, *supra* note 1.

³⁸ See DIGEST OF UNITED STATES PRACTICE IN INTERNATIONAL LAW 2006, at 891–92 (Sally J. Cummins ed., 2007).

³⁹ See U.S. Dep’t of State Archive, International Health Regulations, U.S. Note to Depository (Dec. 13, 2006), at <https://2001-2009.state.gov/s/l/2007/112669.htm> [<https://perma.cc/6NN3-AF3U>].

⁴⁰ Amended IHR, *supra* note 2, Art. 59(1).

⁴¹ See Letter of Republican Senators to President Joseph R. Biden, Jr. (May 1, 2024), at <https://mustreadalaska.com/wp-content/uploads/2024/05/ZTv63l-WHO-letter-to-Biden-signed-5-1-24.pdf> [<https://perma.cc/7SBW-3HDQ>]. The “No WHO Pandemic Preparedness Treaty Without Senate Approval Act” has also been introduced in both houses of Congress. See S. 444, 118th Cong., 2d Sess. (2024); H.R. 1425, 118th Cong., 2d Sess. (2024).

⁴² See Pub. L. 643, 80th Cong., 62 Stat. 441 (June 14, 1948).

* This is the corrected version of a paper first published on November 15, 2024, containing minor typesetter errors.

¹ See Office of the U.S. Trade Representative, Four-Year Review of Actions Taken in the Section 301 Investigation: China’s Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation (May 14, 2024), at <https://ustr.gov/sites/default/files/USTR%20Report%20Four%20Year%20Review%20of%20China%20Tech%20Transfer%20Section%20301.pdf> [<https://perma.cc/WN5L-GDFX>] [hereinafter Section 301 Review].

² See White House Press Release, Memorandum on Actions by the United States Related to the Statutory 4-Year Review of the Section 301 Investigation of China’s Acts, Policies, and Practices Related to Technology