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Articles & Analyses

New International Health Regulations Will Affect Global Companies And Governments

By Linda Horton and Eleftheria Nearchou, Hogan & Hartson LLP

Global companies have started hearing about the International Health Regulations (IHRs). The American Bar Association had a webcast last month on this subject.

What are the IHRs, anyway?

The IHRs are an international legal instrument drafted by the World Health Organization (WHO) and its Member States dealing with public health emergencies of international concern. The IHRs aim to prevent and control international spread of disease, to protect the public health in ways that are proportionate with, and restricted to, the public health risks, and to avoid unnecessary interference with international travel and trade.

What do IHRs have to do with me and my business?

Each nation's response to a crisis can have a direct effect on companies. With the IHRs, it is hoped that harmonization of international rules will reduce national differences in crisis-handling procedures and promote uniformity.

The International Health Regulations (IHRs) are legally binding on all WHO Member States that have not rejected them^[1] and on all countries that aren't members of WHO but agree to be bound by them. ^[2] Recent international health crises such as HIV/AIDs, SARS in 2003, and now possibly avian influenza demonstrate the impact of public crises on governments, companies, and even entire business sectors on a global scale. It is hoped that the newly updated IHRs^[3] will strengthen international cooperation in the identification and response to public health emergencies and thus minimize harm to health, the international economy, and prosperity.

The first IHRs,^[4] adopted by WHO in 1969, were narrow and cumbersome. Therefore, the WHO Member States revised the IHRs and, in May 2005, the WHO's World Health Assembly adopted the revised IHRs. These will replace the 1969 IHRs and enter into force June 15, 2007.

The IHRs were originally intended to monitor and control six serious infectious diseases: cholera, plague, yellow fever, smallpox, relapsing fever, and typhus. Under the current IHRs, only cholera, plague, and yellow fever are notifiable, meaning that States are required to notify WHO if and when these diseases, and only these diseases, occur on their territory. One of the principal reforms was to get away from this disease-specific approach in favor of a flexible risk-based strategy that has improved surveillance, enhanced transparency, and increased rapid response capability.

To these ends, the new IHRs—also called "IHR (2005)"—would establish a legal framework for rapidly gathering information, determining when an event is a public health emergency of international concern, and responding to countries' requests for international assistance. The main changes the IHRs (2005) will bring about are:

- **Expanded reporting.** WHO Member States are to notify WHO of all events

In This Issue

March 31, 2006

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that may constitute a public health emergency of international concern and to respond to requests for verification of information regarding such events.

- **Creation of National IHR Focal Points.** These contact persons will serve as the operational link between WHO and countries to aid flow of information.
- **Duty of WHO members to maintain public health capabilities.** Countries are supposed to develop, strengthen, and maintain basic public health capacities to respond to risks and potential public health emergencies of international concern.
- **Possibility for WHO to help implement certain recommended measures.** This could involve a member country affected by a public health emergency of international concern, other countries, or operators of international transportation.
- **Establishment of an Emergency Committee.** The Committee would advise the WHO Director-General on whether a particular event is a public health emergency of international concern and offer appropriate temporary recommendations.
- **IHR Review Committee.** This new Committee would advise the Director-General on technical matters relating to standing recommendations, the functioning of the Regulations, and amendments thereto.
- **Expanded Definition of “public health emergency of international concern.”** As revised, this term would refer to an extraordinary public health event which is determined to: (1) constitute a public health risk to other countries through the international spread of disease; and (2) potentially require a coordinated international response.^[5]

Key obligations of WHO under the new IHRs are to offer collaboration to countries to deal with an outbreak, designate Contact Points at its headquarters in Geneva or at regional office level, collect information through its surveillance activities, offer technical cooperation to countries in their response to public health risks, offer guidance to countries, recommend measures for use by countries, prepare supporting guides, and propose amendments to the IHRs as necessary to maintain scientific and regulatory validity. The IHRs also establish a single code of practice for public health measures at international airports, ports, and some ground crossings, as the IHRs provide for routine inspection and control activities at international airports and ports.

The new IHRs also contain a dispute settlement mechanism to resolve conflicts arising among countries concerning the application and the interpretation of the Regulations. Amicable settlement of differences is preferred but disputes may also be referred to the Director-General of WHO or, if all parties agree, to arbitration.

Global companies with people all over the world have a keen interest in effective implementation of the IHRs. There are several factors influencing the impact of an international public health crisis on a global company, as was discussed by participants in the American Bar Association's webcast on the International Health Regulation, November 17, 2005:

- **Nature of the business:** sectors most likely to face difficulties during a health crisis are the transportation, tourism, consumer goods, food, beverage, and pharma sectors.
- **Government policies:** how each country deals with a crisis and the measures it decides to take can have a direct effect on companies; it is hoped that international rules will reduce differences among crisis-handling procedures and promote uniformity.
- **Company policies:** The reputation of a company is defined by the way it reacts to a crisis at an early stage, what actions it takes to deal with the longer-lasting effects, and what kind of outreach program it would apply.

Consequently, companies need to have policies in place to deal with an international health crisis, based on vigorous planning for unpredictable situations. As with all good corporate emergency preparedness plans, there is a need for a solid company structure that provides for clear delegations of duties, for learning from experience with crises, and handling international issues.

The new 2005 IHRs can help global companies by promoting international cooperation in dealing with such crisis and providing a common, international framework of action that can allow the companies to get more easily prepared and

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[Florida Appeals C](#)
[Hospital No Long](#)
[Public Records L](#)
[Private Entity](#)

[Florida Appeals C](#)
[Genuine Issue Re](#)
[Apparent Agency](#)
[Contractor Anesth](#)

[Senators Questio](#)
[On Enforcement \(](#)
[Hospital Moratori](#)

[Federal Circuit Ur](#)
[Of Nurse For Pati](#)

[Study Says Baby](#)
[Not Be Primary D](#)
[Hospital Demand](#)

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[OIG, CMS Officia](#)
[Focus On Curbing](#)
[Fraud Before Sen](#)

Medicare

[Report Finds Mos](#)
[Plans Restrict Ac](#)
[Formulary Drugs](#)

[U.S. Court In Mar](#)
[Finding Of Overp](#)
[Wheelchairs](#)

[CMS Agrees To E](#)
[Period For Certain](#)
[Dual Eligibles](#)

[GAO Concludes \(](#)
[Methodology Ade](#)
[Estimating Medic](#)
[Errors](#)

[CMS Issues Final](#)
[Guidance](#)

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[OIG Releases 20](#)

[JCAHO Launches](#)

diminish the negative effects on their business.

However, many thorny issues linger on:

- Will the IHRs be in place to help cope with avian flu/human pandemic flu risks?
- Will the 2005 IHRs have universal applicability? Will they be agreed to, and implemented by, countries that are not WHO members?
- Can Member States, and under which circumstances, apply additional Health measures if no recommendations were made by the WHO to apply additional measures? In that case, will the Member States be able to provide a rational justification through the IHR procedures for the additional measures they have taken?
- Will the 2005 IHRs be applied to armed forces?
- Will the WHO under the 2005 IHRs be able to tackle deliberate release of a chemical, biological, or radio nuclear agent?
- Will countries with federal systems of government manage to make all regional jurisdictions comply?

The 2005 IHRs constitute an important step in strengthening the world's collective defenses against infectious disease risks.

[1] The U.S. government must act affirmatively to adopt standards issued by WHO. See 42 U.S.C. 290d (June 14, 1948).

[2] The IHRs (2005) will become legally binding on all WHO Member States except those that have rejected them or submitted reservations within eighteen months of notification of adoption of the IHRs (2005) by the World Health Assembly. However, if a reservation is compatible with the object and purpose of the IHRs and it has not been objected to by at least one-third of the other States within six months of its notification, the Regulations enter into force for the reserving State, subject to the reservation. Non-Member States of WHO may notify the Director-General of WHO that they agree to be bound by the Regulations.

[3] The revised IHRs are available at http://www.who.int/gb/ebwha/pdf_files/WHA58/WHA58_3-en.pdf

[4] Old version is available at http://policy.who.int/cgi-bin/om_isapi.dll?infobase=IHRsseg&softpage=Browse_Frame_Pg42

[5] Also, in order to assess events occurring within their territory and to notify WHO of those that may constitute a public health emergency of international concern States should take into account the following criteria: (1) seriousness of the public health impact of the event; (2) unusual or unexpected nature of the event; (3) potential for the event to spread internationally; and/or (4) the risk that restrictions to travel or trade may result because of the event.

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