INITIAL U.S. GOVERNMENT COMMENTS ON THE FIRST DRAFT OF THE PROPOSED REVISION OF THE INTERNATIONAL HEALTH REGULATIONS (IHRs)

NOTE TO WHO AND MEMBER STATES:

We are very pleased that the World Health Organization (WHO) is moving forward with the process to revise the International Health Regulations (IHR). We find the first WHO draft proposal to be a very good initial effort, but we do have a number of concerns regarding this draft. Since the WHO will not be revising this draft until after the regional consultations, and since these consultations begin in March, we are providing a set of general and specific comments, as well as suggested issues for clarification, which we hope will be helpful to both the WHO Secretariat and Member States during these early Consultations. We plan to provide detailed comments and specific recommendations regarding these draft revisions. We will share these comments with the WHO Secretariat and Member States as soon as practicable.
I. GENERAL COMMENTS

Because the IHRs will be binding regulations, the term “shall” should only be used where mandatory obligations are necessary and reasonable for realizing the fundamental purpose of the IHRs.

The draft IHRs contain several references to “applicable international agreements.” The WHO should provide Member States with information concerning those international agreements that it considers applicable to facilitate Member State consideration of the nature of the obligations set forth in the draft IHRs.

II. SPECIFIC COMMENTS

Definitions

There are a number of terms in the draft IHRs that need to be defined if the nature of the obligations incumbent upon Member States is to be clearly understood. Also, there are a number of definitions already in the draft IHRs that we believe need to be clarified.

ADD definition for “bill of health.” (See Article 30 and other references throughout.)

ADD definition for “international traffic.” (See the Foreword, definition for “container loading area,” Articles 2, 4, 7, 8 and other references throughout.)

ADD definition for “invasive medical examination.” (See Article 36.2 and other references throughout.)

ADD definition for “measures.” (See Article 16.6 and other references throughout.)

ADD definition for “public health emergency of international concern.” This term needs to be defined, not only for naturally occurring incidents but also for intentional incidents.
ADD definition for “quarantine.” A definition for “quarantine” is needed to differentiate between “isolation” and “quarantine,” both of which are used in the IHRs.

ADD definition for “suspected intentional release.” (See Article 41 and other references throughout.)

REVISE definition of “health authority.” The definition of “health authority” should be revised to remove the reference to “local authority,” since the real issue is the “authority or entity immediately responsible” for implementing the IHRs, which may or may not be a “local authority.” Depending on either the system or circumstance, the authority could be federal, state, provincial, or other.

REVISE definition of “public health risk.” The definition of “public health risk” should be revised to include the possibility that an event may be intentional as well as a natural occurrence.

REVISE definition of “suspect.” The definition of “suspect” references exposure to a “public health risk” which in turn is defined as an “event.” Is exposure to an event appropriate terminology to define a “suspect?”

REVISE definition of “traveller.” The definition of “traveller” should be revised to distinguish a “traveller” from one seeking permanent or temporary residency.

REVISE definition of vector. The definition of “vector” should be revised to include potential bioweapons delivery mechanisms.

**A Disease-Specific List is Needed in Addition to an Algorithm**

We support the use of an algorithm to determine certain “public health emergencies of international concern” (PHEIC). We, however, strongly believe the IHRs also should require reporting of a defined list of certain known, serious, communicable diseases that have the potential for creating a PHEIC. Although the concept is a good one, relying solely on the nonspecific construct PHEIC is insufficient.
Under Article 5 of the draft IHRs, parties to the IHRs are required to notify the WHO of all events that potentially constitute a PHEIC that are occurring in their territory. Under Article 11, the WHO is required to make appropriate temporary recommendations, which could include health measures to be implemented by the WHO Member State that is experiencing the PHEIC or by other Member States. The procedures used by the WHO in making temporary recommendations are set forth in Annex 3 of the draft IHRs. The draft IHRs use an algorithm to determine what constitutes a PHEIC, which might not in all instances result in the notification of all diseases we believe should be subject to notification.

The IHR should specify triggering diseases—information that we cannot afford to miss if Member States rely solely on an algorithm that, by its nature, is subject to interpretation. The list should be expandable to include future emerging diseases and should accompany and supplement the algorithm designed to capture PHEIC.

The diseases that we propose (see below) should be on the list because they fall within one or more of the following categories:

- Communicable diseases that can be spread through the droplet or aerosol route and have life-threatening or severe consequences;
- Selected communicable diseases among those eradicated or targeted for eradication by the WHO;
- Communicable diseases without an effective control strategy or for which isolation is deemed an essential part of the control strategy, which are transmitted easily from person to person and which, if spread in the population, would have severe public health consequences, including potentially high case fatality rates;
- Selected vector-borne diseases that can be translocated to non-endemic countries with compatible vectors;
- Selected zoonotic diseases, identified in animals that pose a potential public health risk to human populations.

We believe that these diseases should be reported in all circumstances and that this list should complement the PHEIC algorithm:
We propose that this list be added to Annex 2 and be reviewed on a periodic basis for relevance and currency by the “IHR Advisory Panel” to be convened by the WHO Director General as outlined in Annex 3. The World Health Assembly should adopt any changes on the recommendation of the Executive Board.

Bioterrorism

Given both the obvious law enforcement and national security concerns that could arise in a suspected intentional release situation, the distinction between mandatory reporting requirements and permissive reporting requirements needs to be addressed, preferably in an Annex (See Article 41). In addition, the IHRS could establish a consultative or facilitative role for the WHO through which it could assist Member States in their recognition or detection of "suspected intentional releases," and their investigation, confirmation, and public health response to such releases. We recognize that this is a complex issue. A revised Article 41 might not be sufficient to accommodate this, and, as above, consideration should be given to developing an Annex for issues related to intentional release, such as an operational definition of what constitutes “a suspected intentional release” that would qualify for reporting to the WHO Secretariat or other action under Article 41, and criteria or parameters for determining reportability as
an issue of international public health interest vs. potential international public health impact. The Annex could also address the process and content of reporting where it is appropriate, while recognizing law enforcement and national security considerations.

**Sovereignty**

The current iteration of the draft IHRs raises two state sovereignty concerns. The first relates to the extent to which several provisions in the draft IHRs would prevent a State from implementing measures to protect against international public health risks if such measures go beyond those recommended by the WHO or those otherwise authorized by “applicable international agreements.” See, e.g., Articles 21(2) and 27(2). We believe these are inappropriate restrictions on a Member State’s prerogative to apply additional measures to protect its nationals or others residing within its borders where such measures are consistent with international law and sound public health practice such as vaccination requirements. We are conscious of the WHO’s desire to strike a balance between the need to provide security against the international spread of disease, while avoiding unnecessary interference with international traffic. However, some of the measures proposed, including the examples cited above, do not strike the right balance and constitute an impermissible infringement on a Member State’s sovereign prerogatives.

The second concern relates to provisions in the draft IHRs that, for example, purport to give the WHO Secretariat the authority to require that Member States collaborate with WHO teams sent into a country – in the absence of a Member State’s request – to conduct on-the-spot studies of the severity of a threat or the adequacy of a Member State’s control measures to address a potential threat. See, e.g., Art. 10 (3). We are concerned that any provision that purports to authorize the WHO to conduct on-the-spot studies in a Member State in the absence of a Member State’s request and/or requires that a Member State “collaborate with WHO in assessing the severity of the threat” in-country, in the absence of an invitation to the WHO, is an infringement on that Member State’s sovereign prerogatives. Other provisions with similar implications are also problematic – such as the IHRs’ discouragement of “excessive” public health measures (defined as beyond the limits defined within the IHR). Member States should not be required to concede the right to take action beyond the requirements of the IHRs. See e.g., Articles 8(3)(b), 19(1), 21(1), 21(2), 23(1) and 24.
Also, Member States should have the right to regulate “goods” based on reasons unrelated to IHR issues and to institute border actions according to what they determine to be an appropriate level of protection.

**Jurisdictional Concerns**

We believe that some provisions in the draft IHRs would create obligations that fall beyond the jurisdiction of the federal (or central) governments of some WHO Member States and therefore would require the cooperation of states, provinces or other sub-national authorities, if such obligations are to be implemented by parties to the IHRs. The IHRs will need to accommodate federal systems of government in those countries where the authority to implement certain public health functions generally resides with local authorities and not the central government.

**Amendments**

Amendments to the annexes of the IHRs should be subject to the same treatment as other amendments to the IHRs. Every Member State should have a right to consider amendments to which it might become party. Article 46(2) appears to give the Executive Board the right to approve amendments to the IHRs without consideration of such amendments by the World Health Assembly as provided for in Articles 21 and 22 of the WHO Constitution.
Areas in the Proposed Revision that Need Further Clarification

**Article 4.2** “Possible interference with international traffic”— A more specific explanation of “possible interference with international traffic” will be necessary.

**Article 7.2** “immediately”— the WHO should consider fixed reporting periods in place of this vague term.

**Article 7.3** “As soon as possible by most efficient means available”— Instead of using these vague terms to discuss reporting times, the WHO should consider fixed reporting times.

**Article 7.4** “Unnotified event”— What constitutes an “unnotified” event? Are “exit screening” and “stop lists” included among the health measures described in Article 7.4?

**Article 8.1** “of public health risks”— what constitutes “rumours” of public health risks?

**Article 8.3(b)** “When necessary”— How is “when necessary” defined with respect to the WHO’s prerogative to send an investigative team to evaluate an event? The circumstances under which a team would be authorized should be outlined. We are concerned that the IHRs not be used as a justification, for example, for the WHO’s becoming involved in national outbreak responses without an invitation.

**Article 9.3** “That a public health emergency of international concern has ended”— This paragraph is one of the few examples where attention is paid to turning off alert/advisory mechanisms (see also Article 12 “terminate such recommendations”). In the IHRs, more attention should be paid to turning off alert/advisory mechanisms; the current draft focuses almost exclusively on turning such mechanisms on.

**Article 10.3** “Collaborate”— This should be clarified so that the “collaboration” discussed in this paragraph should be required
only if the Member State accepts the WHO’s offer of assistance.

**Article 15** “Sufficiently important”-- How is “sufficiently important [volume of international traffic]” defined?

**Article 16.2** “Sanitary condition”-- How is “sanitary condition” for travellers’ points of entry defined?

**Article 17** “Applicable international agreements”-- What are the “applicable international agreements” to which this Article refers? (See note in General Comments section above.)

**Article 18.3** “Evidence”-- “Evidence” needs to be more clearly defined.

**Article 19.1** “Affected area”-- The term “affected area” might be too narrow.
- “Control”-- Should the word “control” be replaced by the word "supervision" or "direction?"
- “Evidence”-- What type of “evidence” is sufficient to allow measures to be applied?

**Article 19.2** “Evidence”-- What type of “evidence” is sufficient to allow measures to be applied?

**Article 20.3(a)** “The measures recommended by WHO have been effectively carried out”-- Who determines whether “the measures recommended by the WHO have been effectively carried out” for purposes of this subparagraph?

**Article 21.4** “As long as possible,” “immediately,” and “illness”-- These phrases are vague and subject to interpretation, and, as such, need to be clarified.

**Article 22** “Immediate public health risk”-- How is “immediate public health risk” defined? Does this Article prevent the use of quarantine at the point of entry?
Article 25.3 “Sufficiently important”-- What does "sufficiently important" mean in this context? What criteria define “the volume of international traffic” as “sufficiently important?”

Article 29.2 “Any health measure applied”-- Does the requirement for the pilot in command of an aircraft to report “any health measure applied” on board refer to measures applied under the IHRs, or any health measure at all, including the provision of first aid, drugs, defibrillation, etc.? This needs to be clarified, preferably to refer only to measures related to the IHRs.

Article 36.1 “The rights of persons” -- We seek clarification as to the nature of the “rights of persons” referred to in this paragraph.

Article 37.2 “Standards of hygiene on conveyances”-- this paragraph refers to “standards of hygiene on conveyances” applicable under these regulations. With the possible exception of an indirect reference in footnote 1 of Article 20, these regulations do not appear to contain specific standards of hygiene. What standards are being referred to in this Article?

Article 40 “Health care settings”-- To what health care settings does this apply?

Annex 1.A.3. (f) “Rapid communications”-- How is the “rapid” requirement to be applied in countries that might not have highly developed communication capabilities?

Annex 1.B.1. (e) “Near points of entry”-- Please clarify what is meant by “near points of entry?” Existing IHRs use a radius of 10 kilometers. Thus, not defining this in the revision would be a departure from current practice.

Annex 2.1.2 “An area of high population density”-- Should “an area of high population density” be more clearly defined?
Annex 6.1 “Vaccines or other prophylaxis under the Regulations”—We seek clarification as to the meaning of this phrase. Does this refer to all vaccines that might be administered to travelers or only to certain vaccines specified by the IHRs (e.g. yellow fever vaccine)?

Annex 10 It would be helpful to identify the areas of expertise that should be represented on the Review Committee, recognizing the need to ensure effective representation.