

CDC Collaborating Center Promoting Health through Law WHO/PAHO Collaborating Center on Public Health Law and Human Rights

Comments on Department of Health and Human Services, Control of Communicable Diseases (Proposed Rule), 42 CFR Parts 70 and 71 (November 30, 2005)¹

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¹ These comments are derived from L. O. Gostin, "Federal Executive Power and Communicable Disease Control: CDC Quarantine Regulations," *Hastings Center Report*, Forthcoming March-April, 2006; D. P. Fidler, L. O. Gostin, "The New International Health Regulations: An Historic Development for International Law and Public Health," *J. Law, Med. & Ethics*, Forthcoming March 2006.

Introduction

The federal government has a major interest in protecting American citizens from the threat of communicable diseases. Recent SARS and West Nile Virus outbreaks, combined with the impending threats of pandemic or avian influenza, clarify the need for federal power to prevent the spread of infectious diseases entering the United States, crossing state lines, or threatening national security.² As such, the Center for Law and the Public's Health at Georgetown and Johns Hopkins Universities commends the new recommendations³ from the Centers for Disease Control and Prevention (CDC) that attempt to modernize quarantine law, one of the essential tools of public health law needed to avert a potentially tragic health disaster.

CDC's proposed quarantine regulations update federal power to protect the United States from a dangerous category of health threats. However, as written, they also raise concerns about accountability, personal liberty, due process, privacy, and international law. Power in a democracy, especially in times of public fear and anxiety, requires observance of the rule of law. The role of public health law is greater than simply authorizing government action. Public health law also serves to limit the power of the state to ensure that structural

(e.g. separation of powers, federalism) and rights-based (e.g. privacy, liberty, autonomy) concerns are not unnecessarily violated. Public health interventions, such as quarantine, require a balance between the communal good and the interests of individuals. These comments largely discuss whether the proposed CDC regulations adequately protect individual civil rights and economic interests.

1. The scope of federal power needs to be more narrowly defined.

The Public Health Service Act (PHSA) authorizes the "apprehension, detention, or conditional release" of individuals for only a small number of diseases listed by Executive Order—cholera, diphtheria, infectious tuberculosis, yellow fever, viral hemorrhagic fevers, SARS, and novel influenza viruses with pandemic potential.⁴ CDC's proposed rules significantly expand the scope of federal power by defining "ill person" to include anyone with signs or symptoms commonly associated with quarantinable diseases (e.g., fever, rash, headache, persistent cough, diarrhea, severe bleeding, jaundice, and changes in cognitive functioning).⁵ This inclusive approach embodies an important conceptual shift, affording CDC greater flexibility and adaptability to utilize quarantine power.

The proposed rule, however, captures a wide, undifferentiated range of signs and symptoms, allowing for the unfettered exercise of discretion by directors of federal quarantine stations. By contrast,

² L. O. Gostin, R. Bayer, A. L. Fairchild, "Ethical and Legal Challenges Posed by Severe Acute Respiratory Syndrome: Implications for the Control of Severe Infectious Disease Threats," *Journal of the American Medical Association* 290 (2003): 3229-3237.

³ Department of Health and Human Services, Control of Communicable Diseases (Proposed Rule), 70 Fed. Reg. 71892-71948 (November 30, 2005) (to be codified at 42 CFR Parts 70 and 71). These proposed rules update the Public Health Service Act §§361-368 (42 U.S.C. 264-271) (authorizing the Secretary to make and enforce regulations to prevent the introduction or transmission of communicable diseases from foreign countries and from one state into another).

⁴ Executive Order 13295, of April 4, 2003 and Executive Order 13375, of April 1, 2005. Also see 68 Fed. Reg. 17255 (April 9, 2003) and 70 Fed. Reg. 17299 (April 5, 2005).

⁵ 70 Fed. Reg. 71929 (November 30, 2005) (to be codified at 42 C.F.R. 70.1); 70 Fed. Reg. 71937 (November 30, 2005) (to be codified at 42 C.F.R. 71.1).

WHO's new International Health Regulations (IHR 2005) contain detailed specifications of health threats that come within its authority. An agency's jurisdiction and power must be contained within clear boundaries, which create accountability to the public generally and to affected communities in particular. CDC's proposed regulations need to more specifically articulate the bounds of their quarantine authority.

In particular, specificity is needed in the definition of quarantine standards. The regulations empower the CDC to provisionally quarantine ill passengers for up to 3 business days. Thereafter, officers can order full quarantine on grounds of a reasonable belief that a person or group is in the qualifying stage of a quarantinable disease.⁸ This standard for deprivation of liberty is too vague. Quarantine should be based on some more definitive standard (perhaps clear and convincing evidence) that the individual poses a significant risk to the public. Otherwise, there is a serious risk that individual liberty and autonomy will be unjustifiably restricted. The regulations must clarify the criteria under which a person may be quarantined. Ideally, these criteria will incorporate rigorous scientific measures of risk, and will be structured to only allow quarantine when there is a significant probability that an individual poses a serious threat to the population. 9,10

2. Quarantined individuals must have access to high quality health care.

When the protection of a community's health requires that individual liberty and autonomy are restricted, it is of the utmost importance that individuals receive all of the necessities of life. During quarantine, this includes being housed in safe, humane conditions and receiving high quality professional care. CDC's proposed quarantine rule does not ensure these conditions. HHS is authorized to pay for necessary medical and other services, but it is not bound to do so.¹¹ The rule should require the federal government to provide and pay for safe, humane conditions, the necessities of life, and adequate medical services. In addition, the IHR 2005's provisions on care and treatment of persons detained for health reasons include references to the need for sensitivity on gender, religious, and ethnic sensitivity issues ¹²

3. Due process protections are necessary for provisionally quarantined individuals.

at Georgetown and Johns Hopkins Universities. *The Model State Emergency Health Powers Act*.

Washington, DC; 2001. Available at http://www.publichealthlaw.net/MSEHPA/MSEHPA
2.pdf. Accessed January 30, 2006. These issues are specifically addressed in the Model Act's definition of a public health emergency (§§ 104(m) and 401) and the discussion of quarantine (§§ 604 and 605).

10 For an example of such criteria in the international

⁶ See D. Fidler, L. O. Gostin, "The New International Health Regulations: An Historic Development for International Law and Public Health," *J. Law, Med. & Ethics*, forthcoming 2006.

⁷ 70 Fed. Reg. 71933 (November 30, 2005) (to be codified at 42 C.F.R 70.14); 70 Fed. Reg. 71942 (November 30, 2005) (to be codified at 42 C.F.R 71.17).

⁸ 70 Fed. Reg. 71933 (November 30, 2005) (to be codified at 42 C.F.R 70.16); 70 Fed. Reg. 71942 (November 30, 2005) (to be codified at 42 C.F.R 71.19).

⁹ For an example of such criteria in the domestic context, see Center for Law and the Public's Health

¹⁰ For an example of such criteria in the international context, see World Health Assembly, *Revision of the International Health Regulations*, WHA58.3 (May 23, 2005) Articles 43.1-43.2.

¹¹ 70 Fed. Reg. 71934 (November 30, 2005) (to be codified at 42 C.F.R 70.21); 70 Fed. Reg. 71943 (November 30, 2005) (to be codified at 42 C.F.R 71.24).

¹² World Health Assembly, *Revision of the International Health Regulations*, WHA58.3 (May 23, 2005) Article 32.

The CDC does not intend to provide individuals with hearings during provisional quarantine.¹³ While a full hearing for provisional quarantine may not be feasible or practical, procedural protections are still needed. Specifically, individuals must receive some notice of their suspected exposure to an infectious disease and be permitted to speak with counsel. If they cannot afford counsel, one should be appointed at the government's expense.¹⁴ This will provide the quarantined individual with an opportunity to prepare for a subsequent hearing, which must be held as soon as possible after a quarantine order is issued.

A related concern has to do with the proposed regulation that allows provisional quarantine for up to 3 business days. 15 While a provisional quarantine is sometimes necessary to perform tests and collect evidence of exposure, the 3 business day window creates an unreasonable delay during which the individual remains in custody. If the event is adjacent to a weekend and/or holiday, 3 business days could stretch into 6 actual days. Given that the person is suspected of posing a serious risk to the population, the evaluation process should be expedited, regardless of the day of the week. The proposed rule should be changed to reflect an absolute limit on the length of a provisional quarantine,

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minimizing this window to only the time necessary for establishing exposure.

4. Due process protections for full quarantine need to be strengthened.

CDC's proposed regulations articulate commendable due process protections for full quarantine. ¹⁶ The hearing's purpose is not to review the legal authority (which is available through habeas corpus), but the factual and scientific evidence of exposure to or infection with a quarantinable disease. The administrative hearing comports with some basic elements of due process: notice, hearing officer, and communication with counsel.

The regulatory provision of federal procedural due process for full quarantine is overdue and constitutionally required.¹⁷ Still, there are notable deficiencies in the proposed regulations that violate fundamental principles of due process (absent other federal provisions). First, the regulations require that individuals must affirmatively request a hearing, which may delay or prevent independent review for those who cannot understand or act on information provided in the quarantine order. The hearing initiation procedure needs to be clearly communicated to all quarantined individuals, with an emphasis on ensuring access for those with linguistic or cognitive barriers. Second, quarantined individuals should have a right to paid legal representation if they cannot afford it themselves. 18 Thus, the regulations should

¹³ 70 Fed. Reg. 71895-71896 (November 30, 2005). Also see *United States v. Shinnick*, 219 F. Supp. 789 (E.D.N.Y. 1963) (upholding federal isolation of an arriving passenger in a hospital for 14 days).

¹⁴ For an example of a provision on right to counsel,

¹⁴ For an example of a provision on right to counsel, see Center for Law and the Public's Health at Georgetown and Johns Hopkins Universities. *The Model State Emergency Health Powers Act.* § 605(e)(1). Washington, DC; 2001. Available at http://www.publichealthlaw.net/MSEHPA/MSEHPA 2.pdf. Accessed January 30, 2006.

¹⁵ 70 Fed. Reg. 71933 (November 30, 2005) (to be codified at 42 C.F.R 70.14); 70 Fed. Reg. 71942 (November 30, 2005) (to be codified at 42 C.F.R 71.17).

¹⁶ 70 Fed. Reg. 71934 (November 30, 2005) (to be codified at 42 C.F.R 70.20); 70 Fed. Reg. 71943 (November 30, 2005) (to be codified at 42 C.F.R 71.23)

¹⁷ L. O. Gostin, *Public Health Law: Power, Duty, Restraint* (Berkeley and New York: University of California Press and Milbank Memorial Fund (2000)): 323-324.

¹⁸ See Center for Law and the Public's Health at Georgetown and Johns Hopkins Universities. *The*

include an expressed right to paid legal representation for the indigent. Third, the proceedings can be informal, even permitting the hearing to be exclusively based on written or electronic documents. The evidentiary and procedural requirements should be made more formal, and should include an opportunity for the quarantined individual to present oral or written testimony.

Finally, and most importantly, the lack of independent judicial review is concerning. The regulations designate that the hearing officer may be a CDC employee who makes a recommendation to the CDC Director. The CDC regulations thus envisage an informal hearing by an employee who is both in the executive branch and one of the parties. Denying an affected individual an opportunity to be heard before an independent tribunal is fundamentally unfair. CDC points to the flexibility of due process, but the constitutional principle is not so elastic as to permit less-than-independent hearings on matters of personal liberty. ¹⁹ The European Court of Human Rights found a similar scheme in the United Kingdom to violate Article 5 of the European Convention on Human Rights.²⁰ Article 5 requires a hearing by a "court" that is independent of the executive and the parties to the case. The CDC quarantine regulations should conform to this standard.²¹

5. Information privacy concerns should be addressed.

Model State Emergency Health Powers Act. Section 605(e)(1). Washington, DC; 2001. Available at http://www.publichealthlaw.net/MSEHPA/MSEHPA 2.pdf. Accessed January 30, 2006.

The health information privacy implications of the proposed rules are concerning. The transportation industry will be asked to collect highly sensitive personal data from passengers, such as their medical history, friends and family, and sexual partners.²² The electronic form facilitates rapid movement of data and creates the capacity of officials to match multiple data sets (e.g., public health, medical, security, crime). The use of data to trace contacts means that personal information, implicitly or explicitly, may be communicated to third persons. The data trail could move from travel agents and airline or cruise personnel to the CDC and other federal agencies (e.g., DHS, FBI, CIA, USCIS). Data may be disclosed to state or local health agencies and could potentially make its way into the private sector (i.e., clinics or hospitals providing treatment or quarantine services).

Public health surveillance, contact tracing, and epidemiological investigations are historical, well-accepted public health practices that sustain the acquisition, use, and disclosure of identifiable health data. However, privacy implications cannot be ignored. Protecting health information privacy is essential for accomplishing public health objectives, including during public health emergencies. Given a lack of comprehensive public health privacy protections at the federal level, specific data practices pertaining to public health are needed.²³ A CDC public health privacy project in 1996, for example, proposed significant restrictions on sharing data for

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¹⁹ Hamdi v. Rumsfeld, 124 S. Ct. 2633 (2004).

²⁰ X v. United Kingdom, judgment of 27 November 1981, 46 Eur. Ct. H.R. (ser. A).

²¹ See also Section 7 below on international law.

²² 70 Fed. Reg. 71930 (November 30, 2005) (to be codified at 42 C.F.R 70.4); 70 Fed. Reg. 71940 (November 30, 2005) (to be codified at 42 C.F.R

²³ The HIPAA Privacy Rule, for example, largely exempts public health data from its extensive coverage. See L. O. Gostin, J. G. Hodge Jr., R. O. Valdiserri, "Informational Privacy and the Public's Health," *American Journal of Public Health* 91 (2001): 1388-1392.

non-public health purposes such as criminal justice, immigration, and social welfare benefits. In 1999, model public health privacy provisions were developed under the auspices of CDC in the drafting of the Model State Public Health Privacy Act. 24 These provisions were further incorporated into the *Center's* Model State Emergency Health Powers Act 25 and the comprehensive Turning Point Model State Public Health Act. 26 Given that CDC's proposed regulations pertain to federal (and not state) use of quarantine power, detailed privacy standards to ensure fair health informational practices are still needed. 27

6. Economic interests and the public's health have been appropriately balanced.

While CDC's proposed regulations raise concerns about civil liberties, the provisions concerning economic interest are generally appropriate. The PHSA empowers CDC to provide for inspection, fumigation, disinfection, sanitation, pest extermination, and destruction of infected or contaminated

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animals or goods.²⁸ The proposed rules specify that CDC shall not bear the expense of sanitary measures, so that the property owner incurs the costs.²⁹ The owner, however, may appeal an order for the destruction or export of animals or goods, if there is a "genuine and substantial issue of material fact in dispute."³⁰

The government's power to inspect premises and abate hazardous conditions has historical precedent and broad judicial acceptance. The courts have upheld searches of persons or property under the 4th Amendment to prevent an imminent threat to health or safety. Similarly, the judiciary has founds that individuals at border crossings or ports of entry and heavily regulated industries have reduced expectations of privacy. The key question is whether administrative searches at quarantine stations should be based on probable cause with, or without, a judicial warrant.

CDC's claim is that routine inspections are essential for the rapid identification of health hazards.³⁴ CDC's objectives are to safeguard health, not enforce criminal laws. Health officials can rarely find probable cause for searching passengers, baggage, or cargo. Even if individualized grounds for a search were

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²⁴ Center for Law and the Public's Health at Georgetown and Johns Hopkins Universities. *The Model State Public Health Privacy Act*. Washington, DC; 1999. Available at http://www.publichealthlaw.net/Resources/Resources

PDFs/modelprivact.pdf. Accessed January 30, 2006

²⁵ Center for Law and the Public's Health at Georgetown and Johns Hopkins Universities. *The Model State Emergency Health Powers Act*. Washington, DC; 2001. Available at http://www.publichealthlaw.net/MSEHPA/MSEHPA
<a href="http://www.publichealthlaw.net/MSEHPA/M

Turning Point Public Health Statute Modernization Collaborative. *Model State Public Health Act*. Seattle, WA; 2003. Available at http://www.hss.state.ak.us/dph/improving/turningpoint/PDFs/MSPHAweb.pdf. Accessed January 30, 2006

²⁷ See L. O. Gostin, J. G. Hodge Jr., R. O. Valdiserri, "Informational Privacy and the Public's Health," *American Journal of Public Health* 91 (2001): 1388-1392.

²⁸ 42 C.F.R. 70.2.

²⁹ 70 Fed. Reg. 71932 (November 30, 2005) (to be codified at 42 C.F.R. 70.11); 70 Fed. Reg. 71941 (November 30, 2005) (to be codified at 42 C.F.R. 71.13).

³⁰ 70 Fed. Reg. 71936 (November 30, 2005) (to be codified at 42 C.F.R. 70.31); 70 Fed. Reg. 71944 (November 30, 2005) (to be codified at 42 C.F.R. 71.33).

³¹ *North American Cold Storage v. Chicago*, 211 U.S. 306, 315 (1908) (upholding seizure of food unfit for human consumption).

³² *United States v. Flores-Montano*, 541 U.S. 149, 152 (2004) (noting the state's interest at international borders is at its zenith).

³³ New York v. Burger, 482 U.S. 691, 702 (1987).

³⁴ 70 Fed. Reg. 71894-71895.

available, there would seldom be time to secure a warrant. Thus, the proposed regulations regarding administrative searches are appropriate.

The power to seize and destroy private property is one of the more controversial aspects of the rules. The political right has vociferously contested public health regulations that reduce the value of or destroy personal property. Arguing that nuisance abatements should be treated as "regulatory takings," conservative commentators have sought compensation under these circumstances.³⁵ Payment for property losses would be a radical departure from historical practice. Health officials have long held the power to interfere with private property or activities to ameliorate health hazards. Requiring agencies to compensate property owners would chill health regulation and place the cost of private health hazards on the public. This is particularly true for screenings at ports and borders where individuals may be transporting infected or contaminated animals or goods that pose a risk to the public's health. The proposed regulations correctly allow officials the power to seize and destroy private property without compensation.

Finally, the proposed rules require that the transportation industry collect crew and passenger data. The rules impose obligations to: screen passengers at borders (e.g., visual inspection, electronic temperature monitors); report cases of illness or death to the CDC; distribute Health Alert Notices to crew and passengers; collect personal passenger information, maintain it in electronic databases, and transmit it to CDC upon

request; order physical examination of persons believed to have a quarantinable disease; and require from such persons detailed information on familial and social contacts, travel itinerary, and medical history.³⁶ These legal powers may be necessary for the public's health, but also impose high costs on the transportation industry.³⁷ Consideration should be given to public/private collaboration.

7. International law and the proposed quarantine regulations.

Coordinating U.S. government authority and U.S. international legal obligations is important because of globalization's impact on the spread of communicable diseases. The Institute of Medicine's Committee on Quarantine Stations at Points of Entry recommended that the modernized U.S. quarantine system must comply with U.S. international legal obligations and that the IHR 2005 should receive special attention.³⁸ In various places, the CDC regulations recognize the application of international law to actions undertaken by the U.S. government. For example, the CDC regulations apply provisions of the IHR 2005 in § 71.28; and the regulations also reflect U.S. obligations under the Vienna Convention on Consular Relations in § 70.22 and § 71.25.

Nevertheless, we raise two concerns about

³⁵ For a discussion and critique of this argument, see L. O. Gostin, Public Health Law: Power, Duty, Restraint (Berkeley and New York: University of California Press and Milbank Memorial Fund (2000)): 263-265.

³⁶ 70 Fed. Reg. 71930, 71932, 71934, (November 30, 2005) (to be codified at 42 C.F.R. 70.2, 70.4, 70.13, 70.19); 70 Fed. Reg. 71939, 71940, 71942, 71943 (November 30, 2005) (to be codified at 42 C.F.R. 71.6, 71.8, 71.10, 71.16, 71.22).

³⁷ Centers for Disease Control, Division of Global Migration and Quarantine, Regulatory Impact Analysis of Proposed 42 CFR Part 70 and 42 CRF Part 71 (Atlanta, GA: September 26, 2005).

³⁸ Institute of Medicine Committee on Quarantine Stations at Points of Entry, Quarantine Stations at Ports of Entry: Protecting the Public's Health, 68 (2005).

the CDC regulations with respect to international law.

CDC regulations as an opportunity to integrate the IHR 2005 into domestic law

First, the CDC regulations miss an opportunity for the United States to integrate the IHR 2005 into its modernized legal authorities for protecting the American people from communicable disease threats. The IHR 2005 contain many obligations; compliance with these obligations could be facilitated by the new CDC regulations. Even though the IHR 2005 will not enter into force for the United States until 2007 (IHR 2005, Article 59.2), the CDC regulations refer to the IHR 2005 in a way that demonstrates that the entry-into-force date was not a bar to aligning the regulations with the IHR 2005.³⁹ For example, the exercise of the CDC Director's authority to make Maritime Declarations of Health and the Health Part of the Aircraft General Declaration a required condition of arrival at a U.S. port has to be "in accordance with Articles 37 and 38 of the International Health Regulations."40

The IHR 2005's importance for the CDC regulations goes beyond Articles 37 and 38 and includes many provisions that require action from the U.S. government or that place limitations on the exercise of U.S. governmental authority. For example, the IHR 2005 require states parties "to designate a National IHR Focal Point and the authorities responsible within its respective jurisdiction for the implementation of the

³⁹ The CDC regulations define "International Health Regulations" as the "International Health Regulations of the World Health Organization, adopted by the Fifty-Eighth World Health Assembly in 2005, and as may be further amended and ratified by the United States." 70 Fed. Reg. 71937 (November 30, 2005) (to be codified at 42 C.F.R. 71.1).

health measures under these Regulations" (Article 4.1). In keeping with their purpose and their recognition of the global aspects of U.S. public health, the CDC regulations could have designated the National IHR Focal Point as required by the IHR 2005.

The CDC regulations could also have provided domestic legal authority for U.S. actions needed for compliance with other requirements of the IHR 2005, including the obligations to notify events that may constitute a public health emergency of international concern (Article 6.1, Annex 2); to verify disease events at the request of WHO (Article 10.2); to implement only the least intrusive and invasive medical examination of travelers (Articles 23.2 and 43.1); to inform travelers to be vaccinated or offered prophylaxis of any risk associated with vaccination or with non-vaccination and the use or non-use of prophylaxis (Article 23.4); to treat travelers subject to health measures according to specific standards (Article 32); to apply measures no more restrictive of international traffic than reasonably available alternatives (Articles 2 and 43.1); to protect the privacy of information received from other countries and WHO (Article 45.1); and to comply with many other duties.

The CDC regulations constitute an opportunity for the United States to show leadership with respect to the domestic implementation of the IHR 2005. Many other countries will analyze what the United States adopts in revising its domestic legal framework for the challenges globalization poses for control of the international spread of disease. At present, the CDC regulations do not represent a systematic effort to integrate the IHR 2005 into domestic law. We encourage the CDC to consider revising the CDC regulations to achieve this integration and thus provide global leadership on implementation of an international legal framework the United

⁴⁰ 70 Fed. Reg. 71944 (November 30, 2005) (to be codified at 42 C.F.R. 71.28).

States considers vital to its national and public health security.

Compatibility of the CDC regulations with U.S. international legal obligations

The second issue related to international law concerns the compatibility of some provisions in the CDC regulations with U.S. international legal obligations under the IHR 2005 or other treaties. For illustrative purposes, we mention two here. First, earlier we noted that the CDC regulations' failure to afford persons subject to full quarantine the opportunity to be heard before an independent decision maker violated U.S. due process norms. U.S. obligations under the International Covenant on Civil and Political Rights (ICCPR) reinforce this argument.

The ICCPR states that "[a]nyone who is deprived of his liberty by arrest or detention shall be entitled to take proceedings before a court, in order that that court may decide without delay on the lawfulness of his detention and order his release if the detention is not lawful" (Article 9.4). The hearing provided in the CDC regulations can be overseen by a CDC employee, which would make the CDC not only a party to the hearing but also the decision maker. The hearing officer also cannot order a person's release if he or she determines that the quarantine is not justified on factual and scientific grounds because that power only resides with the CDC Director. 41 In addition, a full quarantine order can become final without a requested hearing even being held if, given delays in holding the hearing, three business days pass after a hearing is requested.⁴²

Individuals presently cannot raise ICCPR violations as claims in U.S. federal courts, but this situation should not prevent the U.S. government from complying with its ICCPR obligations. Moreover, governments of foreign nationals subject to quarantine in the United States may argue that the lack of an independent decision maker violates Article 9.4 of the ICCPR. 43 Thus, pursuant to both domestic and international legal due process requirements, the CDC should revise the regulations to provide those subject to full quarantine orders access to an independent decision maker to challenge the factual and scientific basis for the detention.

Second, the CDC regulations authorize the CDC Director to "require a carrier at any foreign port clearing or departing for any U.S. port to obtain or deliver a bill of health from a United States consular or medical officer designated for such purpose." If the CDC Director exercises this authority, the action could violate the IHR 2005.

The IHR 2005 provide that "[n]o health documents, other than those provided for under these Regulations or in recommendations issued by WHO, shall be required in international traffic" (Article 35).

one business day of a request for a hearing (§71.23(a)), which creates problems for those quarantined to organize appropriate representation, particularly foreign nationals who have the right under the Vienna Convention on Consular Relations to have access to consular officials. If the hearing is delayed longer than three business days from the date of the hearing request, the CDC regulations provide that the quarantine order becomes final (§71.23(k)), cutting off the opportunity to challenge the order through a hearing.

⁴¹ 70 Fed. Reg. 71943 (November 30, 2005) (to be codified at 42 C.F.R. 71.23(i)).

⁴² 70 Fed. Reg. 71943 (November 30, 2005) (to be codified at 42 C.F.R. 71.23(k)). The CDC regulations mandate that the CDC Director hold a hearing within

⁴³ As the CDC regulations recognize, the United States has to provide foreign nationals of countries that are states parties to the Vienna Convention on Consular Relations access to consular officials, who will be aware of international legal obligations the United States has under the ICCPR.

⁴⁴ 70 Fed. Reg. 71939 (November 30, 2005) (to be codified at 42 C.F.R. 71.4).

This prohibition does not apply "to document requirements concerning the public health status of goods or cargo in international trade pursuant to applicable international agreements" (Article 35). As defined in the CDC regulations, a "bill of health" is not a document related to a WHO recommendation or required by applicable international agreements but is a document prescribed and required by the CDC Director. ⁴⁵ As such, any issued bill of health would violate the prohibition in Article 35.

In addition, the IHR 2005 provisions on "additional health measures" (Article 43) would not provide an exception for any CDC-issued bill of health requirement. The IHR 2005 allow states parties to implement health measures in response to specific public health risks or public health emergencies of international concern that (1) achieve the same or greater level of health protection than WHO recommendations; or (2) are otherwise prohibited by specific provisions of the IHR 2005 (Article 43.1). This provision does not, however, include the prohibition on health documents in Article 35 in the list of prohibitions subject to the permissive rule on additional health measures.

The summary of proposed changes to Part 72 acknowledges that the existing regulations do not require carriers at foreign ports destined for the United States to obtain bills of health. This summary justifies granting the bill-of-health authority to the CDC Director by stating that "[w]hile the Director does not intend to require a bill of health for carriers engaged in routine traffic, concern over bioterrorism and rapidly emerging infectious diseases makes inclusion of this important public health tool imperative." ⁴⁶ The IHR 2005 do not recognize the bill of health as an imperative

public health tool. If the United States does not want the bill-of-health authority to conflict with its obligations under the IHR 2005, then it may need to revise the CDC regulations to remove the authority or issue a reservation to the IHR 2005 on this issue.

⁴⁵ 70 Fed. Reg. 71937 (November 30, 2005) (to be codified at 42 C.F.R. 71.1).

⁴⁶ 70 Fed. Reg. 71909 (November 30, 2005).