



The 2009 Influenza Pandemic: Selected Legal Issues

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Summary

On June 11, in response to the global spread of a new strain of influenza, the World Health Organization (WHO) raised the level of influenza pandemic alert to phase 6, which indicates the start of an actual pandemic. This change reflected the spread of the new influenza A(H1N1) virus, not its severity. Although currently the pandemic is of moderate severity with the majority of patients experiencing mild symptoms and making a rapid and full recovery, this experience could change. This report provides a brief overview of selected legal issues including emergency measures, civil rights, liability issues, and employment issues.

There are a number of emergency measures which may help to contain or ameliorate an infectious disease outbreak. The Public Health Service Act, the Federal Food, Drug, and Cosmetic Act, the National Emergencies Act, and the Stafford Act contain authorities that allow the Secretary of Health and Human Services or the President to take certain actions during emergencies or disasters. While the primary authority for quarantine and isolation in the United States resides at the state level, the federal government has jurisdiction over interstate and border quarantine. The federal government also issues recommendations regarding such activities as school closures and vaccination programs. States and local governments have the authority to initiate emergency measures such as mandatory vaccination orders and certain nonpharmaceutical interventions such as school closures, which may lessen the spread of an infectious disease. The International Health Regulations adopted by the WHO in 2005 provide a framework for international cooperation against infectious disease threats.

The use of these emergency measures to contain the 2009 influenza pandemic may raise a classic civil rights issue: to what extent can an individual's liberty be curtailed to advance the common good? The U.S. Constitution and federal civil rights laws provide for individual due process and equal protection rights as well as a right to privacy, but these rights are balanced against the needs of the community.

Liability issues may become particularly important during the 2009 influenza pandemic. The Public Readiness and Emergency Preparedness Act limits liability with respect to the use of countermeasures for pandemic flu or other public health threats. A patchwork of federal and state laws generally protect volunteers, which may include volunteer health professionals (VHPs), under certain circumstances. Laws also provide liability protections specifically for VHPs.

Questions relating to employment are among the most significant issues presented by an influenza pandemic, since, if individuals fear losing their employment or their wages, compliance with public health measures such as social distancing and isolation or quarantine may suffer. It would seem possible for a court to conclude that the isolation or quarantine of individuals during a pandemic serves the public good and that the termination of individuals who are isolated or quarantined violates public policy. Employees may also have some job protection under the Family and Medical Leave Act.

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Introduction

On June 11, in response to the global spread of a new strain of influenza, the World Health Organization (WHO) raised the level of influenza pandemic alert to phase 6, the highest level, which indicates the start of an actual pandemic.¹ This change in alert level reflected the spread of the new virus, not its severity. In late April 2009, human cases of infection with a novel influenza A(H1N1) virus were identified. Since then, the virus has become widespread. Although currently the pandemic is of moderate severity with the majority of patients experiencing mild symptoms and making a rapid and full recovery, the virus and its effects may change over time.² This report provides a brief overview of selected legal issues including emergency measures, civil rights, liability issues, and employment issues.

Emergency Measures

Emergency Authorities³

Public Health Emergency Authorities

In response to public health threats, the Secretary of the Department of Health and Human Services (HHS) can provide a considerable degree of assistance to states through the Secretary's general, non-emergency authorities. For example, upon the request of a state health official, and without the involvement of the President, the Centers for Disease Control and Prevention (CDC) can provide financial and technical assistance to states for outbreak investigation and disease control activities. These activities are carried out under the Secretary's general authority to assist states at 42 U.S.C. §§ 243(c) and 247b.

There are also a number of authorities in the Public Health Service (PHS) Act that allow the Secretary of HHS to take certain actions in the face of a "public health emergency." The principal authority is in Section 319 of the PHS Act, 42 U.S.C. § 247d(a), which states that

If the Secretary determines, after consultation with such public health officials as may be necessary, that—(1) a disease or disorder presents a public health emergency; or (2) a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists, the Secretary may take such action as may be appropriate to respond to the public health emergency, including making grants, providing awards for expenses, and entering into contracts and conducting and supporting investigations into the cause, treatment, or prevention of a disease or disorder as described in paragraphs (1) and (2).⁴

¹ Dr. Margaret Chan, Director-General of the World Health organization, "World Now at the Start of 2009 Influenza Pandemic," http://www.who.int/mediacentre/news/statements/2009/h1n1_pandemic_phase6_20090611/en/index.html.

² For information on the pandemic status and U.S. government actions, see <http://www.cdc.gov/swineflu/>, <http://www.dhs.gov/xprepresp/programs/swine-flu.shtm>, and <http://www.flu.gov>. See also CRS Report R40554, *The 2009 Influenza Pandemic: An Overview*, by (name redacted) and (name redacted).

³ This section was written by (name redacted) and (name redacted).

⁴ The Secretary is required to provide written notice of determinations under this section to Congress within 48 hours, but is not required to publish notice of such determinations in the *Federal Register*. 42 U.S.C. § 247d(a).

The then-Acting HHS Secretary issued a nationwide public health emergency declaration in response to human infections from the influenza A(H1N1) virus on April 26, 2009.⁵ Making such a determination enables the Secretary to take three types of actions that can be especially useful for dealing with an emerging influenza outbreak. First, such a determination authorizes the Secretary to draw from a special emergency fund.⁶ Second, it is one of three events that can lead to the issuance of Emergency Use Authorizations under the Federal Food, Drug, and Cosmetic Act to allow for the use of unapproved medical treatments and tests, under specified conditions, if needed during an incident.⁷ Third, if there is a concurrent declaration pursuant to either the Stafford Act⁸ or the National Emergencies Act,⁹ the Secretary is authorized to waive or modify temporarily certain administrative requirements under Section 1135 of the Social Security Act,¹⁰ as necessary to ensure that sufficient healthcare items and services are available to meet the needs of individuals enrolled in Medicare, Medicaid, and the Children's Health Insurance Program (CHIP), and that providers of such services in good faith who are unable to comply with certain statutory requirements are exempted from sanctions for noncompliance, absent fraud or abuse.

With respect to the 2009 influenza pandemic, and pursuant to the Secretary's declaration of a public health emergency under Section 319 of the PHS Act, the Public Health Emergency Fund is available (but is currently unfunded);¹¹ certain Emergency Use Authorizations have been granted by FDA;¹² and, once the President declared a national emergency under the National Emergencies Act, the Secretary authorized waivers and modifications under Section 1135 of the Social Security Act.¹³

National Emergencies Act Declarations

The National Emergencies Act (NEA)¹⁴ authorizes the President to declare a national emergency and activate existing statutory provisions that authorize the exercise of special or extraordinary power. The NEA does not provide any specific emergency authority on its own, but relies upon emergency authorities provided in other statutes. For example, a national emergency declaration under the NEA could authorize the Secretary of HHS to deploy officers in the Commissioned Corps of the Public Health Service to agencies outside of HHS in response to an urgent or emergency public health care need. Emergency statutory provisions are not activated automatically, but must be specifically identified in the President's declaration before they may be given effect.

⁵ This determination, which would have expired after 90 days, was renewed by HHS Secretary Kathleen Sebelius on July 24 at http://www.hhs.gov/secretary/phe_swh1n1.html. It was again renewed on October 1, 2009, for an additional 90 days at <http://www.flu.gov/professional/federal/h1n1emergency100109.html>.

⁶ The Public Health Emergency Fund does not currently have any monies available. For more information, see CRS Report RL33579, *The Public Health and Medical Response to Disasters: Federal Authority and Funding*, by (name redacted).

⁷ See *infra* at "Emergency Use Authorizations (for Unapproved Countermeasures)."

⁸ 42 U.S.C. § 5121 *et seq.*

⁹ 50 U.S.C. § 1601 *et seq.*

¹⁰ 42 U.S.C. § 1320b-5.

¹¹ See *supra* note 6.

¹² See *infra* at "Emergency Use Authorizations (for Unapproved Countermeasures)."

¹³ See *infra* at "National Emergencies Act Declarations" and "Section 1135 Waivers or Modifications."

¹⁴ 42 U.S.C. § 1601 *et seq.* For more information on the National Emergencies Act, and declarations made under it, see CRS Report 98-505, *National Emergency Powers*, by (name redacted).

President Barack Obama declared a state of national emergency pursuant to the National Emergencies Act on October 23, 2009.¹⁵ Specifically, the President proclaimed that because “the rapid increase in illness across the nation may overburden health care resources and ... the temporary waiver of certain standard Federal requirements may be warranted in order to enable U.S. health care facilities to implement emergency operations plans, the 2009 H1N1 influenza pandemic in the United States constitutes a national emergency.” The President further authorized the Secretary of HHS to “exercise the authority under section 1135 of the Social Security Act to temporarily waive or modify certain requirements of the Medicare, Medicaid, and State Children’s Health Insurance programs and of the Health Insurance Portability and Accountability Act Privacy Rule throughout the duration of the public health emergency declared in response to the 2009 H1N1 influenza pandemic.”

Stafford Act Declarations

A presidential declaration under the Stafford Act triggers federal emergency authorities that are independent of the Secretary’s public health emergency authorities. Declarations under the Stafford Act fall into two categories: emergency declarations and major disaster declarations. As of this point in time, there have been no Stafford Act declarations pertaining to the 2009 influenza pandemic.¹⁶ A presidential emergency declaration under the Stafford Act authorizes the President to direct federal agencies to support state and local emergency assistance activities; coordinate disaster relief provided by federal and non-federal organizations; provide technical and advisory assistance to state and local governments; provide emergency assistance through federal agencies; remove debris through grants to state and local governments; provide assistance to individuals and households for temporary housing and uninsured personal needs; and assist state and local governments in the distribution of medicine, food, and consumables.¹⁷ The total amount of assistance available is limited in an emergency declaration to \$5 million, “unless the President determines that there is a continuing need; Congress must be notified if the \$5 million ceiling is breached.”¹⁸

Emergency declarations under the Stafford Act in the event of an outbreak of infectious disease are not unprecedented. In 2000, the detection of West Nile virus in New York and New Jersey

¹⁵ The text of the President’s Proclamation, “Declaration of a National Emergency with Respect to the 2009 H1N1 Influenza Pandemic” may be viewed at <http://www.whitehouse.gov/the-press-office/declaration-a-national-emergency-with-respect-2009-h1n1-influenza-pandemic-0>.

¹⁶ Whether a Stafford Act declaration is appropriate for a pandemic incident may be the subject of some debate. Compare Kevin Robillard, Officials Say Swine Flu Vaccine is Coming, CQ HOMELAND SECURITY, July 9, 2009 (quoting DHS Secretary Janet Napolitano as observing that “the [Stafford] act and the flu do not match up well.”) with Comments of DHS Deputy Secretary Jane Holl Lute, U.S. Congress, House Committee on Homeland Security, Beyond Readiness: An Examination of the Current Status and Future Outlook of the National Response to Pandemic Influenza, 111th Cong., 1st sess., July 29, 2009 (indicating that DHS has planned for contingencies in which the Stafford Act is invoked in response to a pandemic).

¹⁷ 42 U.S.C. § 5192. Although there are currently significant stockpiles of antiviral medications, if there are large numbers of individuals infected with H1N1, the demand for antivirals, potential vaccines, and other medical supplies such as ventilators may exceed the supply. This potential imbalance has led to recommendations for priorities for medical resources for certain categories of individuals. For a discussion of these recommendations see CRS Report RL33381, *The Americans with Disabilities Act (ADA): Allocation of Scarce Medical Resources During a Pandemic*, by (name redacted).

¹⁸ 42 U.S.C. § 5193(b). See also CRS Report RL33053, *Federal Stafford Act Disaster Assistance: Presidential Declarations, Eligible Activities, and Funding*, by (name redacted), at 13-15.

was used as the basis of an emergency declaration under the Stafford Act.¹⁹ However, there may be uncertainty regarding whether a flu pandemic, or any outbreak of infectious disease, would be eligible for *major disaster* assistance under the Stafford Act.²⁰

A major disaster declaration authorizes the President to offer all the assistance authorized under an emergency declaration, and further authorizes funds for the repair and restoration of federal facilities, unemployment assistance, emergency grants to assist low-income migrant and seasonal farm workers, food coupons and distribution, relocation assistance, crisis counseling assistance and training, community disaster loans, emergency communications, and emergency public transportation.²¹ Additionally, the total amount of assistance provided in a major disaster declaration is not subject to a ceiling in the same way as under an emergency declaration.

The authority of the President to declare a major disaster under the Stafford Act in response to a flu pandemic may be subject to some debate and likely depends upon whether a flu pandemic would qualify as a “natural catastrophe” under the Stafford Act. FEMA has historically excluded biological incidents from major disaster declarations under the Stafford Act, but executive policy under the Bush administration appeared to consider biological incidents, or at least flu pandemics, to be eligible for major disaster assistance.²²

Although there are differences between the types and amounts of assistance that are authorized by an emergency or major disaster declaration, either declaration would activate the Secretary’s waiver or modification authority,²³ if concurrent with a public health emergency declaration. There have been no declarations issued under the Stafford Act with respect to the current pandemic.

Section 1135 Waivers or Modifications

Section 1135 of the Social Security Act was added by Section 143 of P.L. 107-188, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, to authorize the HHS Secretary to waive certain regulatory requirements related to the provision of health care services when the President has declared an emergency or major disaster pursuant to either the NEA or the Stafford Act, and the Secretary of HHS has declared a public health emergency. Waivers under Section 1135 involve administrative requirements principally relating to reimbursement through the Medicare and Medicaid programs, in order to facilitate the provision of health care items and services by providers in an emergency area subject to the concurrent declarations.²⁴ An emergency area and an emergency period are defined in Section 1135 as the geographic area in

¹⁹ CRS Report RL33579, *The Public Health and Medical Response to Disasters: Federal Authority and Funding*, by (name redacted), at n.11 and accompanying text; and 65 Fed. Reg. 63589, 67747.

²⁰ See CRS Report RL33579, *The Public Health and Medical Response to Disasters: Federal Authority and Funding*, by (name redacted), at 10-11. For a more detailed discussion see CRS Report RL34724, *Would an Influenza Pandemic Qualify as a Major Disaster Under the Stafford Act?*, by (name redacted).

²¹ 42 U.S.C. §§ 5172-5187.

²² HOMELAND SECURITY COUNCIL, *Implementation Plan for the National Strategy for Pandemic Influenza*, at http://www.whitehouse.gov/homeland/nspi_implementation.pdf. This document “describes more than 300 critical actions, many of which have already been initiated, to address the threat of pandemic influenza.” See, also, CRS Report RL34724, *Would an Influenza Pandemic Qualify as a Major Disaster Under the Stafford Act?*, by (name redacted).

²³ See *infra* at “Section 1135 Waivers or Modifications.”

²⁴ 42 U.S.C. § 1320b-5(b).

which and time period during which there exists an emergency or disaster declared by the President pursuant to the National Emergencies Act or the Stafford Act concurrently with a public health emergency declared by the Secretary pursuant to Section 319 of the PHS Act.²⁵

If Section 1135 conditions are met, then health care facilities may ask the Secretary for “1135 waivers” in response to particular needs within the geographic and temporal areas of the emergency declarations. Generally, these waivers and modifications may assist patients who must be relocated due to the inaccessibility of health care facilities in the emergency area, allow beneficiaries to receive services despite having lost their documentation of eligibility, and allow providers to provide services in alternate temporary facilities. Specifically, the Secretary may take some or all of the following actions:

- waive conditions of participation, certification requirements, program participation, and pre-approval requirements under Medicare, Medicaid, or the Children’s Health Insurance Program;²⁶
- permit health care providers to provide care under Medicare, Medicaid, or the Children’s Health Insurance Program, even if they are not licensed by the state with jurisdiction over the emergency area;²⁷
- waive sanctions under the Emergency Medical Treatment and Active Labor Act (EMTALA) for certain transfers or redirections of patients away from hospital emergency rooms;²⁸
- waive sanctions for violations of the Stark law, which prohibits certain self-referrals by physicians;²⁹
- extend deadlines and other timetables for required activities;³⁰
- waive limitations on payments under Medicare Advantage for care and services provided by out-of-network providers;³¹ or
- waive sanctions and penalties for violations of the HIPAA Privacy Rule such as the use of protected health information for hospital directories, the disclosure of protected health information to patients’ families and friends, the distribution of health care providers’ and insurers’ privacy policies to patients, and individuals’ rights to request restrictions, privacy restrictions, or confidential communications.³²

²⁵ Section 1135(g), 42 U.S.C. §1320b-5(g).

²⁶ 42 U.S.C. § 1320b-5(b)(1).

²⁷ 42 U.S.C. § 1320b-5(b)(2). Providers must have equivalent licensing in another state and must not be affirmatively excluded from practicing in the emergency area.

²⁸ 42 U.S.C. § 1320b-5(b)(3). In the event of a pandemic infectious disease, patients can be relocated pursuant to a state’s pandemic preparedness plan, if one exists. 42 U.S.C. § 1320b-5(b)(3)(B)(ii). For more information on EMTALA’s requirements, see CRS Report RS22738, *EMTALA: Access to Emergency Medical Care*, by (name redacted).

²⁹ 42 U.S.C. § 1320b-5(b)(4). For more information on the Stark law, see CRS Report RS22743, *Health Care Fraud and Abuse Laws Covering Medicare and Medicaid: An Overview*, by Jennifer Staman, at 3-5.

³⁰ 42 U.S.C. § 1320b-5(b)(5).

³¹ 42 U.S.C. § 1320b-5(b)(6).

³² 42 U.S.C. § 1320b-5(b)(7). For more information on HIPAA enforcement, see CRS Report RL33989, *Enforcement of the HIPAA Privacy and Security Rules*, by (name redacted).

These waivers and modifications may be retroactively applied by the Secretary to the beginning of the period during which the concurrent declarations were in effect, and will generally remain in effect until the underlying emergency declarations end, or 60 days have elapsed since the date on which notice of the waivers or modifications was published.³³

On October 27, 2009, HHS Secretary Sebelius invoked Section 1135 to waive or modify the provisions described above, but only to the extent determined necessary or appropriate by the Centers for Medicare and Medicaid Services.³⁴ The invocation of Section 1135 covers the period from October 23, 2009, until expressly revoked, or such time as either the NEA declaration or the PHE declaration is terminated. The one exception to this general rule is the waiver of HIPAA privacy provisions, which is limited to those hospitals that have disaster protocols in operation, and will only apply during the 72 hours following a hospital's implementation of its disaster protocol.

Emergency Use Authorizations (for Unapproved Countermeasures)

Under Section 564 of the Federal Food, Drug, and Cosmetic Act (FFDCA), the Secretary may declare that an emergency exists which justifies the expedited use of certain medical countermeasures (1) on the basis of a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency; (2) on the basis of a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency; or (3) on the basis of a “determination by the Secretary [of HHS] of a public health emergency under Section 247d of Title 42 that affects, or has a significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agents.” Although a declaration under Section 564 of the FFDCA may be based on the declaration of a public health emergency under Section 319 of the PHS Act, the two are distinct. An FFDCA emergency declaration lasts up to a year, but can be renewed.³⁵

Upon a declaration under Section 564, the FDA commissioner may authorize the emergency use of a drug, device, or biological product during the effective period of the declaration.³⁶ An Emergency Use Authorization (EUA) may apply to a product that is not currently approved for commercial use by the Food and Drug Administration (FDA).³⁷ Alternatively, the subject of an EUA may already be an FDA-approved product, but the emergency use justifying the EUA may be one that is not presently approved by the FDA.³⁸ For example, a drug may be approved for use in the adult population but not for use in children, in which case an EUA may sanction its use by

³³ 42 U.S.C. § 1320b-5(e)(1). The Secretary may extend the effect of any waivers or modifications in 60-day increments. 42 U.S.C. § 1320b-5(e)(2).

³⁴ HHS Secretary, “Waiver or Modification of Requirements Under Section 1135 of the Social Security Act,” Oct. 27, 2009, available at http://www.flu.gov/professional/federal/h1n1_1135waiver_10272009.html.

³⁵ 21 U.S.C. § 360bbb-3(b)(2). The HHS Secretary must publish “each declaration, determination, advance notice of termination, and renewal” in the *Federal Register*. 21 U.S.C. § 360bbb-3(b)(4).

³⁶ 21 U.S.C. § 360bbb-3(a)(1). The authority to issue EUAs statutorily resides with the HHS Secretary, but has been administratively delegated to the FDA commissioner. See 21 U.S.C. § 393(d)(2) and FDA, Staff Manual Guide 1410.10.

³⁷ 21 U.S.C. § 360bbb-3(a)(2)(A).

³⁸ 21 U.S.C. § 360bbb-3(a)(2)(B).

children. A drug may also be approved only for a specific disease, in which case an EUA may permit the drug's use for treating different conditions.

The issuance of an EUA must also be supported by a number of findings.³⁹ First, the FDA commissioner must conclude that the underlying agent for which the emergency declaration was made can cause a serious or life-threatening disease or condition. Second, the commissioner must conclude, based on available scientific evidence, that (1) it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing the disease or condition or that the product may be effective in diagnosing, treating, or preventing a serious or life-threatening disease or condition caused by a product authorized for emergency use⁴⁰ and (2) it is reasonable to believe that the known and potential benefits of the product outweigh its known and potential risks. Third, the commissioner must conclude that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition. Finally, the commissioner must conclude that any other criteria for EUAs, which are prescribed in regulation, are met.

On April 27, 2009, the FDA issued four Emergency Use Authorizations in response to requests from the CDC to make available certain drugs, diagnostic tests, and respiratory protection devices for the response to the H1N1 influenza outbreak.⁴¹ In July of 2009, emergency use of a second unapproved diagnostic test was authorized,⁴² in August of 2009, the FDA authorized the emergency use of an H1N1 diagnostic test "to detect the virus in [American] troops serving overseas," and on October 23, 2009, the FDA authorized the emergency use of intravenous antiviral Peramivir for H1N1 influenza for certain patients and in certain settings.⁴³

International Health Regulations (IHR)⁴⁴

Overview of the IHR

In May 2005, the World Health Assembly adopted a revision of its 1969 International Health Regulations, giving a new mandate to the World Health Organization (WHO) and member states to increase their respective roles and responsibilities for the protection of international public health.⁴⁵ The IHR(1969) had focused on just three diseases (cholera, plague, and yellow fever). In

³⁹ 21 U.S.C. § 360bbb-3(c). In making these findings, the commissioner must consult with the directors of the National Institutes of Health and the Centers for Disease Control and Prevention prior to issuing the EUA.

⁴⁰ For example, Vaccinia Immune Globulin (VIG) may be used to treat complications that result from smallpox vaccinations. See CDC, *Smallpox Vaccination – Vaccine Immune Globulin*, available at <http://www.bt.cdc.gov/training/smallpoxvaccine/reactions/vig.html>.

⁴¹ See statement of Joshua M. Sharfstein, Acting Commissioner, FDA, before the Committee on Energy and Commerce, Subcommittee on Health, April 30, 2009, 111th Cong., 1st sess. Washington, D.C. See also the CDC's website at <http://www.cdc.gov/h1n1flu/eua/>.

⁴² See FDA, "FDA Authorizes Emergency Use of Another Test for 2009 H1N1 Influenza Virus," press release, July 24, 2009, <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm150305.htm>.

⁴³ FDA, "FDA Authorizes Emergency Use of H1N1 Test for U.S. Troops Serving Overseas," press release, Aug. 25, 2009, <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm180153.htm>. See also the FDA press release regarding Peramivir at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm187813.htm>.

⁴⁴ This section was written by (name redacted), Legislative Attorney.

⁴⁵ Fifty-eighth World Health Assembly, agenda item 13.1, Revision of the International Health Regulations, May 23, 2005, at <http://www.who.int/csr/ihr/en/>.

addition, compliance of State Parties⁴⁶ with the IHR(1969) was uneven, a result of, among other things, resource limitations in poorer countries, and political factors, such as the reluctance to announce the presence of a contagious disease within one's borders and face economic and other consequences.⁴⁷

The IHR(2005), which entered into force in June 2007, have broadened the scope of the 1969 regulations by addressing existing, new, and re-emergent diseases, as well as emergencies caused by non-infectious disease agents.⁴⁸ The IHR(2005) also include provisions regarding designated national points of contact, definitions of core public health capacities, disease control measures such as quarantine and border controls, and others. The IHR(2005) require WHO to recommend, and State Parties to use, control measures that are no more restrictive than necessary to achieve the desired level of health protection.

The IHR were agreed upon by a consensus process among the member states, and represent a balance between sovereign rights and a commitment to work together to prevent the international spread of disease. The IHR(2005) are binding on all WHO member states as of June 15, 2007, except for those that have rejected the regulations or submitted reservations.⁴⁹ While the IHR(2005) contain mechanisms such as negotiation and arbitration to assist States Parties in reaching mutually acceptable solutions where disputes arise, ultimately IHR(2005) do not provide an enforcement mechanism to compel compliance with WHO provisions.⁵⁰ The United States accepted the IHR(2005) with three reservations, including the reservation that it will implement the IHR(2005) in line with U.S. principles of federalism.⁵¹ Within five years of the entry into force date, State Parties must complete development of public health infrastructure that ensures full compliance with the regulations.

Declaration of a “Public Health Emergency of International Concern”

On April 25, 2009, WHO Director-General Dr. Margaret Chan, upon the advice of the Emergency Committee, declared that the influenza A(H1N1) virus outbreak constituted a “Public Health Emergency of International Concern” under the IHR(2005).⁵² This influenza outbreak marked the first time under the IHR(2005) that the Director-General convened the Emergency Committee and determined that a “Public Health Emergency of International Concern” existed. Article 12(1) of the IHR(2005) authorizes the WHO Director-General to make such a declaration, and Article 1 of the IHR(2005) defines a “Public Health Emergency of International Concern” as “an extraordinary event which is determined ... (i) to constitute a public health risk to other States through the international spread of disease and (ii) to potentially require a coordinated international response.”

⁴⁶ “State Party” is the name for WHO member states that have agreed to be bound by the IHR.

⁴⁷ M.G. Baker and D.P. Fidler, “Global Public Health Surveillance under New International Health Regulations,” *Emerging Infectious Diseases*, vol. 12, no. 7, July 2006, at <http://www.cdc.gov/ncidod/EID/vol12no07/05-1497.htm>.

⁴⁸ The full text of the IHR 2005 may be found at http://www.who.int/csr/ihr/IHR_2005_en.pdf.

⁴⁹ IHR(2005), Article 59.2.

⁵⁰ IHR, Article 56.

⁵¹ HHS Secretary Michael Leavitt announced the acceptance of the IHR(2005) by the United States on December 13, 2006. See News Release at <http://www.pandemicflu.gov/plan/federal/index.html>.

⁵² WHO, Statement by the WHO Director-General on Influenza A (H1N1), April 25, 2009, available at http://www.who.int/mediacentre/news/statements/2009/h1n1_20090425/en/index.html.

WHO Recommendations

Under the IHR(2005), if the WHO Director-General declares a “Public Health Emergency of International Concern,” then the Director-General must issue temporary recommendations which will depend upon the nature of the threat (Article 15(1)). The IHR(2005) do not preclude State Parties from implementing measures that achieve a greater level of health protection than WHO temporary recommendations, provided that such measures are (1) otherwise consistent with the IHR(2005), and (2) not more restrictive of international trade and travel, and not more invasive or intrusive to persons, than reasonably available alternatives that would achieve the appropriate level of health protection (Article 43(1)). Following the declaration of a “Public Health Emergency of International Concern” on April 25, 2009, the Director-General recommended that “all countries should intensify surveillance for unusual outbreaks of influenza-like illness and severe pneumonia.”⁵³ The Director-General, however, did not recommend any travel or trade restrictions.

On June 11, 2009, the WHO Director-General announced that the scientific criteria for an influenza pandemic had been met with regard to the influenza A(H1N1) virus, so that the WHO pandemic alert level was raised from 5 to 6.⁵⁴ Again, no travel, border closures, or trade restrictions were recommended.

International Response to WHO Recommendations

The WHO advised that travel restrictions would have “very little effect on stopping the virus from spreading, but would be highly disruptive to the travel community.”⁵⁵ Despite this recommendation, some countries, such as China and several South American countries, implemented outright travel bans to or from Mexico. Other countries interrupted sales of pork products from the United States, disregarding a WHO determination, confirmed by scientists, that cooked pork does not transmit the virus.⁵⁶

According to the IHR(2005), State Parties may apply measures that affect travel, even if not recommended by the Director-General.⁵⁷ However, such measures must be no more restrictive of travel, or more intrusive to persons, than reasonably available alternatives that would achieve the appropriate level of health protection. Thus, State Parties are not supposed to bar the entry of a conveyance for public health reasons, but rather are to manage a public health threat through isolation, quarantine, disinfection, or other such applicable methods.⁵⁸ If a State Party implements additional health measures significantly interfering with international traffic, the public health

⁵³ Id.

⁵⁴ Dr. Margaret Chan, Director-General of the World Health organization, “World Now at the Start of 2009 Influenza Pandemic,” http://www.who.int/mediacentre/news/statements/2009/h1n1_pandemic_phase6_20090611/en/index.html.

⁵⁵ WHO, Epidemic and pandemic alert and response (EPR)/ Travel: is it safe to travel? Available at http://www.who.int/csr/disease/swineflu/frequently_asked_questions/travel/en/index.html. See also CRS Report R40588, *The 2009 Influenza Pandemic: U.S. Responses to Global Human Cases*, by (name redacted).

⁵⁶ Rebecca Katz, “Use of Revised International Health Regulations During Influenza A(H1N1) Epidemic, 2009,” 15 EMERG INFECT DIS. 1165-1170 (August 2009).

⁵⁷ IHR, Article 42, “Additional Health Measures.” In addition, despite scientific evidence that eating pork does not cause influenza, a number of countries banned pork products. See CRS Report R40575, *Potential Farm Sector Effects of 2009 H1N1 “Swine Flu”: Questions and Answers*, by (name redacted), for a discussion of international responses to restrictions on pork products following the influenza A(H1N1) outbreak.

⁵⁸ IHR, Article 28.1, “Ships and aircraft at points of entry.”

rationale and relevant scientific information for the measures must be provided to WHO. The WHO will then share the information with State Parties and institute procedures to find a mutually acceptable solution.⁵⁹ Ultimately, however, the IHR(2005) do not provide an enforcement mechanism to compel compliance with WHO recommendations.⁶⁰

Quarantine and Isolation Authority⁶¹

Federal Authorities

Although the terms are often used interchangeably, quarantine and isolation are two distinct concepts. Quarantine typically refers to the “(s)eparation of individuals who have been exposed to an infection but are not yet ill from others who have not been exposed to the transmissible infection.”⁶² Isolation refers to the “(s)eparation of infected individuals from those who are not infected.”⁶³ Primary quarantine authority typically resides with state health departments and health officials; however, the federal government has jurisdiction over interstate and border quarantine.

Federal quarantine and isolation authority may be found in Section 361 of the Public Health Service Act, 42 U.S.C. § 264, wherein Congress has given the Secretary of HHS the authority to make and enforce regulations necessary “to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession.”⁶⁴ While also providing the Secretary with broad authority to apprehend, detain, or conditionally release a person, the law limits the Secretary’s authority to the communicable diseases published in an Executive Order of the President.⁶⁵ Executive Order 13295 lists the communicable diseases for which this quarantine authority may be exercised, and specifically includes influenza viruses which have the potential to cause a pandemic.⁶⁶ In 2000, the Secretary of HHS transferred certain authorities, including interstate

⁵⁹ IHR, Article 43, “Additional Health Measures.” While the IHR(2005) do not include an enforcement mechanism for State Parties that fail to comply with their provisions, the WHO considers the potential consequences of non-compliance within the global community, especially in economic terms, to be a powerful compliance tool. The IHR(2005) (Article 56) contain a dispute settlement mechanism to resolve conflicts which may arise among State Parties when applying or interpreting the regulations, including options such as negotiation, mediation, conciliation, or arbitration, or referral to the Director-General of WHO, if agreed to by all the parties to the dispute.

⁶⁰ Lawrence O. Gostin, “Influenza A(H1N1) and Pandemic Preparedness Under the Rule of International Law,” 301 JAMA 2376-2378 (June 10, 2009).

⁶¹ This section was written by (name redacted), Legislative Attorney. For a detailed discussion of quarantine and isolation, see CRS Report RL33201, *Federal and State Quarantine and Isolation Authority*, by (name redacted) and (name redacted).

⁶² Homeland Security Council, National Strategy for Pandemic Influenza: Implementation Plan (GPO May 2006). For a discussion of the history of quarantines in the United States see Felice Batlan, “Law in the Time of Cholera: Disease, State Power, and Quarantines Past and Future,” 80 TEMP. L. REV. 53 (2007).

⁶³ Homeland Security Council, National Strategy for Pandemic Influenza: Implementation Plan (GPO May 2006).

⁶⁴ 42 U.S.C. § 264(a). Violation of federal quarantine and isolation regulations is a criminal misdemeanor, punishable by fine and/or imprisonment, 42 U.S.C. § 271.

⁶⁵ 42 U.S.C. § 264(b).

⁶⁶ See also E.O. 13375, April, 2005, which amended E.O. 13295. The diseases listed are cholera, diphtheria, infectious tuberculosis, plague, smallpox, yellow fever, viral hemorrhagic fevers, severe acute respiratory syndrome (SARS), and influenza viruses which have the potential to cause a pandemic. Other new threats would have to be added to E.O. 13295 in order to be “quarantinable diseases.”

quarantine authority, to the Director of the CDC.⁶⁷ Both interstate and foreign quarantine measures are now carried out by CDC's Division of Global Migration and Quarantine.⁶⁸

HHS also works closely with the Department of Homeland Security (DHS) and its agencies. HHS and DHS signed a memorandum of understanding in 2005 that sets forth specific cooperation mechanisms to implement their respective statutory responsibilities for quarantine and other public health measures.⁶⁹ DHS has three agencies that may aid CDC in its enforcement of quarantine rules and regulations pursuant to 42 U.S.C. § 268(b). They are U.S. Customs and Border Protection, U.S. Immigration and Customs Enforcement, and the United States Coast Guard. In addition to DHS, CDC may also rely on other federal law enforcement agencies and state and local law enforcement agencies.

Federal and State Coordination

While the federal government has authority to authorize quarantine and isolation under certain circumstances, it should be noted that the primary authority for quarantine and isolation exists at the state level as an exercise of the state's police power. States conduct these activities in accordance with their particular laws and policies.⁷⁰ CDC acknowledges this deference to state authority as follows:

In general, CDC defers to the state and local health authorities in their primary use of their own separate quarantine powers. Based upon long experience and collaborative working relationships with our state and local partners, CDC continues to anticipate the need to use this federal authority to quarantine an exposed person only in rare situations, such as events at ports of entry or in similar time-sensitive settings.⁷¹

Section 311 of the PHS Act⁷² provides for federal-state cooperative activities to enforce quarantines. The federal government may help states and localities enforce their quarantines and

⁶⁷ 42 C.F.R. Part 70. Regulations regarding quarantine upon entry into the United States from foreign countries are also administered by the CDC, see 42 C.F.R. Part 71.

⁶⁸ See CDC Division of Global Migration and Quarantine home page at <http://www.cdc.gov/ncidod/dq/index.htm>.

⁶⁹ http://www.dhs.gov/xnews/testimony/testimony_1181229544211.shtm.

⁷⁰ A new development in the law relating to quarantine is the possible use of self-imposed or home quarantines. States may need to consider whether their ability to impose quarantine also includes the authorities necessary to support a population asked to voluntarily stay at home for a period of time. Federal and state authorities generally provide for the care of persons mandatorily quarantined, but voluntary home-quarantine situations may pose new issues. See Steven D. Gravely, et al., *Emergency Preparedness and Response: Legal Issues in a Changing World*, 17 THE HEALTH LAWYER 1 (June 2005).

⁷¹ Q&A on Executive Order 13295, available at http://www.cdc.gov/ncidod/dq/qa_influenza_amendment_to_eo_13295.htm. The complexities of this shared power have been noted. One analysis observed that "When it comes to the exercise of isolation and quarantine powers, reality tends to be messier than the conceptual realm. Public health officials need clear lines of authority in emergency situations, often the moments when isolation and quarantine might be required. Unfortunately, confusion about which level of government should take the lead often occurs, thus revealing the ability of quarantine powers to spotlight difficulties federalism poses for public health." David P. Fidler, Lawrence O. Gostin, and Howard Markel, "Through the Quarantine Looking Glass: Drug-Resistant Tuberculosis and Public Health Governance, Law and Ethics," 35 J. OF LAW, MEDICINE & ETHICS 616 (2007). Another commentator has noted that "Given the variation in due process rights in connection with quarantine, which may be afforded under federal and state law, one can foresee the possibility of considerable conflict." Felice Batlan, "Law in the Time of Cholera: Disease, State Power, and Quarantines Past and Future," 80 TEMP. L. REV. 53, 119 (2007).

⁷² 42 U.S.C. § 243.

other health regulations and, in turn, may accept state and local assistance in enforcing federal quarantines. The federal government may also assist with or take over the management of an *intrastate* incident if requested by a state or if the federal government determines local efforts are inadequate.⁷³ Under the authority of 42 U.S.C. § 97, the Secretary of HHS may request the aid of U.S. Customs and Border Protection, Coast Guard, and military officers in the execution of quarantines imposed by states on vessels coming into ports.

Proposed Federal Regulations

The CDC, on November 22, 2005, announced proposed changes to its quarantine regulations at 42 C.F.R. Parts 70 and 71.⁷⁴ These proposed regulations have not been finalized, but Congress subsequently mandated that they be promulgated by June 10, 2009.⁷⁵ These changes will constitute the first significant revision of the regulations in Parts 70 and 71 in 25 years. The proposed changes are an outgrowth of the CDC's experience during the spread of Severe Acute Respiratory Syndrome (SARS) in 2003, when the agency experienced difficulties locating and contacting airline passengers who might have been exposed to SARS during their travels. In announcing the proposed regulations, then CDC Director Julie Gerberding said, "[t]hese updated regulations are necessary to expedite and improve CDC operations by facilitating contact tracing and prompting immediate medical follow up of potentially infected passengers and their contacts."⁷⁶

The proposed regulations would expand reporting requirements for ill passengers⁷⁷ on board flights and ships arriving from foreign countries. They would also require airlines and ocean liners to maintain passenger and crew lists with detailed contact information and to submit these lists electronically to CDC upon request.⁷⁸ The lists would be used to notify passengers of their suspected exposure if a sick person were not identified until after the travelers had dispersed from an arriving carrier. The proposed regulations address the due process rights of passengers who might be subjected to quarantine after suspected exposure to disease; the regulations also provide for an appeal process.⁷⁹

⁷³ 42 U.S.C. § 264 (c) and 42 C.F.R. § 70.2.

⁷⁴ See 70 *Fed. Reg.* 71892 (November 30, 2005), <http://www.cdc.gov/ncidod/dq/nprm/>. These proposed regulations were available for a 60-day comment period, which was extended for an additional 30 days, closing on March 1, 2006. See 71 *Fed. Reg.* 4544 (January 27, 2006), proposed Section 70.20 and 71.23 of 42 C.F.R.

⁷⁵ Section 121(c) of P.L. 110-392 states: "Not later than 240 days after the date of enactment of this Act, the Secretary of Health and Human Services shall promulgate regulations to update the current interstate and foreign quarantine regulations found in parts 70 and 71 of Title 42, Code of Federal Regulations."

⁷⁶ "CDC Proposes Modernizing Control of Communicable Disease Regulation, USA," *Medical News Today*, November 23, 2005, at <http://www.medicalnewstoday.com/medicalnews.php?newsid=34042>. Since the SARS outbreak, the CDC has increased its quarantine stations nationwide from 8 to 20. See <http://www.cdc.gov/ncidod/dq/index.htm>.

⁷⁷ The definition of ill person would be expanded to include anyone who has a fever of at least 100.4 degrees plus one of the following: severe bleeding, jaundice, or severe, persistent cough accompanied by bloody sputum, or respiratory distress. (Section 70.1 of proposed regulations).

⁷⁸ *Id.* The lists, in electronic format, would have to be kept for 60 days after arrival, and be able to be submitted within 12 hours of a CDC request. The lists would include names, contact information and seat assignments.

⁷⁹ Proposed section 70.20 and 71.23 of 42 CFR.

Border Entry Issues ⁸⁰

Inadmissibility of Infected Aliens

Those most easily excluded from the United States are aliens already infected with the influenza A(H1N1) virus. The Immigration and Nationality Act (INA) specifically bars aliens who are determined to have “a communicable disease of public health significance,” from receiving visas and admission into the United States.⁸¹ “A communicable disease of public health significance” is defined by the Secretary of Health and Human Services by regulation.⁸² Although the regulatory definition does not specifically include influenza A(H1N1), it does include, by reference, communicable diseases as listed in a Presidential Executive Order issued pursuant to section 361(b) of the Public Health Service Act.⁸³ The relevant order, Executive Order 13295, as amended by Executive Order 13375, specifies “[i]nfluenza caused by novel or reemergent influenza viruses that are causing, or have the potential to cause, a pandemic” as a communicable disease for purposes of section 361(b).⁸⁴ Thus, for purposes of the INA, the influenza A(H1N1) virus is a ground for inadmissibility into the United States. Of course, this law only applies to aliens, not citizens, and prior to inadmissibility being triggered, the alien must be diagnosed with the influenza A(H1N1) virus.⁸⁵ These considerations could therefore prevent this provision from being the most effective means to interdict individuals infected with the influenza A(H1N1) virus from entering the country.

Border Quarantines of Citizens or Aliens

There are currently no legal provisions that can exclude American citizens from the United States solely because of an infection with a communicable disease. The primary means to prevent infected citizens from introducing these diseases into the United States is to place them into quarantine or isolation at the border rather than deny them entry outright. As noted above, the Secretary has the authority to promulgate regulations to prevent the entry and spread of communicable diseases from foreign countries into the United States. The implementing regulations at 42 C.F.R. Part 71 specify that when there is reason to believe an arriving person is infected with “any communicable disease listed in an Executive Order, as provided under section 361(b) of the Public Service Act,” the person may be isolated, quarantined, or placed under surveillance or disinfected if deemed necessary to prevent the introduction of the communicable disease.⁸⁶ “Influenza caused by novel or reemergent influenza viruses that are causing, or have the potential to cause, a pandemic” is one such disease that can warrant quarantine.⁸⁷

⁸⁰ This section was written by Yule Kim, Legislative Attorney.

⁸¹ INA § 212(a)(1), 8 U.S.C. §1182(a)(1) (Any alien who is determined (in accordance with regulations prescribed by the Secretary of Health and Human Services) to have a communicable disease of public health significance...is inadmissible).

⁸² 42 C.F.R. § 34.2(b).

⁸³ 42 U.S.C. § 264.

⁸⁴ Exec. Order No. 13295, 68 FR 17255 (April 4, 2003) *as amended by* Exec. Order. No. 13375, 70 FR 17299 (April 1, 2005).

⁸⁵ As a practical matter, there is not currently a real-time test that could be used to determine whether an apparently ill person is infected with this virus. Tests currently available require a day or more to perform.

⁸⁶ 42 C.F.R. § 71.32.

⁸⁷ Exec. Order No. 13295, 68 FR 17255 (April 4, 2003) *as amended by* Exec. Order. No. 13375, 70 FR 17299 (April 1, (continued...))

Closing the Border

The most drastic measure discussed so far is “to close the borders.” Presumably, this would entail a blanket bar on all aliens and citizens seeking entry into the United States regardless of their health. There appear to be no laws specifically authorizing an executive agency to take such action. However, Congress could presumably enact a law to do so, at least with regard to aliens, because the Supreme Court has long recognized “the power to expel or exclude aliens as a fundamental sovereign attribute that is largely immune from judicial control.”⁸⁸ However, United States citizens cannot be barred from entering the United States.⁸⁹ Thus, if Congress were to theoretically “close the borders,” it could do so only by excluding aliens.

In the absence of an act of Congress, it may be possible for the President to “close the borders” to aliens by Executive Order. However, this course of action appears to be fraught with legal and practical challenges, which would likely result in extensive litigation. Because Congress has not given the President authority to conduct blanket closings of borders, it would appear that the President could do so only if the exclusion power is one where he has concurrent authority with Congress.⁹⁰ Although this exclusion power is characterized as a power “exercised by the Government’s political departments largely immune from judicial control,”⁹¹ the President appears to have rarely exercised any authority within this realm outside of the authority expressly delegated by an act of Congress. Considering the rather extensive inadmissibility regime codified within the Immigration and Nationality Act, it would appear unlikely that the President can exercise this power without express congressional authorization.

Airlines and Travel Restrictions⁹²

Airline Corporate Policies

Generally, airlines are under no legal obligation to provide transportation simply because a person has a valid ticket. As a matter of corporate policy, airlines have inserted clauses into their “contract of carriage” reserving the right to deny transportation to any ticketed passenger who presents himself or herself in a condition that may adversely affect the safety and/or security of the flight, its crew, or the other passengers. For example, Midwest Airlines’ “contract of carriage” specifically authorizes the refusal of transportation or removal from a flight if the passenger’s:

age, mental or physical condition, disability or impairment is such that the passenger would need excessive or unusual assistance in the event of an emergency or to take care of his/her physical needs in flight.⁹³

(...continued)

2005).

⁸⁸ *Shaughnessy v. United States ex rel. Mezei*, 345 U.S. 206, 210 (1953). See also *Chae Chan Ping v. United States*, 130 U.S. 581, 609 (1889) (*Chinese Exclusion Case*) (Bradley, J., concurring).

⁸⁹ *United States v. Wong Kim Ark*, 169 U.S. 649, 653 (1898) (holding that a person born in the United States could not be excluded from the country by the Chinese Exclusion Act); *Perez v. United States*, 502 F. Supp. 2d 301, 306 (N.D.N.Y. 2006).

⁹⁰ *Youngstown Sheet and Tube Co. v. Sawyer*, 343 U.S. 579, 637 (1952) (Jackson, J., concurring).

⁹¹ *Mezei*, 345 U.S. at 210.

⁹² This section was written by (name redacted), Legislative Attorney.

Thus, it is conceivable that a person presenting himself or herself for air travel with symptoms of illness could be denied the right to board.⁹⁴ Application and interpretation of this provision appears to be at the sole discretion of the air carrier. Should an individual be refused transportation, he or she may, depending on the terms of the “contract of carriage,” be eligible for a refund for any unused portion of the ticket purchased minus any taxes or applicable service fees.

CDC has issued interim guidance to assist airline crew in identifying passengers who may be infected with influenza A(H1N1).⁹⁵ This guidance provides that any passengers with certain symptoms should be reported immediately to the CDC quarantine station in the airport where the plane is expected to land.

Public Health “Do Not Board” List

Federal agencies have developed a new travel restriction tool to prevent the spread of communicable diseases of public health significance.⁹⁶ The public health Do Not Board (DNB) list was developed by the Department of Homeland Security (DHS) and the CDC, and made operational in June 2007.⁹⁷ The DNB list enables domestic and international health officials to request that persons with communicable diseases who meet specific criteria and pose a serious threat to the public be restricted from boarding commercial aircraft departing from or arriving in the United States. The list provides a new tool for management of emerging public health threats when local public health efforts are not sufficient to keep people with certain contagious diseases from boarding commercial flights.⁹⁸

Federal Airspace Authority

In addition to the legal authority over individual passengers, the federal government possesses the legal authority to regulate and control the navigable airspace of the United States. The notion that every nation has absolute and exclusive sovereignty over the airspace above its defined territory is a hallmark aviation principle that has been recognized by international agreements dating back

(...continued)

⁹³ See *Midwest Airlines, Contract of Carriage*, available at http://www.midwestairlines.com/uploadedFiles/Travel_Tools/Travel_Policies/ContractofCarriage_20081222.pdf

⁹⁴ Airlines also have general authority to refuse to board passengers with communicable diseases under certain circumstances pursuant to Air Carrier Access Act of 1986 (ACAA) regulations. See 49 U.S.C. § 41705, 14 C.F.R. § 382.51. Decisions to deny passengers scheduled to fly must be based on “reasonable judgment that relies on current medical knowledge or on the best available objective evidence,” that the individual poses a direct threat to the health and safety of others. See, discussion, *infra* at “Federal Nondiscrimination Laws”, regarding the application of federal nondiscrimination laws, including the nondiscrimination provisions of the ACAA.

⁹⁵ <http://www.cdc.gov/h1n1flu/aircrew.htm>

⁹⁶ For a summary of recent actions taken by DHS and the CDC to improve procedures to restrict persons with serious communicable diseases who intend to travel despite medical advice, see Government Accountability Office, *Public Health and Border Security: HHS and DHS Should Further Strengthen Their Ability to Respond to TB Incidents*. GAO-09-58. Washington, D.C: October, 2008.

⁹⁷ CDC. *Federal Air Travel Restrictions for Public Health Purposes—United States, June 2007-May 2008*, MMWR 2008 Sep. 19; 57 (37): 1009-12, available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5737a1.htm>.

⁹⁸ The list, which applies to all citizens and foreign nationals, appears to have been developed under the general authority of the Aviation and Transportation Security Act of 2001, at 49 U.S.C. § 114(f) and (h).

to the 1919 Convention for the Regulation of Aerial Navigation.⁹⁹ The United States Congress has, by statute, delegated the legal authority over airspace regulation to the Administrator of the Federal Aviation Administration (FAA).¹⁰⁰ Pursuant to this authority, it appears that the FAA can prevent airplanes from entering the airspace of the United States if they originate from a country experiencing incidents of communicable disease (e.g., airplane from Mexico to any airport in the United States). Similarly, the FAA could deny airspace access to any airplane originating in the United States whose intention it is to operate into a country experiencing incidents of communicable disease (e.g., an airplane from any domestic airport to Mexico). Finally, the FAA can prevent aircraft originating in third countries from utilizing the airspace of the United States to travel to a country experiencing incidents of communicable disease (e.g., airplane originating in Canada destined for Mexico).

School Closures¹⁰¹

Since children tend to be more susceptible than adults to infection and are responsible for more secondary transmission,¹⁰² studies have suggested that community-wide school closures may help mitigate the impact of an influenza pandemic.¹⁰³ The Centers for Disease Control and Prevention (CDC), in interim pre-pandemic planning guidance, included school closures as a tool for mitigation of a pandemic and, in some cases, the period of closure could be as long as 12 weeks.¹⁰⁴ During the spring 2009 H1N1 influenza outbreak over 700 schools closed for varying lengths of time.¹⁰⁵ However, additional information on the virus led to less use of school closures. CDC issued revised guidance on May 5, 2009, and noted that new information, indicating the

⁹⁹ Convention for the Regulation of Aerial Navigation, Oct. 13, 1919, Art. 1, 11 L.N.T.S. 173, 190.

¹⁰⁰ 49 U.S.C. § 40103 (2006).

¹⁰¹ This section was written by (name redacted), Legislative Attorney. For more information on the school closure issue see CRS Report R40554, *The 2009 Influenza Pandemic: An Overview*, by (name redacted) and (name redacted).

¹⁰² U.S. Department of Education, *H1N1 Flu and U.S. Schools: Answers to Frequently Asked Questions*, <http://www.ed.gov/admins/lead/safety/emergencyplan/pandemic/guidance/flu-faqs.pdf>.

¹⁰³ Centers for Disease Control and Prevention, *Interim Pre-pandemic Planning Guidance: Community Strategy for Pandemic Influenza Mitigation in the United States*, at 27. http://www.pandemicflu.gov/plan/community/community_mitigation.pdf. Other school policies may also have an effect on the spread of an influenza virus. The National Association of State Boards of Education (NASBE) updated its statement on influenza and school preparedness to suggest that “[s]tates may want to consider adding the flu vaccination to the list of mandatory immunizations children are required to have to attend school.” <http://www.nasbe.org/index.php/file-repository?func=startdown&id=887>.

¹⁰⁴ Centers for Disease Control and Prevention, *Interim Pre-pandemic Planning Guidance: Community Strategy for Pandemic Influenza Mitigation in the United States*, http://www.pandemicflu.gov/plan/community/community_mitigation.pdf. CDC has also issued guidance relating to higher education. See http://www.cdc.gov/h1n1flu/guidance/guidelines_colleges.htm.

¹⁰⁵ The U.S. Department of Education responded to the spring 2009 H1N1 outbreak by holding a conference call on school closures with state and district education officials, <http://www.ed.gov/admins/lead/safety/emergencyplan/pandemic/guidance/trans042709.pdf>; publishing guidance, U.S. Department of Education, *H1N1 Flu and U.S. Schools: Answers to Frequently Asked Questions*, <http://www.ed.gov/admins/lead/safety/emergencyplan/pandemic/guidance/flu-faqs.pdf>, <http://www.pandemicflu.gov/plan/school/index.html>; and other information, <http://www.ed.gov/admins/lead/safety/emergencyplan/pandemic/guidance/flu-faqs.pdf>, <http://rems.ed.gov/index.cfm?event=PandemicPreparedns4Schools>. In addition, President Obama originally called for school closures if there were students ill with the influenza A(H1N1) virus, <http://www.whitehouse.gov/blog/09/04/30/The-Presidents-Remarks-on-H1N1>. As of May 5, 2009, 726 schools out of more than 100,000 nationwide were closed due to the outbreak. Frank Wolfe, “NASBE: Schools Should Consider Mandatory Flu Shots,” 42 *Education Daily* No. 83, at 3 (May 6, 2009).

disease severity was similar to that of seasonal influenza, warranted revision of the original recommendation.¹⁰⁶

On August 7, 2009, CDC issued new guidelines for elementary and secondary schools to help decrease the spread of flu among students and school staff.¹⁰⁷ This guidance emphasizes that “[t]he decision to dismiss students should be made locally and should balance the goal of reducing the number of people who become seriously ill or die from influenza with the goal of minimizing social disruption and safety risks to children sometimes associated with school dismissal.”¹⁰⁸ The recommended school responses are staying home when sick for at least 24 hours after a fever, separating ill students and staff, using hand hygiene, routinely cleaning commonly touched surfaces, treating high-risk students and staff early, and considering selective school dismissals.¹⁰⁹ If the flu appears to be causing more severe disease, other additional measures may be recommended, including active screening for fevers, advising high-risk students and staff to stay home, advising students with ill household members to stay home, and school dismissals.¹¹⁰ WHO has issued similar advice relating to schools, noting that “[e]xperience to date has demonstrated the role of schools in amplifying transmission of the pandemic virus, both within schools and into the wider community.”¹¹¹

CDC and the Department of Education (ED) have established a school dismissal monitoring system in order to track school dismissals.¹¹² During testimony before the Senate Committee on Homeland Security and Government Affairs on October 21, 2009, Secretary Duncan stated that from August 3 through October 9, 501 schools had closed for at least one day.¹¹³ In addition, ED has provided recommendations to help schools maintain the continuity of learning both for individuals or small groups of students and for large groups of students disrupted by school dismissals or large numbers of faculty absences.¹¹⁴

¹⁰⁶ The updated guidance recommended that schools not close for suspected or confirmed cases of influenza A(H1N1) unless the number of faculty or students absent interferes with the school’s ability to function. In addition, it was recommended that the schools that were closed reopen. http://www.cdc.gov/h1n1flu/K12_dismissal.htm; <http://www.cdc.gov/h1n1flu/mitigation.htm>.

¹⁰⁷ <http://www.flu.gov/plan/school/schoolguidance.html>; <http://www.flu.gov/plan/school/k12techreport.html>. See also “Preparing for the Flu (Including 2009 H1N1 Flu): A Communication Toolkit for Schools (Grades K-12),” <http://www.flu.gov/plan/school/toolkit.html>. Separate updated guidance for child care settings will be issued.

¹⁰⁸ <http://www.flu.gov/plan/school/schoolguidance.html>. School closures have a direct economic cost due to worker absenteeism, including absenteeism by health care workers. A study by the Brookings Institute found that closing all the schools in the U.S. for four weeks could cost between \$10 billion and \$47 billion dollars and lead to a reduction of 6% to 19% in key health care personnel. Howard Lempel, Ross A. Hammond, Joshua M. Epstein, “Economic Cost and Health Care Workforce Effects of School Closures in the U.S.,” *Center on Social and Economics Dynamics Working Paper No. 55* (September 30, 2009), http://www.brookings.edu/papers/2009/0930_school_closure_lempe_hammond_epstein.aspx.

¹⁰⁹ *Id.*

¹¹⁰ *Id.*

¹¹¹ WHO, “Measures in School Settings,” Pandemic (H1N1) 2009 Briefing Note 10, http://www.who.int/csr/disease/swineflu/notes/h1n1_school_measures_20090911/en/index.html.

¹¹² http://www.cdc.gov/h1n1flu/schools/dismissal_form/index.htm.

¹¹³ *H1N1 Flu: Monitoring the Nation’s Response: Hearings Before the Senate Committee on Homeland Security and Government Affairs*, 111th Cong. (2009) (Testimony of Secretary Arne Duncan) at http://hsgac.senate.gov/public/index.cfm?FuseAction=Hearings.Hearing&Hearing_ID=cbe5331e-19ab-41d5-bffe-7610f97708f0.

¹¹⁴ “Preparing for the Flu: Department of Education Recommendations to Ensure the Continuity of Learning for Schools(K-12) During Extended Student Absence or School Dismissal,” <http://www.ed.gov/admins/lead/safety/emergencyplan/pandemic/guidance/continuity-recs.pdf>. CDC also has issued guidance for institutions of higher (continued...)

School closures may spawn numerous policy issues including when and how long schools should be closed; how schools can comply with standardized testing requirements; and whether school meals programs should continue.¹¹⁵ However, school closures also raise legal issues. The main question is who has the legal authority to institute a school closure. A CDC-requested study of state legal authorities to close schools found that school closure is legally possible in most jurisdictions during both routine and emergency situations.¹¹⁶ The study also indicated that state authority for closure may be vested at various levels of government and in different departments, generally the state or local education agencies or state or local departments of health.¹¹⁷ However, if there is a state or local declaration of emergency, the authority to close schools shifts to the state emergency management agencies in most jurisdictions.¹¹⁸ These varying laws may create legal controversies over who has the authority to make the school closure decision. In addition, there could be legal challenges to whatever school closure decision is made, particularly if the duration of a school closing is lengthy. Issues may also arise regarding whether school employees will be paid for the time the schools are closed.¹¹⁹

Other legal issues regarding school closures may be raised under the Individuals with Disabilities Education Act (IDEA).¹²⁰ IDEA requires that states receiving IDEA funding provide children with disabilities a free appropriate public education (FAPE).¹²¹ Although IDEA does not specifically address school closures due to a pandemic, the Department of Education has stated that schools must be careful not to discriminate on the basis of disability when providing educational services.¹²² ED noted that if schools are closed due to H1N1 and no educational services are provided to any children, services do not have to be provided to children with disabilities. However, if services are provided to the general student body, students with disabilities must have

(...continued)

education regarding responses to H1N1. Like the guidance for elementary and secondary schools, the higher education guidance contains two main sets of recommendations: (1) recommendations which assume that H1N1 has a severity similar to the spring/summer outbreak, and (2) recommendations to consider if the disease becomes more severe. These recommendations parallel those for elementary and secondary school but also address issues relating to the close living conditions experienced in college dormitories. “CDC Guidance for Responses to Influenza for Institutions of Higher Education during the 2009-2010 Academic Year,” <http://www.cdc.gov/h1n1flu/institutions/guidance/>.

¹¹⁵ For a discussion of these issues and others see U.S. Department of Education, *H1N1 Flu and U.S. Schools: Answers to Frequently Asked Questions*, <http://www.ed.gov/admins/lead/safety/emergencyplan/pandemic/guidance/flu-faqs.pdf>; <http://www.pandemicflu.gov/plan/school/index.html>.

¹¹⁶ James G. Hodge, Jr., Dhruvajyoti Bhattacharya, and Jennifer Gray, “Legal Preparedness for School Closures in Response to Pandemic Influenza and Other Emergencies,” <http://www.pandemicflu.gov/plan/school/schoolclosures.pdf>. This study was summarized in James G. Hodge, Jr. “The Legal Landscape for School Closures in Response to Pandemic Flu or Other Public Health Threats,” 7 *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science* 45 (2009).

¹¹⁷ See James G. Hodge, Jr. “The Legal Landscape for School Closures in Response to Pandemic Flu or Other Public Health Threats,” 7 *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science* 45 (2009), <http://www.prepare.pitt.edu/pdf/school-closures.pdf>.

¹¹⁸ *Id.* at 49. “The ability of departments of health and education in nonemergencies to close schools is largely supplanted by the legal authority of state emergency management agencies during declared emergencies in 98% of the jurisdictions studied.”

¹¹⁹ <http://www.law.com/jsp/tx/PubArticleTX.jsp?id=1202430362015&slreturn=1>.

¹²⁰ 20 U.S.C. §1400 *et seq.*

¹²¹ For a more detailed discussion of IDEA see CRS Report R40690, *The Individuals with Disabilities Education Act (IDEA): Statutory Provisions and Recent Legal Issues*, by (name redacted).

¹²² “Guidance on Flexibility and Waivers for SEAs, LEAs, Postsecondary Institutions, and Other Grantee and Program Participants,” <http://www.ed.gov/admins/lead/safety/emergencyplan/pandemic/index.html>.

equal access to these opportunities.¹²³ ED also observed that compensatory services may need to be provided for a student with a disability in certain circumstances.¹²⁴

Vaccinations

Background¹²⁵

Vaccination with a matched strain of influenza virus is considered the most effective measure to prevent severe illness from flu.¹²⁶ Since influenza viruses continuously change, creating a matched strain is not possible until a virus is circulating. The production of a vaccine is time consuming, and the vaccine will become available in phases, not all at one time. When the vaccine is first produced, it is likely that the demand for the H1N1 vaccine will be greater than the supply.¹²⁷ The first doses have become available but due to manufacturing issues, there is not as much vaccine currently available as was anticipated.¹²⁸ It should be noted that a mass vaccination campaign presents an array of challenges, including how to transport vaccines safely, redistribute vaccines, track vaccinations, and monitor adverse effects.¹²⁹

Vaccines may be mandated in some circumstances; however, except for the Department of Defense and with respect to immigration, it is generally a matter of state, rather than federal, authority.¹³⁰ The current federal plans for a possible pandemic flu vaccination campaign in the fall assume that any such campaign would be voluntary.¹³¹

¹²³ *Id.*

¹²⁴ *Id.*

¹²⁵ This section was written by (name redacted).

¹²⁶ For a more detailed discussion of vaccine development, licensing, and use see CRS Report R40554, *The 2009 Influenza Pandemic: An Overview*, by (name redacted) and (name redacted).

¹²⁷ http://www.who.int/csr/disease/swineflu/frequently_asked_questions/vaccine_preparedness/production_availability/en/index.html. CDC has stated that “We do not expect that there will be a shortage of novel H1N1 vaccine, but flu vaccine availability and demand can be unpredictable and there is some possibility that initially, the vaccine will be available in limited quantities.” “CDC Novel H1N1 Vaccination Planning Q&A,” <http://www.cdc.gov/h1n1flu/vaccination/statelocal/qa.htm>.

¹²⁸ <http://www.cdc.gov/h1n1flu/vaccination/vaccinesupply.htm>.

¹²⁹ Trust for America’s Health, *H1N1 Challenges Ahead*, <http://healthyamericans.org/reports/h1n1/TFAH2009challengesahead.pdf>.

¹³⁰ CRS Report RS21414, *Mandatory Vaccinations: Precedent and Current Laws*, by (name redacted); CRS Report RL34708, *Religious Exemptions for Mandatory Health Care Programs: A Legal Analysis*, by Cynthia Brougher; CRS Report R40570, *Immigration Policies and Issues on Health-Related Grounds for Exclusion*, by (name redacted) and (name redacted).

¹³¹ “With the new H1N1 virus continuing to cause illness, hospitalizations and deaths in the US during the normally flu-free summer months and some uncertainty about what the upcoming flu season might bring, CDC’s Advisory Committee on Immunization Practices has taken an important step in preparations for a voluntary novel H1N1 vaccination effort to counter a possibly severe upcoming flu season.” CDC, Novel H1N1 Vaccination Recommendations, at <http://www.cdc.gov/h1n1flu/vaccination/acip.htm>.

Allocation of Vaccines¹³²

Overview

To implement the voluntary mass vaccination campaign, the federal government has purchased the vaccine and a blended public- and private-sector distribution approach is being used.¹³³ The federal government provides guidance to the states and localities on how the vaccine should be allocated but actual allocation decisions would be made at the state and local levels. CDC has stated, however, that “State and local health departments are strongly encouraged to adhere to national guidelines on vaccine prioritization. Uniformity in prioritizing vaccine is considered a significant national interest. There may be instances where specific local needs should be taken into consideration when implementing prioritization, but deviation from national guidelines should be minimized.”¹³⁴ States have generally been following this guidance.¹³⁵

Selected Federal Actions Prior to 2009

The federal government examined the issue of how to set priorities for scarce resources, including vaccines, prior to the current H1N1 pandemic.¹³⁶ The 2005 Homeland Security Council Implementation Plan,¹³⁷ as supplemented by the two-year summary implementation plan, required HHS with the Department of Homeland Security (DHS) to make priority recommendations for access to pre-pandemic and pandemic influenza vaccines.¹³⁸ The recommendations were to reflect the pandemic response goals as well as maintaining national security.¹³⁹ On December 14, 2006, HHS issued a request for information (RFI) in the *Federal Register* asking for “input on pandemic influenza vaccine prioritization considerations from all interested and affected parties.”¹⁴⁰ In addition, the RFI indicated that limiting transmission may be an objective. The federal interagency working group used the input gained from this RFI to issue draft guidance on October 17, 2007.¹⁴¹

After consideration of comments, HHS and the Department of Homeland Security issued final guidance on July 23, 2008, in the form of a report entitled “Guidance on Allocating and Targeting

¹³² This section was written by (name redacted). It should be noted that allocation of other medical resources such as hospital beds and medical equipment may be necessary in certain circumstances. For a discussion of these issues see “Mass Medical Care with Scarce Resources,” <http://www.ahrq.gov/prep/mmcessentials/>; “State and Local Pandemic Influenza Preparedness: Medical Surge,” <http://oig.hhs.gov/oei/reports/oei-02-08-00210.pdf>.

¹³³ CDC, Clinician Outreach and Communication Activity (COCA), conference call on H1N1 vaccine, July 15, 2009, transcript and presentation at <http://emergency.cdc.gov/coca/callinfo.asp>.

¹³⁴ CDC Novel N1N1 Vaccination Planning Q & A, <http://www.cdc.gov/h1n1flu/vaccination/statelocal/qa.htm>.

¹³⁵ For a state by state listing of vaccine priorities see <http://www.astho.org/h1n1-vaccineprioritization.aspx>.

¹³⁶ For a detailed examination of the federal actions see CRS Report RL33381, *The Americans with Disabilities Act (ADA): Allocation of Scarce Medical Resources During a Pandemic*, by (name redacted).

¹³⁷ *National Strategy for Pandemic Influenza*, November 2005, at <http://www.flu.gov/plan/federal/index.html#national>.

¹³⁸ *Id.* “Implementation Plan Two Year Summary” Section 6.1.14.1.

¹³⁹ *Id.* These goals are reducing health, societal, and economic impacts and maintaining national and homeland security, and public values.

¹⁴⁰ 71 Fed.Reg. 75252 (December 14, 2006).

¹⁴¹ “Draft Guidance on Allocating and Targeting Pandemic Influenza Vaccine,” <http://www.pandemicflu.gov/vaccine/prioritization.html>.

Pandemic Influenza Vaccine.”¹⁴² The guidance creates tiers for coverage, and varies the vaccination priority depending on the severity of the pandemic. Since pandemics that have higher case fatality rates are more likely to disrupt essential services, threaten public order and homeland security, and disrupt supply chains, individuals who are necessary for these functions would receive a higher priority in a severe pandemic. Conversely, individuals with high-risk conditions making them more vulnerable to serious illness would receive greater priority in a less severe pandemic.¹⁴³ The guidance gives its highest rank to deployed forces, critical health care workers, fire and police, and pregnant women, infants, and toddlers. The importance of maintaining homeland and national security is highlighted and the guidance recognizes the following objectives as the most important:

- protecting those who are essential to the pandemic response and providing care for persons who are ill,
- protecting those who maintain essential community services,
- protecting children, and
- protecting workers who are at greater risk of infection due to their job.¹⁴⁴

However, the guidance also recognizes that the plans must be flexible because “the guidance may be modified based on the status of vaccine technology, the characteristics of pandemic illness, and risk groups for severe disease—factors that will remain unknown until a pandemic actually occurs.”¹⁴⁵

Federal Actions After Emergence of Influenza A(H1N1)

On July 8, 2009, CDC issued recommendations for state and local planning for a pandemic flu vaccination program.¹⁴⁶ These recommendations again emphasized that changing data may change the target populations.¹⁴⁷ The CDC recommendations noted that immunization of military forces may be appropriate given the current circumstances but did not address the military in its allocation discussion. The CDC focused only on the vaccination of civilian populations under the authority of CDC and state and local health departments.¹⁴⁸

¹⁴² U.S. Department of Health and Human Services, U.S. Department of Homeland Security, “Guidance on Allocating and Targeting Pandemic Influenza Vaccine,” (July 23, 2008) <http://www.hhs.gov/news/press/2008pres/07/20080723a.html>.

¹⁴³ *Id.* at 10-11.

¹⁴⁴ *Id.* at 3.

¹⁴⁵ *Id.* at 1.

¹⁴⁶ <http://www.cdc.gov/h1n1flu/vaccination/statelocal/planning.htm>.

¹⁴⁷ CDC recommended the following groups be targeted first for vaccines: students and staff associated with schools and children at or over six months and staff in child care centers (vaccinated at schools and child care centers); pregnant women, children six months to four years old, new parents and household contacts of children (vaccinated at providers’ offices and community clinics); adults under 65 years old with medical conditions that increase the risk of complications from flu (vaccinated at work settings, community clinics, pharmacies, providers’ offices); and health care workers and emergency services sectors personnel (vaccinated at work settings, providers’ offices). <http://www.cdc.gov/h1n1flu/vaccination/statelocal/planning.htm>.

¹⁴⁸ <http://www.cdc.gov/h1n1flu/vaccination/statelocal/planning.htm>.

On July 29, 2009, the CDC's Advisory Committee on Immunization Practices (ACIP) met to make recommendations on H1N1 vaccine priorities. The ACIP recommendations generally track those issued on July 8 by CDC for planning purposes and list the following target groups:

- pregnant women,
- household and caregiver contacts of children younger than 6 months of age (e.g., parents, siblings, and daycare providers),
- health care and emergency medical services personnel,
- persons from 6 months through 24 years of age, and
- persons aged 25 through 64 years who have medical conditions associated with a higher risk of influenza complications.¹⁴⁹

The groups recommended for priority vaccination by the ACIP total approximately 159 million people in the United States.¹⁵⁰ If there is a shortage of vaccine, the ACIP recommends that the following groups receive the vaccine first:

- pregnant women,
- people who live with or care for children younger than six months of age,
- health care and emergency services personnel with direct patient contact,
- children six months through four years old, and
- children 5 through 18 years old who have chronic medical conditions.¹⁵¹

During the press briefing, the ACIP noted that it recommends that 83% of the population be vaccinated for seasonal influenza, but less than 40% are actually vaccinated each year. The demand for the H1N1 vaccine is uncertain because not everyone who is in a priority group may choose to get the vaccine. Hence, with more vaccine potentially available to lower tiers in the priority groupings, ACIP noted in the press briefing that it may be possible that the more limited target groups might not be used.¹⁵² Similarly, CDC stated that a vaccine shortage is not expected; however, availability and demand are unpredictable, thus it is possible that priority groups may be needed.¹⁵³ CDC observed that the ACIP recommendations “leave room for flexibility at the local level depending on the local vaccine supply situation.”¹⁵⁴ As the vaccination campaign has begun, CDC emphasizes that the state and local providers “should be aware of and follow any additional guidance provided by their state or local health departments. If no additional guidance is provided at the state or local level, providers should vaccinate among the initial target group populations on a first come, first served basis.”¹⁵⁵

¹⁴⁹ http://www.cdc.gov/h1n1flu/vaccination/clinicians_qa.htm.

¹⁵⁰ *Id.*

¹⁵¹ <http://www.cdc.gov/media/pressrel/2009/r090729b.htm>.

¹⁵² <http://www.cdc.gov/media/transcripts/2009/t090729b.htm>.

¹⁵³ <http://www.cdc.gov/h1n1flu/vaccination/statelocal/qa.htm>.

¹⁵⁴ *Id.*

¹⁵⁵ http://www.cdc.gov/h1n1flu/vaccination/clinicians_qa.htm.

Legal Issues

The allocation of scarce pandemic vaccine could raise several legal issues. If an individual has an adverse response to the vaccine, there may be liability issues. However, HHS Secretary Kathleen Sebelius issued a declaration under the Public Readiness and Emergency Preparedness Act (PREP Act)¹⁵⁶ that waives vaccine liability, except for willful misconduct, for the United States, and for manufacturers; distributors; program planners; persons who prescribe, administer, or dispense the countermeasure; and employees of any of the above. This declaration would also make funds available under a vaccine compensation fund.¹⁵⁷

Constitutional due process and equal protection issues as well as civil rights issues might also be raised concerning vaccine allocation if a particular covered group was adversely impacted by the vaccine allocation plan.¹⁵⁸ More specifically, issues regarding the Americans with Disabilities Act (ADA)¹⁵⁹ could be raised. However, vaccine allocation plans that are based on a determination that an individual not receive a vaccine because the vaccine would not be effective given his or her health situation would be unlikely to raise ADA concerns, because the determination would be based on a medical determination of treatment. Similarly, the mere fact that a decision would have a disparate impact on individuals with disabilities would not necessarily be sufficient to violate the nondiscrimination mandates.¹⁶⁰

Other potential legal issues could arise concerning state and local decisions about vaccine allocation. Questions may occur about defining subgroups within priority groups. For example, how is a “health care worker” to be defined? Once the groups are defined, issues may arise concerning how vaccination sites will ensure that individuals are within the priority group. For example, would an individual have to “prove” that he or she had a medical condition that increased risk from the flu?¹⁶¹ What form would this proof have to take? Would there be potential liability issues for health care providers if they do not follow guidance concerning who is to be vaccinated? Would vaccinations be provided for illegal aliens who are within the priority groups? Finally, if there is possible liability for individuals or state or local agencies making these decisions, should there be any legal protections available to limit liability?

The CDC “H1N1 Clinicians Questions and Answers” provides guidance for a vaccination provider who is faced with requests for vaccination from individuals not in the initial target group. CDC notes that some providers may have enough doses of vaccine to meet the demand from all patients but, if this is not the case, “the provider may wish to explain their local plan and rationale for vaccination among the initial target groups and ask others to wait to get vaccinated later.” CDC emphasized that “the decision regarding who should get vaccinated is one that should

¹⁵⁶ 42 U.S.C. § 247d-6d, 247d-6e.

¹⁵⁷ For a more detailed discussion of this issue see the subsequent discussion of the PREP Act, and CRS Report RS22327, *Pandemic Flu and Medical Biodefense Countermeasure Liability Limitation*, by (name redacted) and (name redacted).

¹⁵⁸ For a more detailed discussion see the subsequent discussion civil rights issues and CRS Report RL33381, *The Americans with Disabilities Act (ADA): Allocation of Scarce Medical Resources During a Pandemic*, by (name redacted).

¹⁵⁹ 42 U.S.C. §12101 *et seq.*

¹⁶⁰ *Alexander v. Choate*, 469 U.S. 287 (1985).

¹⁶¹ CDC states that “[t]here will be no federal requirements for vaccinators to require documentation of priority group status such as doctor’s note documenting pregnancy or risk status.” <http://www.cdc.gov/h1n1flu/vaccination/statelocal/qa.htm>.

be made between the provider and the patient, weighing whether there are sufficient doses available for those at greatest risk for infection and serious complications as well as the likelihood that patients turned away will come back for vaccine at a later date.”¹⁶² This guidance places the decision between the provider and the patient. It does not directly address the potential liability issue for a provider when an individual who was in a priority group is unable to get vaccinated because of the vaccination of individuals not in the priority group, and this priority group individual suffers adverse consequences due to the lack of timely vaccination. However, a provider who weighs the factors suggested by CDC and makes an individualized determination, most likely would not be found liable to another individual who was unable to obtain vaccination. In addition, the burden of proof for the plaintiff in this scenario would be a difficult one.

Mandatory Vaccinations¹⁶³

History and Precedent

Historically, the preservation of the public health has been the primary responsibility of state and local governments, and the authority to enact laws relevant to the protection of the public health derives from the state’s general police powers.¹⁶⁴ With respect to the preservation of the public health in cases of communicable disease outbreaks, these powers may include the enactment of mandatory vaccination laws.¹⁶⁵ Every state has a law requiring children to be vaccinated before they enroll in a public or private school.¹⁶⁶ All states also allow medical exemptions from school vaccination requirements for those whose immune systems are compromised, who are allergic to vaccines, or have other medical contraindications to vaccines, and many states also provide exemptions for religious or philosophical reasons.¹⁶⁷ Various state laws also require vaccination against hepatitis B and meningococcal disease for incoming college and university students.¹⁶⁸

*Jacobson v. Massachusetts*¹⁶⁹ is the seminal case regarding a state’s or municipality’s authority to institute a mandatory vaccination program as an exercise of its police powers. In *Jacobson*, the Supreme Court upheld a Massachusetts law that gave municipal boards of health the authority to require the vaccination of persons over the age of 21 against smallpox, and determined that the vaccination program instituted in the City of Cambridge had “a real and substantial relation to the protection of the public health and safety.”¹⁷⁰ In upholding the law, the Court noted that “the

¹⁶² http://www.cdc.gov/h1n1flu/vaccination/clinicians_qa.htm.

¹⁶³ This section was written by (name redacted), Legislative Attorney. For a detailed discussion see CRS Report RS21414, *Mandatory Vaccinations: Precedent and Current Laws*, by (name redacted).

¹⁶⁴ See *The People v. Robertson*, 134 N.E. 815, 817 (1922).

¹⁶⁵ Starting with the smallpox vaccine, vaccines have been used to halt the spread of disease for over 200 years. Donald A. Henderson & Bernard Moss, *Smallpox and Vaccinia*, VACCINES 74, 75 (Stanley A. Plotkin & Walter A. Orenstein eds., 3d ed. 1999).

¹⁶⁶ For a more detailed discussion of these issues see CRS Report RS21414, *Mandatory Vaccinations: Precedent and Current Laws*, by (name redacted).

¹⁶⁷ National Conference of State Legislatures, *States with Religious and Philosophical Exemptions from School Immunization Requirements*, updated June, 2009, at <http://www.ncsl.org/Default.aspx?TabId=14376>.

¹⁶⁸ See the Immunization Action Coalition website state charts at <http://www.immunize.org/laws/hepbcollege.asp> and <http://www.immunize.org/laws/menin.asp>.

¹⁶⁹ 197 U.S. 11 (1905).

¹⁷⁰ *Id.* at 31. The Massachusetts statute in question read as follows: “Boards of health, if in their opinion it is necessary for public health or safety, shall require and enforce the vaccination and revaccination of all the inhabitants of their (continued...)”

police power of a State must be held to embrace, at least, such reasonable regulations established directly by legislative enactment as will protect the public health and the public safety.”¹⁷¹ The Court added that such laws were within the full discretion of the state, and that federal powers with respect to such laws extended only to ensure that the state laws did not “contravene the Constitution of the United States or infringe any right granted or secured by that instrument.”¹⁷² In the context of the current H1N1 pandemic, mandatory vaccination issues are less likely to arise than allocation issues, since it is unlikely that there would be sufficient vaccine available to vaccinate the entire population, particularly in the early stages of vaccine availability.¹⁷³

Health Care Workers and Mandatory Vaccinations

A number of states have laws requiring employees of certain health care facilities, such as nursing homes, to be vaccinated against diseases such as measles, mumps and rubella. Such laws, which vary widely, generally contain opt-out provisions where a vaccine is medically contraindicated or if the vaccine is against the individual’s religious or philosophical beliefs.¹⁷⁴ A few states have laws pertaining to influenza vaccination of health care workers, and most that do provide for voluntary influenza immunization programs and staff education measures for employees; however, a few states have mandatory requirements for influenza vaccinations for health care workers.¹⁷⁵ For example, Alabama has a law requiring that employees of nursing homes receive an annual vaccination against the influenza virus, unless the vaccine is medically contraindicated, or the vaccine is against the individual’s religious beliefs, or if the individual refuses the vaccine after being fully informed of the health risks of not being immunized.¹⁷⁶

In August 2009, the New York State Health Department amended its regulations to require that health care workers at hospitals, in home health care agencies, and in hospice care be immunized against influenza viruses as a precondition to employment and on an annual basis.¹⁷⁷ This regulation, issued on an emergency basis, did not permit any exceptions to the influenza vaccination mandate except for medical contraindications. Lawsuits were filed challenging the regulation’s validity, and on October 16, 2009, a state judge issued a temporary restraining order suspending its application to New York health care workers.¹⁷⁸ However, on October 22, 2009,

(...continued)

towns, and shall provide them with the means of free vaccination. Whoever refuses or neglects to comply with such requirement shall forfeit five dollars.” M.G.L.A. c. 111, § 181 (2004).

¹⁷¹ *Id.* at 25.

¹⁷² *Id.*

¹⁷³ For a discussion of issues raised by the allocation of vaccine see preceding section of this report, “Allocation of Vaccines,” and CRS Report RL33381, *The Americans with Disabilities Act (ADA): Allocation of Scarce Medical Resources During a Pandemic*, by (name redacted).

¹⁷⁴ Lindley, Megan C. et al., *Assessing State Immunization Requirements for Healthcare Workers and Patients*, *Am J Prev Med* 2007;32(6): 459-465.

¹⁷⁵ The CDC maintains a continuously updated online database of state laws pertaining to vaccination requirements at <http://www.cdc.gov/vaccines/vac-gen/laws/state-reqs.htm>.

¹⁷⁶ ALA. CODE § 22-21-10.

¹⁷⁷ This regulation could apply to the influenza A(H1N1) virus if a vaccine becomes available in sufficient supply. The text of the regulation may be viewed at <http://www.health.state.ny.us/regulations/emergency/>. See also a press release issued by New York State Health Commissioner Richard F. Daines at http://www.health.state.ny.us/press/releases/2009/2009-09-24_health_care_worker_vaccine_daines_oped.htm.

¹⁷⁸ The temporary restraining order issued by state Supreme Court Judge Thomas J. McNamara, may be accessed at <http://op.bna.com/hl.nsf/r?Open=sfak-7wvsxh>. This order requires the parties to return to court for a hearing on (continued...)

Governor David A. Paterson announced the suspension of the flu shot mandate for health care employees due to the current shortage of both the seasonal flu vaccine and the influenza A(H1N1) vaccine.¹⁷⁹

In the private sector, employers can require health care workers to be vaccinated against communicable diseases as a condition of employment, unless a state law applies which permits employees to opt out.¹⁸⁰ Virginia Mason Medical Center in Seattle, WA, became the first hospital in the nation, in 2004, to make vaccination a condition of employment for all its employees. Within three years, the hospital reported 98% staff coverage, except for 2% of the staff who refused for medical or religious reasons, and, because of their refusal, were required to wear surgical masks when in the hospital.¹⁸¹

In 2008, the Department of Defense (DOD) issued a policy directive requiring “all civilian health care personnel who provide direct patient care in DoD military treatment facilities to be immunized against seasonal influenza infection each year as a condition of employment, unless there is a documented medical or religious reason not to be immunized.”¹⁸²

Vaccination Orders During a Public Health Emergency

Many states also have laws providing for mandatory vaccinations during a public health emergency or outbreak of a communicable disease.¹⁸³ Generally, the power to order such actions rests with the governor of the state or with a state health officer. For example, a governor may have the power to supplement the state’s existing compulsory vaccination programs and institute additional programs in the event of a civil defense emergency period.¹⁸⁴ Or, a state health officer may, upon declaration of a public health emergency, order an individual to be vaccinated “for communicable diseases that have significant morbidity or mortality and present a severe danger to public health.”¹⁸⁵ In addition, exemptions are generally provided for medical reasons or where

(...continued)

October 30, 2009.

¹⁷⁹ See press release at http://www.ny.gov/governor/press/press_1022094.html.

¹⁸⁰ See *Vaccination of Healthcare Workers for H1N1 and Other Communicable Diseases*, American Federation of Teachers, Frequently Asked Questions, at <http://www.aft.org/healthcare/download/FAQ%20-%20H1N1.pdf>. This FAQ notes that the Joint Commission requires accredited organizations to offer influenza vaccinations to staff, including those with close patient contact, as a condition of accreditation.

¹⁸¹ Manning, Anita., *Hospitals Shoot for Employees to Get Flu Vaccine*, September 16, 2007, at http://www.usatoday.com/news/health/2007-09-16-flu-doctors_N.htm. A union dispute regarding the flu shot mandate resulted in an exemption for union employees, but all other hospital employees are covered.

¹⁸² Department of Defense/Joint Forces, HA Policy: 08-005, Policy for Mandatory Seasonal Influenza Immunization for Civilian Health Care Personnel Who Provide Direct Patient Care in Department of Defense Military Treatment Facilities, April 4, 2008, available at <http://mhs.osd.mil/Content/docs/pdfs/policies/2008/08-005.pdf>.

¹⁸³ Following the then-Acting HHS Secretary’s public health emergency declaration on April 26, 2009, a number of states issued their own statewide or territorial emergency declarations relating to the H1N1 influenza outbreak. See the continuously updated list of such states and territories at <http://www.astho.org/h1n1-emergency.aspx>.

¹⁸⁴ HAW. REV. STAT. § 128-8 (2008). In Arizona, the Governor, during a state of emergency or state of war emergency in which there is an occurrence or the imminent threat of smallpox or other highly contagious and highly fatal disease, may “issue orders that mandate treatment or vaccination of persons who are diagnosed with illness resulting from exposure or who are reasonably believed to have been exposed or who may reasonably be expected to be exposed.” ARIZ. REV. STAT. § 36-787 (2009).

¹⁸⁵ FLA. STAT. § 381.00315 (2008).

objections are based on religion or conscience.¹⁸⁶ However, if a person refuses to be vaccinated, he or she may be quarantined during the public health emergency giving rise to the vaccination order. The legality of a particular mandatory vaccination program will hinge upon balancing the severity of the public health emergency with the effectiveness and safety of the vaccine involved, and the availability of less intrusive methods of dealing with the situation. For example, dealing with the introduction of smallpox by a terrorist might involve the use of national security powers and involve some consequential restrictions on individual civil liberties. However, most programs for protecting the public health also recognize and protect constitutional rights to personal liberties, such as freedom from physical restraint, bodily invasion, or the right to refuse medical treatment.¹⁸⁷

Model State Emergency Health Powers Act

In addition to the current laws, many states have considered and have passed some or all of the provisions set forth in the Model State Emergency Health Powers Act (Model Act).¹⁸⁸ The Model Act was drafted by The Center for Law and the Public's Health at Georgetown and Johns Hopkins Universities.¹⁸⁹ It seeks to “grant public health powers to state and local public health authorities to ensure strong, effective, and timely planning, prevention, and response mechanisms to public health emergencies (including bioterrorism) while also respecting individual rights.” With respect to vaccinations, the Model Act includes provisions similar to the current laws discussed above. Under the Model Act, during a public health emergency, the appropriate public health authority would be authorized to “vaccinate persons as protection against infectious disease and to prevent the spread of contagious or possibly contagious disease.” The Model Act requires that the vaccine be administered by a qualified person authorized by the public health authority, and that the vaccine “not be such as is reasonably likely to lead to serious harm to the affected individual.” The Model Act recognizes that individuals may be unable or unwilling to undergo vaccination “for reasons of health, religion, or conscience,” and provides that such individuals may be subject to quarantine to prevent the spread of a contagious or possibly contagious disease.¹⁹⁰

Role of the Federal Government

Federal jurisdiction over public health matters derives from the Commerce Clause, which states that Congress shall have the power “[t]o regulate Commerce with foreign Nations, and among the

¹⁸⁶ See, e.g., CONN. GEN. STAT. § 19a-222 (2009) (exemption for physician's determination of sickness); VA. CODE ANN. § 32.1-48 (2009) (vaccination waived if detrimental to person's health, as certified by a physician); WIS. STAT. § 252.041 (2008) (vaccination may be refused for reasons of religion or conscience). See also, CRS Report RL34708, *Religious Exemptions for Mandatory Health Care Programs: A Legal Analysis*, by Cynthia Brougher.

¹⁸⁷ Mariner, Wendy K. et al., *Jacobson v Massachusetts: It's Not Your Great-Great-Grandfather's Public Health Law*, AM J PUB HEALTH, 2005;95(4):581-90.

¹⁸⁸ The Center for Law and the Public's Health tracks state legislative activity relating to the Model Act at <http://www.publichealthlaw.net/Resources/Modellaws.htm#MSEHPA>. According to James G. Hodge Jr., Executive Director of the Center for Law and the Public's Health, 44 states have introduced legislation based on the Model Act and 38 states have adopted some parts of it. Marcia Coyle, “Legal Issues Swell If Swine Flu Spreads,” *The National Law Journal* (May 4, 2009), available at http://law.com/jsp/nlj/PubArticleNLJ.jsp?id=1202430383777&Legal_Issues_Swell_If_Swine_Flu_Spreads&slreturn=1

¹⁸⁹ The text of the Center's Model State Emergency Health Powers Act from 2001 is available at <http://www.publichealthlaw.net/ModelLaws/index.php>.

¹⁹⁰ *Id.* See Section 604 of the Model Act for provisions relating to quarantine.

several States.”¹⁹¹ Thus, under the Public Health Service Act, the Secretary of Health and Human Services has authority to make and enforce regulations necessary “to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession.”¹⁹² With regard to foreign countries, the Secretary has the power to restrict the entry of groups of aliens for public health reasons.¹⁹³ This power includes the authority to issue vaccination requirements for immigrants seeking entry into the United States.¹⁹⁴ With regard to interstate commerce, the Public Health Service Act deals primarily with the use of quarantine measures to halt the spread of certain communicable diseases.¹⁹⁵ The Public Health Service Act does not specifically authorize any mandatory vaccination programs; nor do there appear to be any regulations regarding the implementation of a mandatory vaccination program at the federal level during a public health emergency.

As noted above, state and local governments have the primary responsibility for protecting the public health, and this has been reflected in the enactment of the various state laws authorizing mandatory vaccination procedures during a public health emergency. Any federal civilian mandatory vaccination program applicable to the general public would likely be limited to areas of existing federal jurisdiction, i.e., interstate and foreign commerce, similar to the federal quarantine authority.¹⁹⁶ Aliens seeking admission to the United States, for example, are already required to show proof of required vaccinations.¹⁹⁷ This limitation on federal jurisdiction acknowledges that states have the primary responsibility for protecting the public health, but that under certain circumstances, federal intervention may be necessary.

Civil Rights¹⁹⁸

Introduction

Infectious diseases, such as the 2009 influenza pandemic, may raise a classic civil rights issue: to what extent can an individual’s liberty be curtailed to advance the common good?¹⁹⁹ The United

¹⁹¹ U.S. CONST. art. I, § 8.

¹⁹² 42 U.S.C. 264(a). Originally, the statute conferred this authority on the Surgeon General; however, pursuant to Reorganization Plan No. 3 of 1966, all statutory powers and functions of the Surgeon General were transferred to the Secretary.

¹⁹³ 8 U.S.C. § 1182.

¹⁹⁴ Currently, vaccines recommended by the Advisory Committee on Immunization Practices for the general U.S. population are also required for immigrants who seek permanent residence in the United States, and people currently living in the United States who seek to adjust their status to become permanent residents. See the CDC Division of Global Migration and Quarantine website for information on vaccination requirements for immigrants at <http://www.cdc.gov/ncidod/dq/diseases.htm#vaccine>, and a recent CDC Federal Register notice seeking comment, “Criteria for Vaccination Requirements for U.S. Immigration Purposes,” 74 Fed. Reg. 15986 (April 8, 2009). For further information about health-related grounds for exclusion of immigrants see CRS Report R40570, *Immigration Policies and Issues on Health-Related Grounds for Exclusion*, by (name redacted) and (name redacted).

¹⁹⁵ See 42 C.F.R. Parts 70 (interstate matters) and 71 (foreign arrivals).

¹⁹⁶ It has been suggested that in the case of a serious outbreak of a communicable disease, the federal government might enact policies to encourage vaccinations or place restrictions on those who refuse. Bureau of Justice Assistance, U.S. Department of Justice, *The Role of Law Enforcement in Public Health Emergencies*, September, 2006 at 19.

¹⁹⁷ 8 U.S.C. § 1182(a)(1)(A).

¹⁹⁸ This section was written by (name redacted), Legislative Attorney.

States Constitution and federal civil rights laws provide for individual due process and equal protection rights as well as a right to privacy, but these rights are balanced against the needs of the community. With the advance of medical treatments in recent years, especially the use of antibiotics, the civil rights of the individual with a contagious disease have been emphasized. However, classic public health measures such as quarantine, isolation, and contact tracing are, nevertheless, available in appropriate situations and, as new or resurgent diseases have become less treatable, some of these classic public health measures have been increasingly used. Therefore, the issue of how to balance these various interests in a modern culture that is sensitive to issues of individual rights has become critical.²⁰⁰

Constitutional Rights to Due Process and Equal Protection

Constitutional rights to due process and equal protection may be implicated by the imposition of a quarantine or isolation order.²⁰¹ The Fifth and Fourteenth Amendments prohibit governments at all levels from depriving individuals of any constitutionally protected liberty interest without due process of law. What process may be due under certain circumstances is generally determined by balancing the individual's interest at stake against the governmental interest served by the restraints, determining whether the measures are reasonably calculated to achieve the government's aims,²⁰² and deciding whether the least restrictive means have been employed to further that interest.

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¹⁹⁹ For a discussion of balancing individual legal rights and responsibility and communal objectives, see Institute of Medicine, *Guidance for Establishing Crisis Standards of Care for Use in Disaster Situations* (September 2009).

²⁰⁰ For a detailed discussion of constitutional issues relating to quarantine see Michelle A. Daubert, "Pandemic Fears and Contemporary Quarantine: Protecting Liberty Through a Continuum of Due Process Rights," 54 *BUFFALO L. REV.* 1299 (January 2007). For an analysis of how to balance the sometimes competing interests of personal and economic liberties with the public's health and security see Lawrence O. Gostin, "When Terrorism Threatens Health: How Far are Limitations on Personal and Economic Liberties Justified?" 55 *Fla. Law Rev.* 1105 (December 2003). See also David P. Fidler, Lawrence O. Gostin, and Howard Markel, "Through the Quarantine Looking Glass: Drug-Resistant Tuberculosis and Public Health Governance, Law and Ethics," 35 *J. OF LAW, MEDICINE & ETHICS* 616 (2007), where the authors note that courts have set four limits on isolation and quarantine authority: the subject must actually be infectious or have been exposed to infectious disease, the subject must be placed in a safe and habitable environment, the authority must be exercised in a non-discriminatory manner, and there must be procedural due process.

²⁰¹ It has been argued that the federal quarantine authority may not pass constitutional muster since it does not specifically provide for a right to a fair hearing. See Howard Markel, Lawrence O. Gostin, and David P. Fidler, "Extensively Drug-Resistant Tuberculosis: An Isolation Order, Public Health Powers, and a Global Crisis," 298 *JAMA* 83-84 (July 4, 2007). It should be noted that the proposed CDC quarantine regulations contain detailed due process procedures including a right to a hearing for full quarantine. 70 *Fed. Reg.* 71,892 (November 30, 2005), <http://www.cdc.gov/ncidod/dq/nprm/>. However, these proposed regulations have been strongly criticized for what commentators have described as constitutional failings. These criticisms have highlighted the lack of independent judicial review for individuals subject to quarantine, the broad discretion accorded to directors of federal quarantine stations, the lack of hearings during provisional quarantine, and privacy concerns. See, e.g., Lawrence O. Gostin, Benjamin E. Berkman, and David P. Fidler, *Comments on Department of Health and Human Services, Control of Communicable Diseases (Proposed Rule)*, 42 *C.F.R. Parts 70 and 71* (November 30, 2005), <http://www.publichealthlaw.net/Resources/BTlaw.htm>; The New England Coalition for Law and Public Health, *Comments on the Interstate and Foreign Quarantine Regulations Proposed by the Centers for Disease Control and Prevention*, <http://64.233.169.104/u/UMBaltimore?q=cache:fsSm0xxCULQJ:www.umaryland.edu/healthsecurity/docs/New%2520England%2520Coalition%2520Comments%2520CDC%2520revisions.pdf+%22new+england+coalition+for+law+and+public+health%22&hl=en&ct=clnk&cd=1&gl=us&ie=UTF-8>; Felice Batlan, "Law in the Time of Cholera: Disease, State Power, and Quarantines Past and Future," 80 *TEMP. L. REV.* 53 (2007).

²⁰² See, e.g., *Jacobson v. Massachusetts*, 197 U.S. 11, 27 (1905) (enforcement of public health laws must have some "real or substantial relation to the protection of the public health and the public safety"); *Jew Ho v. Williamson*, 103 F. (continued...)

In *O'Connor v. Donaldson*,²⁰³ the Supreme Court examined the civil commitment of an individual to a mental hospital and held that “a State cannot constitutionally confine without more, a nondangerous individual who is capable of surviving safely in freedom by himself or with the help of willing and responsible family members or friends.”²⁰⁴ Arguably, an individual who is highly contagious with a serious illness may be considered dangerous, and thus subject to involuntary confinement if there is no less restrictive alternative. The lesson of *Donaldson* is that such confinements must be carefully examined in order to comport with the constitutional right to due process. *Donaldson* also raises the issue of whether less restrictive programs are required prior to the imposition of the more restrictive application of isolation or quarantine. It could be argued that the least restrictive alternative must first be applied or more restrictive alternatives will run afoul of constitutional requirements.²⁰⁵

The unequal treatment of certain socially disfavored groups with regard to quarantine also raises equal protection issues. For example, in *Wong Wai v. Williamson*²⁰⁶ a board of health resolution mandated Chinese residents to be quarantined for bubonic plague unless they submitted to inoculation with a serum with “the only justification offered for this discrimination ... a suggestion ... that this particular race is more liable to the plague than any other.”²⁰⁷ The court struck the resolution as a violation of the equal protection clause.²⁰⁸

Although the Constitution does not specifically grant a right to travel, the Supreme Court has held that there is a fundamental right to travel.²⁰⁹ This right, and the applicable due process procedures, have been examined in the context of transportation security, particularly regarding alleged terrorists.²¹⁰ Generally, restrictions on travel, such as identification policies for boarding airplanes, have not been found to violate the Constitution.²¹¹ If the public safety arguments have

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10 (C.C.N.D. Cal. 1900) (quarantine of San Francisco district inhabited primarily by Chinese immigrants purportedly to control the spread of bubonic plague was invalidated).

²⁰³ 422 U.S. 563 (1975).

²⁰⁴ *Id.* at 576.

²⁰⁵ See Wendy D. Parmet, “Legal Power and Legal Rights—Isolation and Quarantine in the Case of Drug-Resistant Tuberculosis,” 357 *NEW ENG. J. OF MEDICINE* 433, 435 (August 2, 2007). Professor Parmet argues that compulsory measures are not the most effective and may prompt individuals who may be subject to them to evade authorities. “By ensuring that coercion is used only when less restrictive alternatives will not work and with due regard for the rights of those detained, the law can foster public trust, minimizing the need for compulsion and laying the groundwork for the comprehensive and costly control programs needed to prevent the spread of XDR tuberculosis and other contagious pathogens.” *Id.*

²⁰⁶ 103 F. 1 (N.D. Cal. 1900).

²⁰⁷ *Id.* at 15.

²⁰⁸ One commentator observed that it is unlikely that such blatantly discriminatory actions would occur today, but noted that “studies of New York City’s use of isolation orders for tuberculosis in the 1990s show that more than 90% of the people detained were non-white and more than 60% were homeless.... Although these figures may reflect the democracy (sic) of non-compliant patients with tuberculosis in New York City at that time, the fact that the most potent public health tool was used primarily against marginalized, nonwhite persons underscores the need for legal oversight—if only so that affected communities can be assured of the absence of discrimination.” Wendy D. Parmet, “Legal Power and Legal Rights—Isolation and Quarantine in the Case of Drug-Resistant Tuberculosis,” 357 *NEW ENG. J. OF MEDICINE* 433, 434 (August 2, 2007).

²⁰⁹ *United States v. Guest*, 383 U.S. 745 (1966); *Shapiro v. Thompson*, 394 U.S. 618 (1969).

²¹⁰ See CRS Report RL32664, *Interstate Travel: Constitutional Challenges to the Identification Requirement and Other Transportation Security Regulations*, by (name redacted); Justin Florence, “Making the No Fly List Fly: A Due Process Model for Terrorist Watchlists,” 115 *Yale L.J.* 2148 (2006).

²¹¹ See *Gilmore v. Gonzales*, 435 F.3d 1125 (9th Cir. 2006), cert. den. 549 U.S. 1110 (2007). “We reject Gilmore’s (continued...)”

prevailed regarding restrictions due to transportation security, they would be likely to prevail against a serious public health threat. However, the seriousness of the threat and the due process procedures used would be key to any constitutional determination.

Federal Nondiscrimination Laws

In addition to constitutional issues, discrimination against an individual with an infectious disease may be covered by certain federal laws, notably Section 504 of the Rehabilitation Act,²¹² the Americans with Disabilities Act (ADA),²¹³ and the Air Carrier Access Act (ACAA).²¹⁴ However, under these statutes, an individual with a contagious disease does not have to be given access to a place of public accommodation or employment if such access would place other individuals at a significant risk.²¹⁵

Section 504 of the Rehabilitation Act

Although the language of Section 504 does not specifically discuss contagious diseases, the Supreme Court dealt with discrimination issues in the context of tuberculosis and Section 504 in *School Board of Nassau County v. Arline*.²¹⁶ The Court found that in most cases an individualized inquiry is necessary in order to protect individuals with disabilities from “deprivation based on prejudice, stereotypes, or unfounded fear, while giving appropriate weight to such legitimate concerns of grantees as avoiding exposing others to significant health and safety risks.”²¹⁷ The Court adopted the test enunciated by the American Medical Association amicus brief and held that the factors which must be considered include “findings of facts, based on reasonable medical judgments given the state of medical knowledge, about (a) the nature of the risk (how the disease is transmitted), (b) the duration of the risk (how long is the carrier infectious), (c) the severity of the risk (what is the potential harm to third parties) and (d) the probabilities the disease will be transmitted and will cause varying degrees of harm.” The Court also emphasized that courts “normally should defer to the reasonable medical judgments of public health officials.”²¹⁸

(...continued)

rights to travel argument because the Constitution does not guarantee the right to travel by any particular form of transportation.” 435 F.3d 1125, 1136(9th Cir. 2006).

²¹² 29 U.S.C. §794. For a more detailed discussion of Section 504 generally see CRS Report RL34041, *Section 504 of the Rehabilitation Act of 1973: Prohibiting Discrimination Against Individuals with Disabilities in Programs or Activities Receiving Federal Assistance*, by (name redacted).

²¹³ 42 U.S.C. §§12101 *et seq.* For a more detailed discussion of the ADA generally see CRS Report 98-921, *The Americans with Disabilities Act (ADA): Statutory Language and Recent Issues*, by (name redacted). The ADA was recently amended by the ADA Amendments Act, P.L. 110-325, which rejects certain Supreme Court interpretations of the definition of disability and generally increases the likelihood that an individual will fall within the coverage of the definition. For a more detailed discussion of these amendments see CRS Report RL34691, *The ADA Amendments Act: P.L. 110-325*, by (name redacted).

²¹⁴ 42 U.S.C. §1374(c). For a more detailed discussion of the ACAA generally see CRS Report RL34047, *Overview of the Air Carrier Access Act*, by (name redacted).

²¹⁵ For a more detailed discussion of this issue in the ADA context see CRS Report RS22219, *The Americans with Disabilities Act (ADA) Coverage of Contagious Diseases*, by (name redacted).

²¹⁶ 480 U.S. 273 (1987).

²¹⁷ *Id.* at 287.

²¹⁸ *Id.* at 288. These standards are incorporated into the regulations for the Air Carrier Access Act at 14 C.F.R. §382.51.

The Americans With Disabilities Act (ADA)

The Americans with Disabilities Act (ADA) is a broad civil rights act prohibiting discrimination against individuals with disabilities.²¹⁹ Four main issues are raised under the ADA by the H1N1 pandemic: whether an individual infected with the H1N1 virus is an individual with a disability; to what extent can an employer make possibly disability related inquiries; what are the requirements for reasonable accommodation; and to what extent does the ADA “direct threat” language allow certain actions.

Individual with a Disability

The ADA Amendments Act defines the term disability with respect to an individual as “(A) a physical or mental impairment that substantially limits one or more of the major life activities of such individual; (B) a record of such an impairment; or (C) being regarded as having such an impairment (as described in paragraph (3)).”²²⁰ Whether an individual infected with the H1N1 virus is an individual with a disability is a fact-specific inquiry but the EEOC indicates that if the illness is similar to seasonal influenza, it would not be a disability.²²¹

Disability-Related Inquiries

Generally, the ADA prohibits an employer from making disability-related inquiries except in certain limited situations.²²² An employer may attempt to plan for absences during a pandemic by making inquiries about an employee. The EEOC has stated that an employer may not ask an individual if he or she has a chronic health condition that would make the employee more susceptible to influenza complications, unless there is evidence of a direct threat.²²³ However, an employer may use a survey to identify which employees may not be available for work if the survey includes questions not only about chronic health conditions but also about the need to care for a child or take public transportation.²²⁴

Reasonable Accommodation

The ADA prohibits discrimination against an individual with a disability and requires the provision of reasonable accommodations to the individual’s disability unless it imposes an undue hardship on an employer.²²⁵ During a pandemic, reasonable accommodations continue to be required. For example, if an individual with low vision requires a screen reader at work, this must

²¹⁹ 42 U.S.C. §§12101 et seq. For a more detailed discussion of the ADA, see CRS Report 98-921, *The Americans with Disabilities Act (ADA): Statutory Language and Recent Issues*, by (name redacted). For a more detailed discussion of the ADA and employment issues raised by a pandemic see CRS Report R40866, *The Americans with Disabilities Act (ADA): Employment Issues and the 2009 Influenza Pandemic*, by (name redacted).

²²⁰ P.L. 110-325, §4(a), amending 42 U.S.C. §12102(3). The ADA Amendments Act of 2008 expanded the definition of disability from previous Supreme Court interpretations. For a more detailed discussion see CRS Report RL34691, *The ADA Amendments Act: P.L. 110-325*, by (name redacted).

²²¹ http://www.eeoc.gov/facts/pandemic_flu.html.

²²² 42 U.S.C. § 12112(d).

²²³ http://www.eeoc.gov/facts/pandemic_flu.html.

²²⁴ *Id.*

²²⁵ 42 U.S.C. §12112(a)(5).

also be provided on a laptop if laptops are provided to employees to enable them to work at home during a pandemic.²²⁶ In addition, an employee who is at high risk for complications during a pandemic may request telework as a reasonable accommodation.²²⁷

Direct Threat

The ADA provides nondiscrimination protections to individuals with contagious diseases, but balances this protection with requirements designed to protect the health of other individuals. Title I of the ADA, which prohibits employment discrimination against otherwise qualified individuals with disabilities, specifically states that “the term ‘qualifications standards’ may include a requirement that an individual shall not pose a direct threat to the health or safety of other individuals in the workplace.”²²⁸ During an influenza pandemic, the EEOC indicates that employers would be permitted to advise employees to go home if they have influenza symptoms. This would be true both if the illness is not considered to be a disability because it is similar to the seasonal influenza, and if the illness were serious since it would then pose a direct threat.²²⁹

Like Title I, Title III, which prohibits discrimination in public accommodations and services operated by private entities, states the following:

Nothing in this title shall require an entity to permit an individual to participate in or benefit from the goods, services, facilities, privileges, advantages and accommodations of such entity where such individual poses a direct threat to the health or safety of others. The term ‘direct threat’ means a significant risk to the health or safety of others that cannot be eliminated by a modification of policies, practices, or procedures or by the provision of auxiliary aids or services.²³⁰

Although Title II, which prohibits discrimination by state and local government services, does not contain such specific language, it does require an individual to be “qualified” which is defined in part as meeting “the essential eligibility requirements of the receipt of services or the participation in programs or activities.”²³¹ This language has been found by the Department of Justice to require the same interpretation of direct threat as in Title III.²³²

Contagious diseases were discussed in the ADA’s legislative history. The Senate Report noted that the qualification standards permitted with regard to employment under Title I may include a requirement that an individual with a currently contagious disease or infection shall not pose a direct threat to the health or safety of other individuals in the workplace and cited to *School Board of Nassau County v. Arline*,²³³ the Section 504 case discussed previously.²³⁴ Similarly, the

²²⁶ See http://www.eeoc.gov/facts/pandemic_flu.html.

²²⁷ *Id.*

²²⁸ 42 U.S.C. §12113(b). See also CRS Report RL33609, *Quarantine and Isolation: Selected Legal Issues Relating to Employment*, by (name redacted) and (name redacted).

²²⁹ http://www.eeoc.gov/facts/pandemic_flu.html.

²³⁰ 42 U.S.C. §12182(3).

²³¹ 42 U.S.C. §12131(2).

²³² 28 C.F.R. Part 35, Appx A.

²³³ 480 U.S. 273, 287, note 16 (1987).

²³⁴ S.Rept. 101-116, 101st Cong., 1st Sess. reprinted in Vol. I, Committee Print Serial No. 102-A *Legislative History of P.L. 101-336, The Americans with Disabilities Act*, prepared for the House Committee on Education and Labor at 139 (continued...)

House report of the Committee on Education and Labor reiterated the reference to *Arline* and added, “[t]hus the term ‘direct threat’ is meant to connote the full standard set forth in the *Arline* decision.”²³⁵

The Air Carrier Access Act²³⁶

The Air Carrier Access Act (ACAA) prohibits discrimination by air carriers against “otherwise qualified individual[s]” on the basis of disability.²³⁷ Enacted in 1986,²³⁸ prior to the ADA, the ACAA contains no statutory reference to communicable diseases, but the regulatory text specifically addresses them.²³⁹ Additionally, the regulatory definition of “individual with a disability” appears to include individuals with communicable diseases.²⁴⁰ The regulations prohibit various actions by carriers against individuals with communicable diseases. A carrier may not “(1) [r]efuse to provide transportation to the passenger; (2) [d]elay the passenger’s transportation; (3) [i]mpose on the passenger any condition, restriction, or requirement not imposed on other passengers; or (4) [r]equire the passenger to provide a medical certificate.”²⁴¹ However, an exception applies when “the passenger’s condition poses a direct threat.”²⁴² The regulations define “direct threat” as “a significant risk to the health or safety of others that cannot be eliminated by a modification of policies, practices, or procedures, or by the provision of auxiliary aids or services.”²⁴³

(...continued)

(December 1990).

²³⁵ H.Rept. 101-485, 101st Cong., 2nd Sess., reprinted in Vol. I, Committee Print Serial No. 102-A *Legislative History of P.L. 101-336, The Americans with Disabilities Act*, prepared for the House Committee on Education and Labor at 349 (December 1990). See also 136 Cong. Rec. 10858 (1990).

²³⁶ This subsection was written by (name redacted), Legislative Attorney. For a more detailed discussion of the ACAA see CRS Report RL34047, *Overview of the Air Carrier Access Act*, by (name redacted).

²³⁷ 49 U.S.C. §41705.

²³⁸ Air Carrier Access Act of 1986, 100 Stat. 1080 (1986) (current version at 49 U.S.C. §41705).

²³⁹ 14 C.F.R. § 382.21 (2009).

²⁴⁰ 14 C.F.R. § 382.3 (2009) (referring to “a physical or mental impairment that, on a permanent or temporary basis, substantially limits one or more major life activities, has a record of such an impairment, or is regarded as having such an impairment”). Similarly, courts generally accept communicable diseases as falling within the scope of “disability” under the ADA if the diseases meet the same parameters that other physical or mental impairments must satisfy. See *Bragdon v. Abbott*, 524 U.S. 624, 631-42 (1998). Although no federal court has reached the issue, it follows that courts would likely reach similar conclusions under the ACAA.

²⁴¹ 14 C.F.R. § 382.21(a) (2009).

²⁴² 14 C.F.R. § 382.21(a) (2009).

²⁴³ 14 C.F.R. § 382.3 (2009).

Liability Issues

The Public Readiness and Emergency Preparedness Act (PREP Act)²⁴⁴

The “Public Readiness and Emergency Preparedness Act” (PREP Act)²⁴⁵ created § 319F-3 of the Public Health Service Act, which can limit claims based on public health “countermeasures,” such as drugs or vaccines, when used under specified emergency conditions. Specifically, upon a determination by the Secretary of HHS that either a public health emergency or the credible risk of such emergency exists,²⁴⁶ the Secretary may declare that, with one exception, certain “covered persons” shall be immune from suit under state and federal law with respect to claims arising from the administration or use of a “covered countermeasure.”

“Covered persons” include the United States, manufacturers, distributors, program planners,²⁴⁷ persons who prescribe, administer or dispense the countermeasure, and employees of any of the above. A “covered countermeasure” includes (A) “a qualified pandemic or epidemic product,” (B) “a security countermeasure,” or (C) a drug, biological product, or device that is authorized for emergency use in accordance with section 564 of the Federal, Food, Drug, and Cosmetic Act.²⁴⁸ Each of the terms in (A), (B), and (C) is itself defined in the PREP Act.

The one exception to absolute immunity applies to suits which allege that death or serious physical injury resulted from the willful misconduct of a covered person. These cases may be brought exclusively under a new federal cause of action, with special pleading requirements and procedures specified under the PREP Act. Some potential defendants, such as state or local officials and health care providers who administer or dispense the countermeasure, may also avoid liability for a death or physical injury if they act consistently with guidance issued by the Secretary of HHS and also notify public health authorities of any resulting death or injury within seven days after the death or injury is discovered.²⁴⁹

As an alternative to litigation, victims may accept payment under the “Covered Countermeasure Process Fund,” if Congress has appropriated money for that purpose.²⁵⁰ Amounts and types of

²⁴⁴ This section was written by Vanessa Burrows, Legislative Attorney. For a more detailed discussion of the PREP Act see CRS Report RS22327, *Pandemic Flu and Medical Biodefense Countermeasure Liability Limitation*, by (name redacted) and (name redacted).

²⁴⁵ Division C of P.L. 109-148 (2005), 42 U.S.C. §§ 247d-6d, 247d-6e.

²⁴⁶ This declaration authority is independent of the Secretary’s authority under Section 319 of the Public Health Service Act, 42 U.S.C. 247d, and other similar authorities.

²⁴⁷ Program planners include “a State or local government, including an Indian tribe, a person employed by the State or local government, or other person who supervised or administered a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure.” 42 U.S.C. § 247d-6d(i)(6).

²⁴⁸ See *supra* at “Emergency Use Authorizations (for Unapproved Countermeasures).”

²⁴⁹ 42 U.S.C. § 247d-6d(c)(4).

²⁵⁰ Such an appropriation is currently pending. See CRS Report R40554, *The 2009 Influenza Pandemic: An Overview*, by (name redacted) and (name redacted), under “Appropriations and Funding.” Compensation is also available to eligible individuals whose countermeasure-caused injuries were not the result of willful misconduct.

compensation under this fund would be the same as are provided for persons injured by certain smallpox countermeasures under the Smallpox Emergency Personnel Protection Act of 2003.²⁵¹ These include medical benefits, compensation for lost employment income, and death benefits; damages for pain and suffering or other non-economic injuries are not available.

On June 25, 2009, HHS Secretary Kathleen Sebelius issued a declaration under the PREP Act for the use of H1N1 pandemic vaccines that are currently under development, thereby providing immunity and enabling the compensation program, contingent upon appropriations.²⁵² Earlier, on June 19, the Secretary amended an earlier declaration, providing immunity and enabling compensation (contingent upon appropriations) for the use of the antiviral drugs Tamiflu and Relenza for treatment of illnesses caused by H1N1 pandemic flu.²⁵³

Civil Liability of Volunteers and Volunteer Health Professionals²⁵⁴

When disasters occur, it is common for volunteer health professionals (VHPs) to go to affected areas and offer their medical services. Typically, such individuals are licensed medical professionals who gratuitously provide their services in response to these regions' clear need for medical skills and services. In these scenarios, questions have arisen regarding the potential civil liability of VHPs, particularly with regard to medical malpractice liability. The civil liability of VHPs may be a concern that arises within the context of the 2009 influenza pandemic depending upon the development of the pathogen and how future events unfold.

A patchwork of federal and state laws generally operates to protect volunteers, which may include VHPs, and there are also laws that trigger liability protection specifically for VHPs. Whether a VHP is protected from civil liability depends on a number of factors, including under whose control the VHP operates and whether or not a state of emergency has been declared. It is important to note that liability protections shield volunteers from all civil liability for negligent conduct, i.e., a failure to take adequate care that results in injuries or losses to others. Civil liability for conduct that is more egregious than mere negligence, such as willful, or grossly negligent conduct, is generally not protected.

Volunteer Protection Acts

Laws shielding volunteers from liability have been enacted on both the federal and state level; these statutes apply in non-emergency situations as well as emergency situations. On the federal level, Congress passed the Volunteer Protection Act (VPA) in 1997.²⁵⁵ This statute provides immunity to volunteers (not only medical volunteers) of non-profit organizations or governmental entities for ordinary negligence so long as certain conditions are met.²⁵⁶ The VPA does not

²⁵¹ P.L. 108-20, § 2 (2003), codified at 42 U.S.C. §§ 239c, 239d, and 239e.

²⁵² DEPARTMENT OF HEALTH AND HUMAN SERVICES, Office of the Secretary, "Pandemic Influenza Vaccines—Amendment," 74 Fed. Reg. 30294-30297 (June 25, 2009).

²⁵³ DEPARTMENT OF HEALTH AND HUMAN SERVICES, Office of the Secretary, "Pandemic Influenza Antivirals—Amendment," 74 Fed. Reg. 29213-29214 (June 19, 2009).

²⁵⁴ This section was written by (name redacted), Legislative Attorney. For a more detailed analysis of these issues see CRS Report R40176, *Emergency Response: Civil Liability of Volunteer Health Professionals*, by (name redacted).

²⁵⁵ P.L. 105-19, codified, as amended, 42 U.S.C. § 14501 *et seq.* For background, see CRS Report 97-490, *Volunteer Protection Act of 1997*, by (name redacted).

²⁵⁶ 42 U.S.C. § 14503(a).

prohibit the non-profit or governmental entity from bringing a civil action against its own volunteers; nor does the VPA shield from liability the non-profit or governmental entity for the actions of its volunteers. Furthermore, it expressly preempts state standards that provide less protection.²⁵⁷ All 50 states and the District of Columbia have enacted their own volunteer protection statutes that provide liability protection greater than the federal VPA but to varying degrees. Additionally, many states have enacted statutory provisions geared specifically toward providing VHPs with immunity from civil liability and that, like the VPA, are not dependent on, or triggered by, an emergency situation.²⁵⁸

Liability Protection During a State of Emergency

Except insofar as they waive it, the federal and state governments enjoy sovereign immunity from suit. The federal government has waived its immunity with the passage of the Federal Tort Claims Act,²⁵⁹ and some state governments have similar statutory provisions. Such acts generally immunize government employees from tort liability for torts committed within their scope of employment, and instead allow the government to be held liable in accordance with the law of the state where a tort occurred.

An additional way to shield VHPs from individual civil liability during an emergency is to declare them non-paid employees of the federal government or a state government for liability purposes.²⁶⁰ This can be done for particular volunteers in all situations or only when a general state of emergency or public health emergency has been declared.²⁶¹ Emergencies can be declared at both federal and state levels.²⁶² Every state has a regime for declaring a general emergency or disaster, and such a declaration can explicitly trigger liability protections or allow the governor to do so.²⁶³ In addition to general emergency procedures, some states have regimes for public health emergencies, which, like general emergency management statutes, provide varying degrees of coverage. The declaration of a public health emergency triggers special protections for medical

²⁵⁷ *Id.* at § 14503(d). However, the VPA permits states to enact statutes that declare the non-applicability of the act “to any civil action in a State court against a volunteer in which all parties are citizens of the State.” *See id.* at § 14502. Thus far, only New Hampshire has done so.

²⁵⁸ In addition to VPAs, every state and the District of Columbia has enacted its own “Good Samaritan” statute, which protects individuals who gratuitously provide emergency assistance from civil liability.

²⁵⁹ 28 U.S.C. §§ 1346(b), 2671-80. *See* CRS Report 95-717, *Federal Tort Claims Act (FTCA)*, by (name redacted) and (name redacted)

²⁶⁰ The Pandemic and All-Hazards Preparedness Act, P.L. 109-417, provides an example of such tort liability protections. Under 42 U.S.C. § 300hh-11(d)(1), the Secretary of the HHS may appoint volunteer health professionals as intermittent personnel of the National Disaster Medical System (NDMS), which provides medical services when a disaster overwhelms local emergency services. NDMS volunteers benefit from the same immunity from civil liability as the employees of the Public Health Service. The Secretary may also accept the assistance of the VHPs as temporary volunteers under 42 U.S.C. § 217b. Under applicable regulations, such volunteers may receive legal protections including protection from civil liability claims under the FTCA. *See e.g.*, 45 C.F.R. § 57.5; *see* <http://www.hhs.gov/aspr/opeco/ndms/join/index.html>.

²⁶¹ *See also* CRS Report RS20984, *Public Health Service Act Provisions Providing Immunity from Medical Malpractice Liability*, by (name redacted); CRS Report 97-577, *Making Private Entities and Individuals Immune from Tort Liability by Declaring Them Federal Employees*, by (name redacted).

²⁶² *See* Sharona Hoffman, *Responders’ Responsibility: Liability and Immunity in Public Health Emergencies*, 96 *Geo. L.J.* 1913, 1921 (2008).

²⁶³ For a discussion of state public health emergency response authorities, *see* James G. Hodge and Evan D. Anderson, *Principles and Practice of Legal Triage During Public Health Emergencies*, 64 *N.Y.U. Ann. Surv. Am. L.* 649 (2008), available at, http://www1.law.nyu.edu/pubs/annualsurvey/issues/documents/64_NYU_ASAL_249_2008.pdf.

personnel, which often include liability protection for VHPs. Even where emergency or public health emergency statutes do not explicitly grant liability protections to VHPs, these statutes generally allow governors to impose such protections for volunteers where appropriate.

Emergency Mutual Aid Agreements

Emergency mutual aid agreements may be instituted among political subdivisions and Indian tribal nations within a state, out-of-state with neighboring political subdivisions, or internationally with Canadian provinces. Approved by Congress in 1996, the Emergency Management Assistance Compact (EMAC)²⁶⁴ provides a prearranged structure for a state to request aid from other states when affected by disaster. Since 1996, all 50 states have agreed to the terms of EMAC, as have the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and Guam. Under EMAC, a person from one state who renders assistance in another and who holds a license, certificate, or other permit for the practice of professional, mechanical, or other skills is considered to be licensed, certified, or permitted to exercise those duties in the requesting state, subject to limitations or conditions set by the governor of the requesting state. Notwithstanding the recognition of out-of-state licenses, reciprocity is not automatically extended to VHPs who do not provide services pursuant to an EMAC request for assistance. Following September 11, 2001, Congress created the Emergency System for Advance Registration of Volunteer Health Professionals so that emergency managers and others can have the ability to quickly identify and facilitate the use of VHPs in local, state, and federal emergency response.²⁶⁵

Employment Issues

Introduction²⁶⁶

Questions relating to employment are among the most significant issues presented by an influenza pandemic, since, if individuals fear losing their employment or their wages, compliance with public health measures such as isolation or quarantine may suffer. Controlling or preventing an influenza pandemic involves the same strategies used for seasonal influenza. These strategies are vaccination, treatment with antiviral medications, and the use of infection control measures.²⁶⁷ CDC states that vaccination planners should assume that shipping of H1N1 vaccine will begin mid-October, although some vaccine may be available for shipping earlier.²⁶⁸ Therefore, the use of other infection control measures may be critical. These measures can include having workers

²⁶⁴ P.L. 104-321. EMAC is intended to encourage mutual assistance in “any emergency or disaster that is duly declared by the governor of the affected state(s),” including “natural disaster, technological hazard, man-made disaster, civil emergency aspects of resources shortages, community disorders, or enemy attack.” EMAC, Art. I. See also CRS Report RL34585, *The Emergency Management Assistance Compact (EMAC): An Overview*, by (name redacted).

²⁶⁵ Public Health Security and Bioterrorism Preparedness and Response Act § 107, 42 U.S.C. §247d-7b.

²⁶⁶ This section was written by (name redacted), Legislative Attorney. The ADA and other civil rights acts may also cover employment decisions during a pandemic. For a discussion of these issues see the previous section on civil rights, CRS Report R40866, *The Americans with Disabilities Act (ADA): Employment Issues and the 2009 Influenza Pandemic*, by (name redacted), and http://www.eeoc.gov/facts/pandemic_flu.html.

²⁶⁷ Homeland Security Council, *National Strategy for Pandemic Influenza: Implementation Plan 107* (GPO May 2006).

²⁶⁸ “CDC Novel H1N1 Vaccination Planning Q&A,” <http://www.cdc.gov/h1n1flu/vaccination/statelocal/qa.htm>.

stay home when they are sick. However, this is difficult for the large number of private sector workers who do not have paid sick leave.²⁶⁹

The uses of quarantine and isolation, as well as social distancing and “snow days,” are discussed in the Homeland Security Council’s Pandemic Influenza Implementation Plan²⁷⁰ as ways to attempt to limit the spread of influenza.²⁷¹ Quarantine is defined as the “separation of individuals who have been exposed to an infection but are not yet ill from others who have not been exposed to the transmissible infection.”²⁷² Isolation is defined as the “separation of infected individuals from those who are not infected.”²⁷³ Social distancing is defined as “infection control strategies that reduce the duration and/or intimacy of social contacts and thereby limit the transmission of influenza.”²⁷⁴ Social distancing can include the use of face masks, teleconferencing, or school closures. “Snow days,” a type of social distancing, are the recommendation or mandate by authorities that individuals and families limit social contacts by remaining within their households.²⁷⁵

The Centers for Disease Control and Prevention (CDC) issued interim planning guidance for communities to mitigate the impact of pandemic influenza.²⁷⁶ This guidance introduced a Pandemic Severity Index, which ranks the severity of a pandemic like the categories given to hurricanes and links the severity to specific community interventions. The community interventions include isolation and voluntary quarantine, school dismissals, and the use of social distancing measures to reduce contact. The social distancing measures include the cancellation of large public gatherings and the alteration of workplace environments and schedules to decrease social density.²⁷⁷ The guidance noted the importance of workplace leave policies that would “align incentives and facilitate adherence with the nonpharmaceutical interventions.”²⁷⁸ Strategies to minimize the impact of workplace absenteeism were discussed in some detail and included the use of staggered shifts and telework. Unemployment insurance was mentioned as potentially available, as was disaster unemployment assistance. The guidance also observed that the Family and Medical Leave Act may offer some job security protections.²⁷⁹

²⁶⁹ See The Trust for America’s Health, *H1N1 Challenges Ahead*, <http://healthyamericans.org/reports/h1n1/TFAH2009challengesahead.pdf>.

²⁷⁰ *Id.* at 72-73, 107-109.

²⁷¹ Although the precise effectiveness of these measures is not known, a study by the Institute of Medicine indicated that there is a role for community-wide interventions such as isolation or voluntary quarantine. Institute of Medicine, “Modeling Community Containment for Pandemic Influenza: A Letter Report,” Dec. 11, 2006.

²⁷² Homeland Security Council, *National Strategy for Pandemic Influenza: Implementation Plan* 209 (GPO May 2006).

²⁷³ *Id.* at 207.

²⁷⁴ *Id.* at 209.

²⁷⁵ *Id.*

²⁷⁶ Centers for Disease Control and Prevention (CDC), *Interim Pre-pandemic Planning Guidance: Community Strategy of Pandemic Influenza Mitigation in the United States—Early, Targeted, Layered Use of Nonpharmaceutical Interventions* (February 2007), <http://www.pandemicflu.gov/plan/community/mitigation.html>. The American Public Health Association has also issued recommendations with regard to comprehensive national planning for an influenza pandemic. See American Public Health Association, *APHA’s Prescription for Pandemic Flu* (February 2007) <http://www.apha.org/NR/rdonlyres/D5017DB9-F400-4399-A656-939C4C8DF259/0/FLUpolicycomplete.pdf>.

²⁷⁷ *Id.* at 19.

²⁷⁸ *Id.*

²⁷⁹ *Id.* at 51-52.

The National Governors Association Center for Best Practices (NGA Center) conducted nine regional pandemic preparedness workshops during 2007 and 2008 to “examine state pandemic preparedness, particularly in non-health-related areas such as continuity of government, maintenance of essential services, and coordination with the private sector.” A report analyzing the information gained during these workshops identified areas in which new or improved policies and procedures are necessary to improve pandemic preparedness. One of these areas was workforce policies. The NGA Center concluded:

Every sector examined in this report will be affected by the availability of workers during a pandemic. In general, states and the private sector should develop and test policies affecting the willingness and ability of personnel to perform their duties, whether in traditional or alternative settings. Potential strategies and or guidance addressing telecommuting, alternative schedules, or modified operating hours for retail establishments and Internet or distance-learning programs for school children would be particularly useful. During a pandemic, almost everyone will be susceptible to the illness. A central disease control strategy will be keeping sick people away from others to minimize the spread of infection. Employers should examine their human resource policies and, if needed, create new policies that would allow sick workers to stay at home during a pandemic. When possible, states and private sector employers should collaboratively develop policies that effectively balance the need of some workers to care for sick (or healthy) family members for extended periods of time with the requirements government and private sector continuity of operations plans.²⁸⁰

Wrongful Discharge in Violation of Public Policy²⁸¹

The employment-at-will doctrine governs the employment relationship between an employer and employee for most workers in the private sector. An employee who does not work pursuant to an employment contract, including a collective bargaining agreement that may permit termination only for cause or identify a procedure for dismissals, may be terminated for any reason at any time.

Although the employment-at-will doctrine provides the default rule for most employees, it has been eroded to some degree by the recognition of certain wrongful discharge claims brought against employers. In general, these wrongful discharge claims assert tort theories against the employer. A cause of action for wrongful discharge in violation of public policy is one such claim. If isolation or a quarantine were used to attempt to limit the spread of a pandemic influenza virus and an employee was terminated because of absence from the workplace, a claim for wrongful discharge in violation of public policy might arise.

A claim for wrongful discharge in violation of public policy is grounded in the belief that the law should not allow an employee to be dismissed for engaging in an activity that is beneficial to the public welfare. In general, the claims encompass four categories of conduct:

- refusing to commit unlawful acts (e.g., refusing to commit perjury when the government is investigating the employer for wrongdoing);

²⁸⁰ National Governors Association Center for Best Practices, *Pandemic Preparedness in the States: An Assessment of Progress and Opportunity*, (September 2008).

²⁸¹ This section was written by (name redacted), Legislative Attorney.

- exercising a statutory right (e.g., filing a claim for workers' compensation, reporting unfair labor practices);
- fulfilling a public obligation (e.g., serving on jury duty); and
- whistleblowing.²⁸²

Although most states appear to recognize a claim for wrongful discharge in violation of public policy, it is possible that a state may allow a claim only under certain circumstances. For example, Texas recognizes such a claim only if an employee is terminated for refusing to perform an illegal act or inquiring into the legality of an instruction from the employer.²⁸³

While the four categories of conduct identified above represent the classic fact patterns for a claim of wrongful discharge in violation of public policy, other actions could be deemed beneficial to the public welfare and result in a wrongful discharge claim if an employee is terminated for engaging in such actions. Some courts have broadly defined what constitutes "public policy." For example, in *Palmateer v. International Harvester Co.*, the Illinois Supreme Court indicated that

[t]here is no precise definition of the term. In general, it can be said that public policy concerns what is right and just and what affects the citizens of the State collectively. It is to be found in the State's constitution and statutes and, when they are silent, in its judicial decisions.²⁸⁴

Similarly, in *Boyle v. Vista Eyewear, Inc.*, the Missouri Court of Appeals stated that public policy "is that principle of law which holds that no one can lawfully do that which tends to be injurious to the public or against the public good."²⁸⁵ These broad definitions suggest that an employee's isolation or quarantine during a pandemic in some states could possibly provide a public policy exception to the at-will rule of employment. It would seem possible for a court to conclude that the isolation or quarantine of individuals during a pandemic serves the public good and that the termination of individuals who are isolated or quarantined violates public policy. Some observers insist, however, that no court has ever held that it violates public policy to discharge an individual because he or she missed work because of a quarantine.²⁸⁶

If the government were to mandate individuals to isolate or quarantine themselves either because they were infected or because of the risk of infection, it would seem that such an action would constitute an even stronger argument for the public policy exception to the at-will rule of employment. In such case, the government would appear to be identifying a significant policy that would benefit the public good.

However, even if the government merely recommended isolation or quarantine rather than mandated such actions, a strong argument for a public policy exception to the at-will rule would still seem possible. In its guidance for employers to plan and respond to the 2009-2010 influenza

²⁸² See Steven L. Willborn et al., *Employment Law: Cases and Materials* 82 (1993); John F. Buckley and Ronald M. Green, 2006 State by State Guide to Human Resources Law 5-46 (2006).

²⁸³ See Buckley and Green at 5-59.

²⁸⁴ 421 N.E.2d 876, 878 (Ill. 1981).

²⁸⁵ 700 S.W.2d 859, 871 (Mo. Ct. App. 1985).

²⁸⁶ See Mark A. Rothstein and Meghan K. Talbott, *Job Security and Income Replacement for Individuals in Quarantine: The Need for Legislation*, 10 J. Health Care L. & Pol'y 239 (2007).

season, the CDC recommends that all sick people should remain at home and away from the workplace during an influenza pandemic.²⁸⁷ The CDC further recommends that employees with influenza-like illness should avoid the workplace until at least 24 hours after they are free of fever or the signs of a fever without the use of fever-reducing medications.²⁸⁸ One might suggest that the CDC recommendations establish a policy in furtherance of the public's best interests, and that these recommendations could support a claim for wrongful discharge in violation of public policy.

The Family and Medical Leave Act²⁸⁹

Overview of Family and Medical Leave Rights

The Family and Medical Leave Act (FMLA)²⁹⁰ guarantees employees 12 workweeks of unpaid leave during any 12-month period for one or more of the following reasons:

- because of the birth of a son or daughter of the employee and in order to care for such son or daughter;
- because of the placement of a son or daughter with the employee for adoption or foster care;
- in order to care for a spouse or a son, daughter, or parent of the employee, if such spouse, son, daughter, or parent has a serious health condition; and
- because of a serious health condition that makes the employee unable to perform the functions of the position of such employee.²⁹¹

The FMLA applies to any employer in the private sector that engages in commerce, or in any industry or activity affecting commerce, that has at least 50 employees who are employed for each working day during each of 20 or more calendar workweeks in the current or preceding calendar year.²⁹² To be eligible for family and medical leave benefits, an individual must have been employed for at least 12 months by the employer from whom leave is requested, and must have been employed for at least 1,250 hours of service with such employer during the previous 12-month period.²⁹³

²⁸⁷ Centers for Disease Control and Prevention, *Guidance for Businesses and Employers to Plan and Respond to the 2009-2010 Influenza Season 3* (2009), <http://pandemicflu.gov/professional/business/guidance.pdf>.

²⁸⁸ *Id.* at 7.

²⁸⁹ This section was written by (name redacted), Legislative Attorney.

²⁹⁰ 29 U.S.C. §§ 2601-2654. See also 5 U.S.C. §§ 6381-6387 (providing family and medical leave for civil service employees). For additional discussion of the FMLA, see CRS Report RS22090, *The Family and Medical Leave Act: Background and U.S. Supreme Court Cases*, by (name redacted).

²⁹¹ 29 U.S.C. § 2612(a)(1).

²⁹² 29 U.S.C. § 2611(4)(I). See also 29 U.S.C. § 2611(2)(B)(ii). (Employers who employ 50 or more employees within a 75-mile radius of an employee's worksite are subject to the FMLA even if they may have fewer than 50 employees at a single worksite.)

²⁹³ 29 U.S.C. § 2611(2).

The FMLA also covers public agencies, including federal, state, and local governments.²⁹⁴ Unlike employers in the private sector, public employers do not have to employ at least 50 employees to be subject to the FMLA. Employees of public agencies, however, must have worked generally for a specified number of weeks to be eligible for benefits.

During an influenza pandemic, the FMLA would seem to provide infected employees and employees who care for certain infected relatives with the opportunity to be absent from the workplace.²⁹⁵ The FMLA defines a “serious health condition” to mean “an illness, injury, impairment, or physical or mental condition” that involves either “inpatient care in a hospital, hospice, or residential medical care facility; or ... continuing treatment by a health care provider.”²⁹⁶ An employee who was affected by a pandemic influenza virus may be found to have a serious health condition. If the FMLA’s eligibility requirements were met, such an employee would likely be granted leave under the statute.²⁹⁷

In addition, because the FMLA grants leave to an employee to care for a spouse, child, or parent with a serious health condition, an employee could be granted leave to care for a relative who was affected by a pandemic influenza virus if the employee met the statute’s eligibility requirements. While on leave, the employee with the serious health condition or the employee caring for a spouse, child, or parent with a serious health condition could be isolated or quarantined without the fear of termination for at least 12 workweeks.²⁹⁸

An employee who was not infected by a pandemic influenza virus or who was not responsible for the care of a spouse, child, or parent infected by such a virus would not be protected by the FMLA. If such an employee sought isolation or quarantine to avoid exposure and was absent from the workplace, the FMLA would not prohibit the employer from terminating the employee.

The U.S. Office of Personnel Management (OPM) has attempted to help federal agencies with planning for pandemic influenza.²⁹⁹ *Planning for Pandemic Influenza* highlights the availability of various leave flexibilities that could assist affected federal employees. For example, the guidance discusses the availability of donated leave and leave without pay if an employee has exhausted his or her sick leave.³⁰⁰ On August 26, 2009, OPM proposed new regulations that would permit an agency to advance up to 240 hours of sick leave to a full-time employee when he or she would, as determined by the health authorities having jurisdiction or by a health care provider, jeopardize the health of others by his or her presence on the job because of exposure to

²⁹⁴ See 29 U.S.C. § 2611(4)(A)(iii) (defining the term “employer” to include any public agency in accordance with section 3(x) of the Fair Labor Standards Act, 29 U.S.C. § 203(x)).

²⁹⁵ See CDC, *supra* note 276 (explaining that absenteeism for child minding could last as long as 12 weeks for a severe pandemic).

²⁹⁶ 29 U.S.C. § 2611(11).

²⁹⁷ It is possible that an employee could be affected by a pandemic influenza virus and not develop a serious health condition. In such case, the employee would not be eligible for leave under the Family and Medical Leave Act.

²⁹⁸ Although the FMLA allows for at least 12 workweeks of leave, it does not guarantee the payment of wages during such leave. Under section 102(d)(2)(B) of the act, 29 U.S.C. § 2612(d)(2)(B), an employer may require the employee to substitute paid vacation or sick leave for the leave granted under the act. If such a substitution is not made, however, the employee is likely to be granted unpaid leave.

²⁹⁹ U.S. Office of Personnel Management, *Planning for Pandemic Influenza* (2009), http://www.opm.gov/pandemic/opm-pandemic_allissuances.pdf. For more information regarding the federal workforce see <http://www.flu.gov/professional/federal/workplace/index.html>.

³⁰⁰ *Id.* at OPM-I-D-1.

a communicable disease.³⁰¹ The proposed regulations would also allow an agency to advance 104 hours of sick leave to a full-time employee to provide care to a family member who has been exposed to a communicable disease.³⁰² In addition to the proposed regulations, OPM has indicated that the 2009 H1N1 vaccine will be offered to federal employees and that this vaccination program will follow the ACIP guidelines for priorities.³⁰³

State and Federal Laws Providing Employment Protections

At least six states, recognizing the lack of statutory protection for employees in a situation where isolation or quarantine may be necessary, have enacted legislation that explicitly prohibits the termination of an employee who is subject to isolation or quarantine. In Delaware, Iowa, Kansas, Maryland, Minnesota, and New Mexico, an employer is prohibited from terminating an employee who is under an order of isolation or quarantine, or has been directed to enter isolation or quarantine.³⁰⁴ Under Minnesota law, an employee who has been terminated or otherwise penalized for being in isolation or quarantine may bring a civil action for reinstatement or for the recovery of lost wages or benefits.³⁰⁵

Two additional states have enacted legislation that addresses the treatment of employees who are subject to quarantine or isolation. Under New Jersey law, an affected employee must be reinstated following the quarantine or isolation.³⁰⁶ Under Maine law, an employer is required to grant leave to an employee who is subject to quarantine or isolation.³⁰⁷ The leave granted by the employer may be paid or unpaid.³⁰⁸

Although federal law does not protect from termination employees who may be absent from the workplace because of isolation or quarantine, there are examples of employee protections that are

³⁰¹ Absence and Leave; Family and Medical Leave, 74 Fed. Reg. 43,064, 43,072 (Aug. 26, 2009) (to be codified at 5 C.F.R. pt. 630).

³⁰² *Id.*

³⁰³ “Immunization of Federal Workers with 2009 H1N1 and Seasonal Flu Vaccines,” (September 30, 2009), http://www.opm.gov/pandemic/memos/h1n1_20090930.asp.

³⁰⁴ Del. Code Ann. tit. 20, § 3136(6)(d); Iowa Code § 139A.13A; Kan. Stat. Ann. § 65-129d; Md. Code Ann., Health-Gen. § 18-906; Minn. Stat. § 144.4196; N.M. Stat. Ann. § 12-10A-16.

³⁰⁵ Minn. Stat. § 144.4196.

³⁰⁶ N.J. Rev. Stat. § 26:13-16.

³⁰⁷ Me. Rev. Stat. Ann. tit. 26, § 875.

³⁰⁸ The availability of wage or income replacement because of quarantine or isolation has been addressed by some commentators. See, e.g., Nan D. Hunter, “Public-Private” Health Law: Multiple Directions in Public Health, 10 J. Health Care L. & Pol’y 89 (2007). Many commentators maintain that existing wage or income replacement programs, such as unemployment and workers compensation, would probably not provide compensation for most employees affected by quarantine or isolation. Replacement wages were, however, reportedly paid during at least one quarantine. During the 1916 polio epidemic, quarantined families in the village of Glen Cove, New York received replacement wages. See Guenter B. Risse, *Revolt Against Quarantine: Community Responses to the 1916 Polio Epidemic*, Oyster Bay, New York, Transactions & Stud. of the College of Physicians of Philadelphia, Mar. 1992, at 34 (“Garbage cans were distributed free of charge, and quarantined families received replacement wages to compensate for loss of income”). Disaster unemployment assistance pursuant to the Stafford Act may also be a possibility if it is determined that the act is applicable to an influenza pandemic. See CRS Report RL34724, *Would an Influenza Pandemic Qualify as a Major Disaster Under the Stafford Act?*, by (name redacted); CRS Report RS22022, *Disaster Unemployment Assistance (DUA)*, by (name redacted) and (name redacted) (discussing the availability of disaster unemployment benefits pursuant to a disaster declaration under the Stafford Act).

arguably analogous.³⁰⁹ The FMLA, for example, does grant leave to an eligible employee who has a serious health condition or who provides care to a spouse, child, or parent with a serious health condition. Moreover, an expansion of the FMLA to allow paid leave because of a serious health condition or to care for a spouse, child, or parent with such a condition has been proposed.³¹⁰ The availability of paid leave would likely minimize concerns about lost wages during an influenza pandemic.³¹¹

The Uniformed Services Employment and Reemployment Rights Act (USERRA) provides another example of employee protection.³¹² USERRA requires the reemployment of an employee who has been absent from a position of employment because of service in the uniformed services. USERRA and the FMLA illustrate Congress's awareness of events that may necessitate an employee's absence from the workplace.

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³⁰⁹ During the SARS (Severe Acute Respiratory Syndrome) epidemic, Canadian laws and regulations were amended to provide for special employment insurance coverage for health care workers who were unable to work because of SARS and to provide for unpaid leave if an individual was unable to work due to a SARS-related event, such as being under individual medical investigation. See Institute for Bioethics, Health Policy and Law, *Quarantine and Isolation: Lessons Learned from SARS* at 58-59 (November 2003).

³¹⁰ See, e.g., Family Leave Insurance Act of 2009, H.R. 1723, 111th Cong. (2009). For additional information on leave benefits available pursuant to federal law, see CRS Report RL34088, *Leave Benefits in the United States*, by (name redacted).

³¹¹ Some states are exploring the availability of paid leave as part of their state disability insurance programs. In 2002, legislation that extends disability insurance benefits to individuals who are unable to perform their work because they are "caring for a seriously ill child, parent, spouse, or domestic partner" was enacted in California. See Cal. Unemp. Ins. Code §§ 3300-3306. Under the so-called Paid Family Leave Insurance Program, an individual who meets the program's requirements is eligible for benefits equal to one-seventh of the individual's weekly benefit amount on any day in which he or she is unable to perform the individual's regular or customary work. Similar legislation has been enacted in New Jersey. See A. 873, 213th Leg., Reg. Sess. (N.J. 2008).

³¹² 38 U.S.C. §§ 4301-4333.

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