

H1N1 Now A “National Emergency”: Examining Portions of Federal Public Health Emergency Law

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Last week, President Obama issued a proclamation stating that the H1N1 influenza pandemic now constitutes a “national emergency.”¹ The proclamation was necessary to empower the Secretary of the U.S. Department of Health and Human Services (HHS), Kathleen Sebelius, to issue waivers of federal law for the nation’s hospitals and other healthcare providers in the event emergency rooms become overwhelmed by individuals suspected of having the virus. As confirmed cases of the H1N1 influenza rise nationwide, thousands of people have lined up in cities waiting to get vaccinated, but the widely anticipated vaccination program has gotten off to a sluggish start.² Some states have requested much more of the vaccine than they have been allotted; only 22 million doses of the vaccine are currently available.³ As a result, some commentators believe the lack of vaccinated individuals may result in overwhelmed health care resources and may push emergency rooms to the brink. Although President Obama’s proclamation issuance was more of a formality than a substantive act, it provides interesting insight to the workings of federal public health emergency law.

Background

The 2009 H1N1 influenza virus got off to a brisk start earlier this year by infecting thousands of individuals worldwide. By the end of April, then-Acting HHS Secretary, Charles E. Johnson, declared a public health emergency pursuant to section 319 of the Public Health Service Act (PSHA)⁴ – one of the major federal laws addressing protocol during public health emergencies. Such a declaration allows the HHS Secretary to take “appropriate action to respond to a public health emergency, including making grants, entering into contracts, and investigating the cause, treatment, or prevention of the disease or disorder.”⁵ Since that time, current HHS Secretary Sebelius has renewed the declaration twice, on July 24, 2009, and on October 1, 2009.⁶ Meanwhile, as the reported cases of H1N1 infections grew worldwide, the World Health Organization (WHO), raised

¹ See Office of the Press Sec’y, The White House, *Declaration of a National Emergency With Respect to the 2009 H1N1 Influenza Pandemic*, Oct. 24, 2009, available at http://www.politico.com/static/PPM145_memo_one.html.

² Jackie Calmes and Donald G. McNeil, Jr., *Swine Flu Is Widespread in 46 States as Vaccines Lag*, N.Y. TIMES, Oct. 25, 2009, http://www.nytimes.com/2009/10/25/us/politics/25flu.html?_r=1.

³ *Id.*

⁴ 42 U.S.C. § 247d-6d (West 2009).

⁵ U.S. Dep’t of Health & Human Servs., *HHS Pandemic Influenza Plan*, available at <http://www.hhs.gov/pandemicflu/plan/appendix.html> (last accessed Oct. 22, 2009); Emily McCormick, editor, *Frequently Asked Questions about Federal Public Health Emergency Law*, (Sept. 2009), based on the Apr. 28, 2009, teleconference FEDERAL PUBLIC HEALTH EMERGENCY LAW: IMPLICATIONS FOR STATE & LOCAL PREPAREDNESS AND RESPONSE, at 10.

⁶ See Office of the Press Sec’y, *supra* note 1; see also Calmes and McNeil, Jr., *supra* note 2.

the worldwide pandemic level to Phase 6 on June 11, 2009.⁷ A Phase 6 alert, the highest assigned by the WHO, is characterized as a global outbreak of the disease and an indication that a global pandemic is underway.⁸ Subsequently, the H1N1 virus has continued to spread, with the number of countries reporting cases nearly doubling. Since August 30, 2009, the Centers for Disease Control and Prevention (CDC), estimates that over 8,000 individuals in the United States have been hospitalized due directly to the H1N1 virus and 411 people died as a result.⁹ There have been nearly 22,000 individuals hospitalized due to “pneumonia and influenza symptoms” and resulting in 2,416 deaths, however, they are not confirmed cases of H1N1.¹⁰ Additionally, the CDC reported that the number of states experiencing widespread influenza activity jumped from 41 to 46 in about one week’s time.¹¹ As a proactive measure and recognizing the potential that the pandemic could overwhelm health care resources, President Obama exercised his authority under federal law and declared the H1N1 influenza virus a “national emergency.”¹²

President Obama’s Declaration Using the National Emergencies Act

In addition to the United States Constitution, there are a number of federal laws that give the President of the United States broad authority to deal with public health emergencies. Among them is the National Emergencies Act (the “Act”),¹³ passed by Congress in 1976, which serves as the basis for President Obama’s recent proclamation. The Act modified specific statutory grants of emergency authority enjoyed by the President prior to 1976 and now requires the President to formally declare the existence of a national emergency and specify what statutory authority would be used; it also provides Congress a means to countermand the President’s declaration and the activated authority being sought.¹⁴ But what is meant by an “emergency”? Harold Relyea, a Specialist in American National Government formerly employed with the Congressional Research Service of the Library of Congress, stated in a report to Congress on Presidential emergency powers that there are at least four aspects of an emergency condition:

⁷ Centers for Disease Control & Prevention, *A Pandemic Is Declared*, <http://www.cdc.gov/h1n1flu/updates/071709.htm> (last accessed Oct. 25, 2009).

⁸ World Health Org., Global Alert and Response, *Current WHO Phase of Pandemic Alert*, http://www.who.int/csr/disease/avian_influenza/phase/en (last accessed Aug. 6, 2009).

⁹ Centers for Disease Control & Prevention, *2009-2010 Influenza Season Week 41 ending October 17, 2009*, <http://www.cdc.gov/flu/weekly/index.htm#MS> (last accessed Oct. 26, 2009) (3 deaths in children less than 2 years, 7 deaths in children 2-4 years, 21 deaths in children 5-11 years, and 22 deaths in individuals 12-17 years).

¹⁰ *Id.*

¹¹ See Centers for Disease Control & Prevention, *2009 H1N1 Flu: Situation Update*, <http://www.cdc.gov/h1n1flu/update.htm> (last updated Oct. 16, 2009) and Centers for Disease Control & Prevention, *2009 H1N1 Flu: Situation Update*, <http://www.cdc.gov/h1n1flu/update.htm> (last updated Oct. 23, 2009)

¹² See Office of the Press Sec’y, *supra* note 1.

¹³ 50 U.S.C. § 1601 *et seq.* (West 2009).

¹⁴ Harold C. Relyea, CRS Report for Congress, *National Emergency Powers*, available at <http://www.fas.org/sgp/crs/natsec/98-505.pdf> (last updated Aug. 30, 2007).

[t]he first is its temporal character: an emergency is sudden, unforeseen, and of unknown duration. The second is its potential gravity: an emergency is dangerous and threatening to life and well-being. The third, in terms of governmental role and authority, is the matter of perception: who discerns this phenomenon? The Constitution may be guiding on this question, but not always conclusive. Fourth, there is the element of response: by definition, an emergency requires immediate action, but is, as well, unanticipated and, therefore...cannot always be “dealt with according to rule.”¹⁵

As enacted, the Act consisted of five titles. Most relevant to this article however is Title II, which provides a procedure for the President to declare a national emergency.¹⁶ Such a declaration lasts for one year unless formally continued by the President; it is terminated by joint resolution of Congress.¹⁷ When declaring a national emergency, the President must indicate the powers and authorities being activated to respond to the exigency at hand¹⁸ – in the current instance – the H1N1 influenza pandemic. In his proclamation, President Obama stated that:

...given that the rapid increase in illness across the Nation may overburden health care resources and that 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. Accordingly, I hereby declare that the Secretary [of HHS] may 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...¹⁹

More specifically, HHS Secretary Sebelius now has the discretion to issue waivers of certain federal requirements of the Emergency Medical Treatment and Active Labor Act (EMTALA) as well as HIPAA, should the need arise.

Section 1135 Waivers of the Social Security Act

Under Section 1135 of the Social Security Act (SSA),²⁰ Secretary Sebelius may waive or modify certain requirements of EMTALA and the HIPAA Privacy Rule as necessary to ensure that health care resources are sufficient to meet demand. Such waivers are only authorized when there is (1) an emergency or disaster declared by the President pursuant to the National Emergencies Act or Stafford Act and (2) a public health emergency has

¹⁵ *Id.* at 7.

¹⁶ *Id.*

¹⁷ *Id.* See also 50 U.S.C. § 1622 (West 2009).

¹⁸ *Id.* See also 50 U.S.C. § 1631 (West 2009).

¹⁹ See Office of the Press Sec’y, *supra* note 1.

²⁰ 42 U.S.C. § 1320b-5 (West 2009).

been declared by the HHS Secretary.²¹ The waiver lists certain requirements that can be waived or modified to assist states in providing surge capacity, such as modification of bed limits for critical access hospitals and transfers of patients without regard to EMTALA regulations.²² The waiver of EMTALA and HIPAA requirements will last as long as the Presidential declaration is in effect or for a 72-hour period following a hospital's implantation of its disaster protocol, whichever comes first.²³

Federal requirements are not automatically waived as a result of the 1135 waiver. Rather, the Centers for Medicare and Medicaid Services (CMS) reviews requests submitted by healthcare providers and makes a case-by-case determination. As a practical matter, a hospital with a waiver could send patients to an off-site facility specifically for those with suspected H1N1 influenza for treatment. However, CDC official David Daigle stated that no hospital, as of yet, has faced a surge of patients so great that an off-site facility has been needed.²⁴

The Stafford Act

Somewhat similar to the National Emergencies Act is the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act),²⁵ which amended the Disaster Relief Act of 1974.²⁶ A public health emergency declaration under Section 319 of the PHSA and a declaration of an emergency or disaster under the Stafford Act are distinct and separate declarations. The Act is triggered when the President declares a major disaster or threat that overwhelms state or local governments.²⁷

The governor of an affected state must first respond to the disaster and execute the state's emergency plan prior to requesting, in writing, that the President declare a major disaster or emergency because the state is unable to handle the situation using existing resources. Such a declaration allows disaster relief funds, appropriated by Congress, and relief from the Federal Emergency Management Agency (FEMA), to be available to states. Typically, the governor of the state requests a Presidential declaration; however, in extraordinary circumstances, the President may unilaterally declare a major disaster or emergency.²⁸ As mentioned above, a Presidential declaration pursuant to the National Emergencies Act or the Stafford Act and a public health emergency declaration by the HHS Secretary is required to allow the Secretary to issue Section 1135 waivers.²⁹

²¹ Emily McCormick, editor, *Frequently Asked Questions about Federal Public Health Emergency Law*, (Sept. 2009), based on the Apr. 28, 2009, teleconference FEDERAL PUBLIC HEALTH EMERGENCY LAW: IMPLICATIONS FOR STATE & LOCAL PREPAREDNESS AND RESPONSE, at p. 11.

²² *Id.*

²³ *Id.* at 12.

²⁴ See Calmes and McNeil, Jr., *supra* note 2.

²⁵ Pub. L. No. 100-707, 100th Cong. (1988); 42 U.S.C. §§ 5121-5207 (West 2008).

²⁶ Pub. L. No. 93-288, 93rd Cong. (1974).

²⁷ See McCormick, *supra* note 21, at 14.

²⁸ *Id.*

²⁹ *Id.* at 15.

The Pandemic and All-Hazards Preparedness Act of 2006

The Pandemic and All-Hazards Preparedness Act of 2006 (PAHPA),³⁰ amends the PSHA and identifies the Secretary of HHS as the lead federal official for public health emergency preparedness and response. It also establishes within the HHS the position of Assistant Secretary for Preparedness and Response (ASPR) – the principle advisor on matters related to public health and medical emergencies. Other duties covered by the ASPR include to: (1) oversee advanced research, development, and procurement of qualified countermeasures and qualified pandemic or epidemic products and (2) provide logistical support for medical and public health aspects of federal responses to public health emergencies.³¹

Conclusion

As the H1N1 influenza virus continues to spread across the country, it will interesting to see whether, and to what extent, Section 1135 waivers are requested and issued to healthcare providers – one of the more substantive aspects of federal public health emergency law.

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³⁰ S.B. 3678, Pub. L. No. 109-417, 109th Cong. (2006).

³¹ *Id.* at Sec. 102.