Public Readiness and Emergency Preparedness Act (PREP)

(And Other Aspects of Federal Public Health Emergency Law)

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Health Law & Policy Institute
University of Houston Law Center
After Halloween, Don’t Forget to Turn Your Clocks Back…
Background: 2009 H1N1 Flu Pandemic

- First Outbreak Observed in Mexico.
- Virus Spread Quickly.
- WHO and CDC stopped counting and focused on tracking.
  - Similar strains were seen in the Spanish flu (1918), Asian flu (1957), Hong Kong flu (1968-69), and briefly in 1976.
- Acting HHS Secretary declares a public health emergency on April 26.
Section 319 of the Public Health Service Act (PHSA)

- PHSA: enacted in 1944.
- Consolidated then-existing public health services into what is now the Department of HHS.
- **Section 319:** “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...”
Section 319 Declaration

As a consequence of confirmed cases of Swine Influenza A (swH1N1) in California, Texas, Kansas, and New York, on this date and after consultation with public health officials as necessary, I, Charles E. Johnson, Acting Secretary of the U.S. Department of Health and Human Services, pursuant to the authority vested in me under section 319 of the Public Health Service Act, 42 U.S.C. § 247d, do hereby determine that a public health emergency exists nationwide involving Swine Influenza A that affects or has significant potential to affect national security.

April 26, 2009

/s/
Acting HHS Secretary Charles E. Johnson
Section 319 Declaration

- Declaration terminates after 90 days or upon a date previously determined by the Secretary – whichever comes first.
  -- Secretary Sebelius renewed the declaration two times: July 24th and October 1st.

- Allows the Secretary to do three important things:
  1. Draw from the Public Health Emergency Fund…no $$ yet!
  2. Authority from the Food, Drug, and Cosmetic Act to issue EUAs.
  3. Issue Section 1135 waivers of EMTALA and HIPAA requirements.
     -- IF there is a Stafford Act or National Emergencies Act declaration.
WHO Declares H1N1 a Pandemic

H1N1 Vaccine Manufacturers

- The U.S. contracted with 5 suppliers of seasonal influenza:
  1. CSL Limited
  2. MedImmune, LLC
  3. Novartis Vaccines and Diagnostics Ltd.
  4. Sanofi Pasteur, Inc.
  5. GlaxoSmithKline (yet to gain FDA approval)

- On September 15th, the FDA announced the vaccine makers.

- Production is slow.

- Currently, only about one-half of the expected doses are available.
The Swine Flu Outbreak in 1976

- Flu hit soldiers at Fort Dix, New Jersey.

- 40 million vaccinated.

- 500,000 developed Guillain-Barre Syndrome.
Public Readiness and Emergency Preparedness Act (PREP)


🍂 Provides immunity from tort lawsuits for manufacturers, administrators, and distributors of vaccines as well as other “qualified persons” who prescribe, administer, or dispense “countermeasures”.

🍂 Countermeasure? Vaccines, Antidotes, Medications, Medical Devices, etc.

🍂 Fund compensates harmed individuals.
**PREP Act: Compensation Fund**

- Not the same fund as the National Vaccine Injury Compensation Program (VCIP).
- Authorizes Congress to appropriate funds. Not funded yet!
- What countermeasures are covered?
  1. Anthrax
  2. Botulism
  3. Pandemic Antivirals (Tamiflu and Relenza)
  4. Small Pox
  5. Acute Radiation Syndrome
  7. H1N1 Vaccine (June 2009).
PREP Act: Who is Provided Immunity?

“Covered Persons”
1. Manufacturers (includes contractor/subcontractor)
2. Distributors
3. Program Planners
4. Qualified Persons
5. The United States
PREP Act: What is Covered?

- The Act provides immunity for any type of loss:
  1. Physical, mental, or emotional injury.
  2. Illness or disability.
  3. Fear of physical, mental or emotional injury including medical monitoring.
  4. Loss of or damage to property including business interruption.
  5. Death.

- Must have a causal relationship to any stage of development, distribution, administration or use of the countermeasure.
PREP Act: What is NOT Covered?

- Immunity is not available for death or serious physical injury caused by willful misconduct.

Willful Misconduct: an act or omission that is taken:
1. Intentionally to achieve a wrongful purpose;
2. Knowingly without legal or factual justification;
3. In disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.

All must be met by clear and convincing evidence.

Not available if outside scope of declaration. Time and Geography.

Not available if not used according to stated uses:
1. Licensed or approved by the FDA;
2. Authorized for investigational use by the FDA;
Emergency Use Authorization (EUA)


- Issued by FDA/HHS to allow:
  1. Use of an unapproved product, or
  2. Unapproved use of an approved product.

- The EUA must meet specific statutory criteria.

- In place for Tamiflu, Relenza, Peramivir IV, and some respirators, influenza diagnostic tests, and the swine flu test.
Difference Between a PREP Act and Section 319 Declaration
A Summary…

- **Section 319:** Secretary may issue based on a determination that:
  1. a disease or disorder presents a public health emergency
  2. a public health emergency, including significant outbreaks, exists.

- **PREP Act:** Secretary determines that a disease or public health condition constitutes a public health emergency or there is risk of a future emergency. Simply triggers the Act’s immunity.
National Emergencies Act

Stafford Act

Pandemic and All-Hazards Preparedness Act
National Emergencies Act

- Passed by Congress in 1976.

- President Obama declared H1N1 on October 24, 2009.

- Most relevant is Title II.

- Terminated by Joint Resolution of Congress.
President Obama’s Declaration

...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…
Section 1135 Waivers

- Section 1135, Social Security Act

- Authorized only when there is:
  1. Presidential declaration via National Emergencies Act or Stafford Act, AND
  2. Section 319 Public Health Emergency Declaration from the Secretary, AND
  3. Secretary invokes her waiver authority; AND
  4. The declaration issued includes a waiver of federal requirements.

- Secretary Sebelius has authority to issue waivers of certain requirements under CHIP, EMTALA and HIPAA.
Section 1135 Waivers

- **EMTALA: Emergency Medical Treatment and Active Labor Act**
  
  Requires hospitals to screen and stabilize all patients who present to the emergency department for care.

- EMTALA Waiver allows a hospital to:
  1. Direct/relocate individuals who come to the ED to alternate, off-campus sites for the medical screening exam (MSE).
  2. Effect transfers normally prohibited under EMTALA of individuals with unstable emergency medical conditions as long as the transfer is necessitated by circumstances of the declared emergency.
EMTALA Examples

- Hospitals request to set up an alternative screening location for patients away from the hospital’s main campus (requiring waiver of sanctions for certain directions, relocations or transfers under EMTALA).

- Hospitals request to facilitate transfer of patients from ERs and inpatient wards between hospitals (requiring waiver of sanctions under EMTALA regulations).

- Critical Access Hospitals requesting waiver of 42 CFR 485.620, which requires a 25-bed limit and average patient stays less than 96 hours.

- Skilled Nursing Facilities requesting a waiver of 42 CFR 483.5, which requires CMS approval prior to increasing the number of the facility’s certified beds.
Section 1135 Waivers

- HIPAA: Health Insurance Portability and Accountability Act

- Applies to the Privacy Rule.

- Secretary may waive sanctions and penalties against a covered entity that does not comply.
HIPAA Examples

- The requirements to obtain a patient's agreement to speak with family members or friends involved in the patient’s care (45 CFR 164.510(b)).

- The requirement to honor a request to opt out of the facility directory (45 CFR 164.510(a)).

- The requirement to distribute a notice of privacy practices (45 CFR 164.520)

- The patient's right to request privacy restrictions (45 CFR 164.522(a))

- The patient's right to request confidential communications (45 CFR 164.522(b)).
Section 1135 Waivers

CMS will review requests submitted by hospitals.

Makes a case-by-case determination.

Waiver lasts for 72 hours after hospital has activated its disaster plan, OR

Until the Presidential or Secretarial declaration terminates.

Does not affect state law requirements.
Practical Steps

- Health care providers submit requests via e-mail to the CMS Regional Office or by calling the State Office.
  
  RODALDSC@cms.hhs.gov

- Have justification ready…

- CMS will review and validate the waiver utilizing a cross-regional Waiver Validation Team.
Stafford Act

- The Robert T. Stafford Disaster Relief and Emergency Assistance Act…..(whew!)

- Triggered when the President declares a major disaster or threat.

- Must be one that overwhelms state resources to respond.
Stafford Act

- Governor responds and executes the state’s emergency plan.
- Requests, in writing, that the President declare a disaster/emergency.
- Allows for disaster relief funds and resources of FEMA.
- President may declare emergency unilaterally.
PAHPA: Pandemic and All-Hazards Preparedness Act

- Enacted in 2006.
- Amends portions of the PHSA.
- Identifies the HHS Secretary as the lead federal official for public health emergency preparedness and response.
- Establishes the ASPR: (Asst. Sec. for Preparedness and Response).
PAHPA

- ASPR: Principle advisor on matters related to public health and medical emergencies. (Not named)
- Oversee advanced R&D and procurement of countermeasures
- Provide logistical support for medical and public health aspects of federal responses to public health emergencies.