Public Health Emergency Law: Emergency Use of Property and Supplies

September 18, 2014
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Public Health Emergency Law: Emergency Use of Property and Supplies

September 18, 2014
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Moderator Introduction

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- Deputy Director, Network for Public Health Law — Western Region
- J.D., Certificate of Health Law, Arizona Statue University Sandra Day O’Connor College of Law
- Research interests/areas of expertise:
  - Legal Research
  - Emergency Legal Preparedness and Response
  - Health Reform
Panel Introduction

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  - Bioterrorism Preparedness
  - Emergency Response
Panel Introduction

**Tina Batra Hershey, J.D., M.P.H.**
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**Research interests/areas of expertise:**
- Legal, policy and ethical issues impacting public health preparedness and authority to close schools
- Public health science and law in the judiciary
- Legal preparedness for Tribal public health emergencies
Panel Introduction

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  - Disaster Response
Panel Introduction

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Panel Introduction

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  - Public Health Law and Ethics
  - Public Health Information Privacy Law and Policy
Presentation Overview

- CDC’s Public Health Law Program
- Project Background
- Methodology
- Organization of the Competency Model
- Discussion
Disclaimer

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Mission and Services
CDC’s Public Health Law Program

• What we do
  • Advance the use of law as a public health tool

• How we do it
  • Provide technical assistance, publications, legal epidemiology, and workforce development
  • We focus on creating tools – something that can be used to influence public health outcomes

• Who we serve
  • CDC programs and state, tribal, local, and territorial (STLT) communities

To submit technical assistance request or learn more about public health law, visit us at

www.cdc.gov/phlp
The Legal Preparedness Competency Model:

Background
In 2010, CDC and ASPH released the Public Health Preparedness & Response Core Competency Model.

Only one competency considered legal issues, and did so broadly:

- Competency #3.4: “Refer matters outside of one's scope of legal authority through the chain of command.”

The Legal Preparedness Competency Model should serve as a supplement to this document.
Why a Legal Preparedness Competency Model?:

CDC’s Office of Public Health Preparedness

- In March 2011, CDC released the *Public Health Preparedness Capabilities: National Standards for State and Local Planning* (PHEP Capabilities).

- Goal is to help state, tribal, local, and territorial planners:
  - Identify gaps in preparedness
  - Determine specific jurisdictional priorities
  - Develop plans for building and sustaining specific competencies and capabilities

- While an understanding of law is integral to each of the 15 PHEP Capabilities, law-based competencies were not specifically considered in their development.
Why a Legal Preparedness Competency Model?:
CDC’s Office of Public Health Preparedness and Response

- Given the significance of public health law to effective public health emergency preparedness, and recognizing this critical gap in existing emergency preparedness competency models, OPHPR approached PHLP and asked that we:


2. Create a cross-walk between the PHEP Capabilities and the model set of Minimum Competencies in Public Health Emergency Law.

3. Create a cross-walk between existing PHLP developed public health emergency law training, tools, and resources, and the model set of Minimum Competencies in Public Health Emergency Law.
How will the model be used?

Advance the inclusion of law-based content in all public health emergency training, resources, and tools

STLT PH Agencies:
• Career ladders and IDPs for employees
• Position descriptions and job qualifications
• Training plans

Trainers/Educators
• Ensure existing and future public health emergency law training courses/curricula are competency-based
The Legal Preparedness Competency Model: Project Methodology
Legal Preparedness Competency Model: Project Methodology

1. Build a competency library (June – July 2012)
2. Convene an informal review workgroup (July – Sept. 2012)
6. Evaluate use and uptake of Competency Model (June – July 2012)
The Legal Preparedness Competency Model:
Organizational Framework
Legal Preparedness Competency Model: Key Definitions

**Legal preparedness** is defined as the

“attainment by a public health system . . . of legal benchmarks essential to the preparedness of the public health system.” The four core elements of public health emergency legal preparedness are

1. Laws
2. Competencies
3. Coordination
4. Information
Legal Preparedness Competency Model: Key Definitions

**Mid-tier public health professional** is defined as:

a. An individual with five years of experience and an MPH equivalent or higher degree in public health, or
b. An individual who does not have an MPH or related degree, but has at least 10 years of experience working in the public health field.

These workers may be responsible for a wide range of program support coordination, management, and implementation.
Legal Preparedness Competency Model: Organizational Framework

• Presents a core set of law-specific skills and legal knowledge necessary for effective public health preparedness and emergency response across STLT jurisdictions.

• Should help practitioners be better able to comply with applicable law, reduce concerns for personal and institutional liability, and recognize and respect the individual rights of community members, all within the context of the broader emergency response effort.
Legal Preparedness Competency Model: Organizational Framework

Three Domains:

Domain 1: Systems *Preparedness and Response*

Domain 2: *Management and Protection of Property and Supplies*

Domain 3: *Management and Protection of Persons*
Legal Preparedness Competency Model:
Domain #1: Systems Preparedness and Response

1.1. **Act** within the scope of federal, state, tribal, and local statutory and regulatory authority during emergencies and through state and/or federal declarations of emergency.

1.2. **Communicate** legal authority and procedures to emergency response partners, such as other public health agencies, health agencies, or government agencies during planning, drills, and actual emergencies.
Legal Preparedness Competency Model:
Domain #1: Systems Preparedness and Response (cont.)

1.3. **Identify** limits to legal knowledge, skill, and authority and identify key system resources, including legal advisors, for referring matters that exceed those limits.

1.4. **Integrate** legal information into the exercise of professional public health judgment within the larger public health response.
Legal Preparedness Competency Model:  
Domain #3: Management and Protection of Persons

3.1. **Implement** the use of relevant legal information, tools, procedures, and remedies related to social distancing, including evacuation, quarantine and isolation orders, closure of public places, and curfews.

3.2. **Recognize** the sources of potential civil and criminal liability of public health personnel and consider due process issues before taking legal action.
Legal Preparedness Competency Model: Domain #2: Management and Protection of Property and Supplies

2.1. **Implement** the use of relevant legal information, tools, procedures, and remedies, including injunctions, closing orders, and abatement orders.

2.2. **Identify** how and under what circumstances legal searches, seizures, and destruction of property or material can take place for public health purposes.

2.3 **Describe** the legal authorities related to the distribution and dispensation of medical supplies and the effect of a state and/or federal emergency or public health declaration on those authorities.
Please Use the Legal Preparedness Competency Model

Public health preparedness leadership:
- Update or revise related job descriptions

Mid-tier public health professionals:
- As a self-assessment tool

Legal Counsel:
- To explain to health department employees which laws may be implicated by each competency, and to identify ways in which they can improve their own knowledge, skills, and abilities in public health emergency law

View the Competencies at:
www.cdc.gov/phlp/publications/topic/phel-competencies.html
Resources


CDC’s Public Health Law Program, Legal Preparedness Competency Model (September 12, 2012). Available at [www.cdc.gov/phlp/docs/legal-preparedness-competencies.PDF](http://www.cdc.gov/phlp/docs/legal-preparedness-competencies.PDF)


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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.
Public Health Emergency Law Related to Property and Supplies

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Objective

To understand the legal principles behind the government’s ability to:

1. Commandeer or close a facility
2. Limit price gouging
3. Procure and/or reallocate supplies and resources
4. Authorize emergency countermeasures
Range of Government Powers Over Property and Supplies

• In appropriate situations, local, state, and federal agencies may:
  o Close or prohibit access to structures, land, and airspace
  o Confiscate and destroy property, including animals, birds, and crops
  o Commandeer and use facilities, equipment, and supplies
  o Regulate the use of property
Questions Raised by These Powers

- What specific *measures* are authorized?
  - For federal officials
  - For state/local officials

- What legal *procedures* must be followed?
  - Due process
  - Special statutory procedures

- When must the government pay *compensation*?
  - How is that compensation valued?
“Public health” responsibility not expressly mentioned

Federal: Art. I, Sec. 8
  - Interstate commerce
  - Taxation and spending

State: 10th Amendment
  police powers to protect safety, health and welfare of its citizens
Constitutional Limits to Governmental Power

• The US Constitution through the 5th and 14th Amendments limits this power
  o **Due Process Clause:** “no person shall ... be deprived of life, liberty, or property, without due process of law”
  o **Takings Clause:** “...nor shall private property be taken for public use, without just compensation”

• These constitutional protections apply in declared emergencies and in non-emergency situations
Commandeering private facilities

Commandeering Property
Both state and federal emergency laws empower government to seize and use property in an emergency

- These powers permit government to act when negotiations for use of private property may not be possible
- These powers also provide leverage in negotiations even where there IS time to negotiate
Property: Emergency Seizure for Government Use

- Seizure should be considered a last resort
  - What justifies “taking” property rather than simply contracting for use?
    - Mistake
    - Poor planning
    - True exigent circumstances
The Governor may ... “Subject to any applicable requirements for compensation ..., commandeer or utilize any private, public or quasi-public property if necessary to cope with the disaster emergency. [35 Pa Const. Stat § 7301(f)(4)]
Some states have specific provisions covering use of healthcare facilities in emergencies:

**Georgia example [Ga Code Ann. §38-3-(d)(4.1)]:**
- Governor may ... “Compel a healthcare facility to provide services or the use of its facility if such services or use are reasonable and necessary for emergency response.”
- Use “may include transferring the management and supervision of the healthcare facility to the Department of Human Resources for a limited or unlimited period of time not extending beyond the termination of the public health emergency.”
• Power to “take” and “use” a facility does **not** automatically include power to “take” and “direct” employees and management of a facility.
  ○ However, some states have laws that **do** allow direction of personnel
  ○ Example: CA Emerg. Service Act §8572
    • “… the Governor is authorized to commandeer and utilize any private property **or personnel** deemed by him necessary in carrying out [his] responsibilities ... and the state shall pay the reasonable value thereof”
Acquiring Private Property: Federal Issues

- Fed government may take property in emergencies
  - Subject to due process and just compensation limitations of the 5th Amendment
  - Rarely used power
- Condemnation under the Stafford Act (Title VI)
  - Right to take immediate possession
  - Preparedness, response, and recovery
- Defense Production Act ("Priority Contracting")
  - May apply to preparedness, response and recovery
  - State or local acquisition contracts
LIMITS ON PRICE GOUGING
Anti-Price Gouging Laws

• Many states have a prohibition or limitation on price increases during declared emergencies
  o Exemption if price increases are due to increased costs of procuring goods/services

• 2 types of laws:
  1. Prohibits sale of goods or services in designated emergency area at “unconscionable” or “excessive prices” during designated emergency period
  2. Caps on the amount by which price of retail goods can be increased during designated emergency period
Upon a triggering event, it is prohibited ... for any person to sell or rent or offer to sell or rent any goods or services which are consumed or used as a direct result of an emergency or which are consumed or used to preserve, protect, or sustain life, health, safety or economic well-being of persons or their property with the knowledge and intent to charge a price that is unreasonably excessive under the circumstances. ... This prohibition shall apply in the area where the state of disaster or emergency has been declared or the abnormal market disruption is found. [NC G.S. §75-38]
PROCURING AND/OR REALLOCATING SUPPLIES
State Procurement Laws

• In certain situations, state contracting and procurement requirements may be suspended
• Usually limited to supplies/services necessary to address the emergency
• General requirement to follow procurement process to the extent possible under the circumstances
Whenever the time required to comply with a requirement of this chapter would endanger the health or safety of the people or their property a procurement officer may make an emergency procurement without following that requirement. An emergency procurement shall be limited to only supplies or services necessary to meet the emergency and shall conform to the requirements of this chapter to the extent practicable under the circumstances. [Mass. Gen Law ch. 30b, §8]
Federal Emergency Resource Reallocation

- Voluntary reallocation of private resources to protect public health

- Reallocate government-owned supplies:
  - Vaccines
  - Strategic National Stockpile
AUTHORIZING EMERGENCY COUNTERMEASURES
Emergency Use Authorization (EUA)  
(21 U.S.C. 360bbb-3)

• Established by the BioShield Act of 2004

• Allows use of unapproved medical products and unapproved uses of approved products to respond to emergency involving chemical/biological/radiological/nuclear agents

• Criteria for issuance
  o Life-Threatening Condition
  o Reasonable belief product may be effective
  o Benefits outweigh risks
  o No alternative
Emergency Use Authorizations

• Updated by the Pandemic and All–Hazards Preparedness Reauthorization Act of 2013
  o Gives authority to develop Emergency Use Instructions to CDC

• As of 2013, the FDA Commissioner can issue an emergency use authorization without a formal public health emergency declaration in order to address a potential public health threat.
  o EUA just issued for Ebola in August 2014
  o EUAs also in place for H7N9 and MERS-CoV
Medical Countermeasures: Liability Protection

Public Readiness and Emergency Preparedness Act, 42 U.S.C. 247d-6d,6e

- Applies to approved countermeasures: medicine, medical devices, technology, etc.
- Authorizes the Secretary of HHS to issue a declaration that provides immunity against claims relating to use of approved countermeasures to respond to a present or future public health emergency.
  - Applies to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of countermeasures

Does NOT cover “willful misconduct”
Experiences from H1N1 and Sandy Responses

Holly M. Dellenbaugh
Nikhil Natarajan

September 18, 2014
Outline

- H1N1 Issues
- Super Storm Sandy Issues
H1N1 Issues

- Price Gouging Concerns
- Monitoring Seasonal Flu Vaccine Stock
- Medical Countermeasure Liability
Price Gouging – Operational Impacts

- Heard concerns from public about price gouging for seasonal flu vaccine and antivirals
- Public unable to obtain needed medications
- Potential for a “black market” or hording of vaccine
Price Gouging – Legal Aspects

- NYS General Business Law § 396-r prohibits price gouging and authorizes NYS Attorney General to seek relief

- Communication was key – provided information to public and health care partners

- Advised public to contact the Office of the AG
Seasonal Flu Vaccine Stock – Operational Impacts

- Concerns re amount of seasonal flu vaccine in NYS
- How would DOH get information if needed?
- Could existing systems (already in statute) be used for this extended purpose?
- What if organizations refused?
Seasonal Flu Vaccine Stock – Legal Aspects

- PHL § 206(25)(b): Commissioner may require reporting by facilities (e.g., hospitals, LTC, home care), pharmacies, manufacturers and distributors doing business in NY who possess “adult immunizing agents” of information needed to respond to an imminent public health emergency

- NOTE – law did not extend to antivirals, other medications
Concerns about liability for H1N1 vaccine

“Buy-in” from LHDs to run clinics vs. sending patients to providers

Joint education of LHDs (preparedness and legal staff) was a key component

Public messaging and rumor control
Liability for Countermeasures – Legal Aspects

- Provided significant outreach and education to LHDs, county attorneys, health care providers about the PREP Act

- One lawsuit: Parker v. St. Lawrence County Public Health Dep’t. (3d Dep’t 2012)
Parker case

• 2009 H1N1 vax clinic by the St. Lawrence County Health Department
  • Plaintiff did not execute a parental consent form for her child
  • Child vaccinated inadvertently
  • Plaintiff alleged negligence and battery

• Supreme Court denied motion to dismiss: Held that PREP Act didn’t apply where there was no consent to vaccinate
Parker case

- Reached out to PHLN, CDC
- Amicus papers filed by USDOJ and NYS AG
- Appellate Division reversed: "Congress intended to preempt all state law tort claims arising from the administration of covered countermeasures by a qualified person"
Sandy Issues

- Emergency Water Donation
- WIC
- Dialysis Services
- Controlled Substances
- EMS Contract
When the Governor . . . finds that a disaster has occurred or is imminent for which local governments are unable to respond adequately, he/she may declare a state disaster emergency. (Exec. Law § 28).

During a State disaster emergency, Governor can issue an executive order suspending or modifying a state or local law if compliance would “prevent, hinder or delay action necessary to cope with the disaster” (Exec. Law § 29-a)
Governor’s Limits on Suspending Laws

- Subject to the Federal and New York Constitutions
- Must “safeguard the health and welfare of the public” and be “reasonably necessary to the disaster effort”
- Must represent the “minimum deviation” from law
- 30-day limit, with possible 30 day extensions
- Legislature can terminate the Governor’s executive order by concurrent resolution at any time
Emergency Water Donation – Operational Impacts

- Anheuser-Busch wanted to donate bottled water

- BUT NYS law requires certain testing + DOH certification of purveyors of bottled water

- Coordination with environmental health staff

- Lack of understanding by many public/private sector organizations on existing processes
Governor issued Exec. Order No. 58 (9 NYCRR 8.58)

Temporarily suspended PHL § 225(5)(u) and 10 NYCRR 5-6 so that bottled or bulk water could be donated for disaster relief efforts if, in the discretion of the Commissioner of Health, the manufacturer of such products had provided sufficient information to show that water was fit for human consumption.
WIC – Operational Impacts

- Food vendor associations reported shortages of certain items in the approved food package for WIC (especially bread, milk, cheese)

- Public messaging and rumor control
WIC – Legal Aspects

- Requested waiver from USDA of “no substitution” requirement for WIC to allow participants to make substitutions of milk, cheese, bread and peanut butter where the approved foods are not available.

- Also needed an Executive Order to suspend NYS regulations that could conflict with the USDA waiver (see 9 NYCRR 8.67).
Dialysis Services – Operational Impacts

- Not enough nurses to provide dialysis services
- Wanted to bring in nurses licensed in other states
- EMAC – time and cost was an issue
- Facility-level issue vs. State-level (existing contracts, etc.)
- Coordination with ESRD Networks
Governor issued Exec. Order No. 57 (9 NYCRR 8.57)

Suspended Article 139 of the NYS Education Law, and associated regs, so that a nurse who is not licensed in NYS may provide nursing services to dialysis patients of a hospital, nursing home or DTC

Required nurse to be licensed and in good standing in another state and dialysis to be within scope of expertise
Controlled Substances – Operational Impacts

- Evacuating persons needed access to medication
- Verification of prescriptions?
- Methadone patients
- Potential for abuse
- Insurance coverage
Governor issued Exec. Order No. 72 (9 NYCRR 8.72)

Suspended PHL § 3333(1) and § 3338(2) so a licensed pharmacist could dispense a controlled substance to a patient whose access to prescriptions or previously dispensed controlled substances had been directly affected by the disaster.

Required pharmacist to verify authenticity of the prescription through use of a shared database and Rx must indicate authorized refills.
EMS Contract – Operational Impacts

- National Ambulance Contract expiring BUT still needed ambulances in hard-hit areas of Nassau County

- DOH wanted to quickly contract for ambulances for undetermined length of deployment

- Long-term costs of NAC vs. local contracting

- Coordination of assets
Determination was made that, under the circumstances, DOH could select a commercial ambulance service to provide services under contract in an expedited and informal manner.

- DOH regulates EMS in NYS

NYS PHL § 206 authorizes the Commissioner to contract with a commercial ambulance service.
EMS Contract – Legal Aspects

- State Finance Law § 163(10)(b) provides:
  - Sole source procurements made to meet emergencies may be made without a formal competitive process
  - Only under unusual circumstances
  - Must include a determination by the state agency that the requirements for said purchase have been designed in a fair and equitable manner
  - Requires documentation of the reasons to purchase from a sole source, the nature of the emergency, and the substantial reasons why a formal competitive process is not feasible
What helped with Executive Orders?

- **Information --**
  - What is the problem (not just which statute)?
  - Why is it important?
  - How is the statute/reg impeding response?
  - Where does the EO need to be in effect? County? State?
  - For how long will this be a problem?
  - How could change affect public health? Precautions?
Q&A

Please type your questions in the Q&A panel.
Thank you for attending.

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