# **Public Health Emergency Law**

# CDC Foundational Course for Front-Line Practitioners Version 4.0

Welcome to Public Health Emergency Law 4.0! The course will begin shortly.

If you have not already done so, please complete the pre-test.

Centers for Disease Control and Prevention

## **Public Health Emergency Law**

CDC Foundational Course for Front-Line Practitioners Version 4.0

Developed by the
Public Health Law Program
Centers for Disease Control and Prevention

Centers for Disease Control and Prevention

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#### **DISCLAIMER**

These course materials are for instructional use only and are not intended as a substitute for professional legal or other advice. While every effort has been made to verify the accuracy of these materials, legal authorities and requirements may vary from jurisdiction to jurisdiction. Always seek the advice of an attorney or other qualified professional with any questions you may have regarding a legal matter.

#### **Icebreaker**

The 10 Great Public Health Achievements: Exploring the Role of Law

#### **Icebreaker**

The 10 Great Public Health Achievements: Exploring the Role of Law

- 1. Vaccination
- 2. Motor-vehicle safety
- 3. Safer workplaces
- 4. Control of infectious diseases
- 5. Decline in deaths from coronary heart disease and stroke
- 6. Safer and healthier foods
- 7. Healthier mothers and babies
- 8. Family planning
- 9. Fluoridation of drinking water
- 10. Recognition of tobacco use as a health hazard

Law's Paramount Role: 10 Great Public Health Achievements, United States, 1900-1999*		
Public Health Achievement	Selected Laws/Legal Tools	
Vaccination	School vaccination laws; childhood vaccination programs	
Motor Vehicle Safety	Speed limits; alcohol laws; helmet and seatbelt laws; child safety seat laws; graduated drivers licensing	
Safer Workplaces	Authority to inspect for unsafe conditions; inspection of workplace safety/minimum standards, including toxic exposure	
Control of infectious diseases	Sanitary codes; drinking water standards; quarantine/isolation laws; mosquito/rodent control; food inspection	
Decline in heart disease/stroke	Education/info programs; food labeling; bike and walking paths	

Law's Paramount Role: 10 Great Public Health Achievements, United States, 1900-1999*		
Public Health Achievement	Selected Laws/Legal Tools	
Safer/healthier foods	Inspection/minimum standards for retail food; mandated enrichment of flour; standards for chemicals; school lunch programs	
Healthier mothers/babies	Milk pasteurization; drinking water code; education/information programs; Medicaid services and funding; WIC	
Family Planning	Authorization for birth control services; authority to provide prenatal/postnatal care to indigent mothers	
Fluoridation of drinking water	Laws/ordinances authorizing drinking water fluoridation	
Recognition of tobacco as a health hazard	Excise taxes; restriction on sale to minors; smoke free laws; education/information programs; lawsuits leading to settlement agreements	



# Public Health Law 101: A Mini Course

# Public Health Law 101: A Mini Course

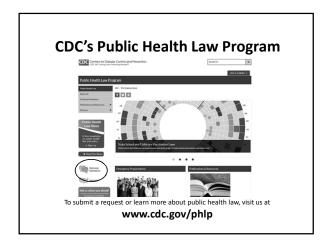
- 1. CDC's Public Health Law Program
- 2. Define Public Health Law
- 3. Key Terms and Concepts
- 4. Four Major Sources of Law

# CDC's Public Health Law Program 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
  - Legal Epidemiology: legal mapping and legal evaluation
  - Legal Guidance for Research: memos, lit. reviews, resource navigation, peer review
  - Research Innovation: methodology reviews, logic modeling, funding, translation
  - Workforce development: webinars, trainings, training materials, fellowships, internships, and externships
- Who we serve
  - CDC programs and state, tribal, local, and territorial (STLT) communities
     To submit a request or learn more about public health law, visit us at

www.cdc.gov/phlp



# Why Public Health Law?

Public health law is the *foundation* for the practice of public health in the US.



## Why Public Health Law? (Cont.)

Law is an effective public health *intervention*.



#### What Is Public Health Law?

According to Larry Gostin:

"The *legal powers and duties of the state* to assure the conditions for people to be healthy, and the *limitations on the power of the state* to constrain the autonomy, privacy, liberty, proprietary, or other legally protected interests of individuals for the protection or promotion of community health."

PUBLIC HEALTH LAW AND ETHICS: A READER
(New York and Berkeley: Milbank Memorial Fund and the
University of California Press, Expanded and Updated 2nd ed., 2010)

## What Is Public Health Law? (Cont.)



Public Health Law Key Terms and Concepts



# Federalism Preemption Police Powers

## **Federalism**

Defined: Relationship and distribution of power between the individual states and national government



#### **Police Powers**

Defined: Powers exercised by the states to enact legislation and promulgate regulations to protect the public health, welfare, and morals, and to promote the common good.



## **Preemption**

- Preemption occurs when a higher level of government restricts or limits a lower level of government's ability to regulate an issue.
- For example, preemption has often been used to undermine local and state tobacco control campaigns and initiatives.



# What Are the Major Sources of Public Health Authority?









#### The US Constitution—What Does It Do?

- "Supreme law of the land"
- Establishes 3 branches of federal government and separation of powers
  - Legislative
  - Executive
  - Judicial
- Confers limited set of enumerated federal powers



# US Constitution and States' Powers The Tenth Amendment

- The Tenth Amendment frames the powers of the states.
- "The powers not delegated to the United States by the Constitution, nor prohibited by it to the states, are reserved to the states respectively, or to the people."

Impact: States retain police powers and other powers not expressly enumerated to US federal government.



## **Constitutional Safeguards**

- First 10 Amendments = Bill of Rights
- Source of individual liberties:
  - freedom of speech and religion
  - right to assemble
  - the right to be free of unreasonable searches and seizures
- Applied to States gradually, following passage of 14<sup>th</sup> Amendment (ratified after the Civil War).

## The 14<sup>th</sup> Amendment: Due Process Clause

"...nor shall any state deprive any person of life, liberty, or property without due process of law..."

# The 14<sup>th</sup> Amendment: Significance of Due Process Clause

- Many governmental actions can affect an individual's life, liberty (self-determination), or property (economic interests)
- 14<sup>th</sup> Amendment: Government cannot deprive individuals of life, liberty, or property without *due* process of law
- Due process: Involves fairness and reasonableness of such actions by government

# US Constitutional Design's Implications for Public Health

- Public health not mentioned
- Some federal public health-related activities carried out under power to
  - Regulate interstate commerce
  - Tax and spend
- Federal government functions in public health carried out through regulatory (e.g., FDA) and non-regulatory (e.g., CDC\*) agencies
- Federal government shapes state and local public health through funding and defunding



## Statutes—What Do They Do?

- Statutes (and ordinances) have several functions
  - Express the intent of the legislative branch
  - Create and empower executive agencies
  - Regulate various activities
  - Provide agencies authority to promulgate regulations and oversee regulated activities
  - Appropriate money
  - Make certain activities crimes



# Example of Federal Statute Public Health Service Act § 311 (Covers Federal-State Cooperation)

The Secretary is authorized to accept from state and local authorities any assistance in the enforcement of quarantine regulations . . . The Secretary shall also assist states . . . in the prevention and suppression of communicable diseases and with respect to other public health matters. . . .

# Example of State Statute GA. CODE ANN. § 31-2A-4

- Establishing agencies
  - "The Department of Public Health shall safeguard and promote the health of the people of this state and is empowered to employ all legal means appropriate to that end."
- Empowering agencies
  - "[The Department of Public Health] is empowered to: (1) Provide epidemiological investigations and laboratory facilities and services in the detection and control of disease . . . ."

## Regulations—What Do They Do?



- Regulations are agency-made rules that
- Implement the letter and intent of statutes
- Prescribe the standards that people and companies must follow in order to be lawful while engaging in a certain activity
  - Substantive (e.g., list of conditions reported)
    Procedural (e.g., forms for disease reporting)
- Tend to be more detailed and more technical than statutes

# Authority to Regulate GA. CODE ANN. § 20-2-771

(b) No child shall be admitted to or attend any school or facility in this state unless the child shall first have submitted a certificate of immunization to the responsible official of the school or facility . . .

(c) The Department of Public Health shall promulgate rules and regulations specifying those diseases against which immunization is required and the standards for such immunizations . . .

# Example of State Regulation GA. COMP. R. & REGS. 290-5.4-.02

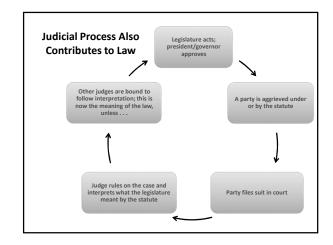
"(1) [I]mmunization . . . against the following named diseases, shall be required for entrance into any school or facility operating in the state: (a) Diphtheria; (b) Pertussis . . .

(2) For any child attending any school or facility in the state of Georgia for the first time, a parent or guardian must submit a valid certificate of immunization . . . "

#### Case Law—What Does It Do?

- "Case law" is made by courts interpreting the Constitution, statutes, and regulations while ruling on disputes between parties.
  - Rulings "attach" to statutes and regulations that are interpreted and ruled upon.
  - Previous rulings impact current disputes that involve the interpretation of the same statutes and regulations.
- If case law comes from the same jurisdiction and is from a higher court, the rulings are binding on the lower court





#### Jacobson v. Massachusetts 197 U.S. 11 (1905)

- · Landmark court case
  - Setting: 1902 smallpox outbreak
  - Law: State statute authorizing compulsory vaccination
  - Violation: Defendant refused vaccination and fined \$5; challenged the constitutionality of the law
  - Ruling: US Supreme Court upheld the law in 1905
    - ├─"[T]here are manifold restraints to which every person is necessarily subject for the common good."



Justice Harlan

# Break! See you in 10 minutes!

# Public Health Emergency Law: Course Overview

- Unit 1: Introduction to Emergency Management Systems Preparedness and Response
- Unit 2: Emergency Powers: Protection of Persons, Volunteers, and Responders
- Unit 3: Emergency Powers: Property and Supplies

#### 8 Practical Questions

- 1. Can a public health emergency be declared?
- 2. Can we investigate contacts?
- 3. Can we examine and test people?
- 4. Can we treat and vaccinate?
- 5. Can we isolate and guarantine?
- 6. Can we use non-governmental personnel?
- 7. Are we liable?
- 8. Can we obtain facilities and supplies?

## **Public Health Emergency Law**

**CDC Foundational Course** for Front-Line Practitioners Version 4.0

#### Unit 1:

Introduction to Emergency Management Systems Preparedness and Response

Centers for Disease Control and Prevention Office for State, Tribal, Local and Territorial St

#### Unit 1: **Introduction to Emergency Management Systems Preparedness and Response**

Unit 1 aligns with Public Health Emergency Law Minimum Competency Domain 1:

Domain 1: Systems Preparedness and Response

- 1.1: Act within the scope of federal, state, tribal, and local statutory and regulatory authority during emergency situations, 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, other health agencies, and other government agencies during planning, drills, and actual emergencies.
- 1.3: Identify limits to legal knowledge, skill, and authority and 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.

#### **Unit 1 Objectives**

By the end of this unit, participants should be able to:

- 1. Define public health legal preparedness and outline the role of agencies' attorneys
- 2. Describe how emergency management operates in the system of federalism
- 3. Identify the basics of state and federal emergency declarations
- 4. Understand roles and legal authorities involved in comprehensive emergency response

#### Objective 1.1

Define public health legal preparedness and outline the role of agencies' attorneys



## **Public Health Preparedness** Requires **Public Health Legal Preparedness**

- Key Components of Public Health Preparedness
  - A professional workforce competent in essential skills
  - Public health agencies that meet defined preparedness performance standards
  - · Collaborative networks of agencies and partners
  - Modern information systems and laboratories
  - · Agencies and partners that are legally prepared

#### **Public Health Legal Preparedness** Defined...

"Public health legal preparedness is a subset of public health preparedness" and is the "attainment by a public health system...of legal benchmarks essential to the preparedness of the public health system."

Source: Moulton AD, Gottfried RN, Goodman RA, Murphy AM, Rawson RD. "What is public health legal preparedness?" J Law Med Ethics 2003; 31:672-683.

# Public Health Legal Preparedness - Core Elements -

- LAWS: Legal authorities based in science and on contemporary principles of jurisprudence
- COMPETENCIES: Professionals who know their operating legal framework and how to apply law to public health goals
- 3. COORDINATION: In implementing law-based action across jurisdictions and sectors
- 4. INFORMATION: On public health law best practices

# Key Actors in a Public Health Emergency Response

- · Elected officials
- · Legal counsel
- Judges
- Public health directors
- Emergency management directors
- First responders (law enforcement, EMS, Hazmat, firefighters, etc.)

# WHY DO WE NEED LAWYERS IN EMERGENCY PREPAREDNESS?

#### Participation in:

- Planning phase
- Response phase
- After-action phase



## Role of the Agency Attorney: Before and During an Emergency

- · Assure agency has necessary authority
- · Assist development of emergency policies
- Anticipate and protect agency against legal liability
- Note: Action may be required even in the face of potential liability—goals are to
  - Maximize effectiveness and minimize legal exposure
  - Recognize small liability concerns, but do not preclude necessary, common-sense responses

## Role of the Agency Attorney: After an Emergency

- Give legal advice to shape response and recovery actions
- · Protect or defend against potential litigation
- · Ensure that after-action reviews determine how to
  - Improve response procedures
  - Develop needed statutory and legal improvements
  - Identify needed law-related competencies

#### Objective 1.1

Define public health legal preparedness and outline the role of agencies' attorneys

#### **Question:**

If you were drafting an emergency plan, what is one question you would bring to your agency's attorney?

#### **Objective 1.2**

Describe how emergency management operates in the system of federalism



#### Constitutional Framework for Emergency Authorities

- The Constitution granted enumerated powers to the federal government:
  - · Interstate commerce
  - · National defense
  - Power to tax and spend for public welfare
- · Powers not enumerated were "reserved" to states
  - · Police Powers: includes public health control powers
- · States may in turn delegate powers to localities
  - Home Rule states vs. Non-Home Rule (Dillon's Rule)
  - Note preemption: federal/state law invalidates/overrules state or local law

#### The Federal System and Local Control

#### All emergencies start (and end) locally

- As scale/complexity increase, local governments request support from the state
- When situation is beyond capability of the state, the Governor may request aid from the President
- Catastrophic response triggers resources from
  - Multiple jurisdictions and agencies
  - Multiple levels of government
- · Unified command replaces local command

Result: A textbook example of federalism.

#### Public Health Powers Within Our Constitutional Framework

- Surveillance
- · Reporting
- · Epidemiological investigation
- · Vaccination (voluntary/involuntary)
- Isolation & Quarantine (voluntary/involuntary)
- Treatment (voluntary/involuntary)
- Other social distancing measures
- Evacuation
- Powers over property

#### **Objective 1.2**

Describe how emergency management operates in the system of federalism

#### Question:

Can you give an example of how federalism may complicate emergency response?

## An Unfolding Story...

- A case appears in a hospital emergency department (ED)
  - A 30-year-old man presents with fever and pustules
  - He has waited in ED for a few hours before being seen by a physician
  - Patients and staff in ED have come and gone in the interval
  - When seen, the physician suspects smallpox

#### The Unfolding Story...

- · Public health officials are notified
  - They close the ED, telling those present that they may not leave
  - Preliminary confirmation of the diagnosis of smallpox is made by the other ED physicians
  - The media pick up the story of a local case of smallpox and widely report it
  - The public begins to show signs of panic, and the local health resources are stressed

#### **Practical Question #1:**

Can a public health emergency be declared?

# **Objective 1.3**

# Identify the basics of state and federal emergency declarations



# Public Health Emergencies can be triggered by...

- Disease outbreaks and pandemics
- Natural disasters
- Technological disasters
- · Intentional acts



#### What Are Declarations?

- · Public announcements
  - "An emergency has occurred and the state will respond to it."
- Legal determinations
  - Special emergency grant by legislature through its powers over lawmaking and expenditure of funds
  - Made by an authorized government official
  - Trigger special emergency powers
  - · Allow expenditure of emergency funds
  - Can be tailored to type of event (e.g., influenza pandemic, drought, fire)

# Types of Emergency Declarations

- Declarations provide particular powers to particular agencies and officials
- · Multiple declarations are common
  - · Local level:
    - State of emergency  $\underline{\text{and}}$  Public health emergency
  - State level:
    - State of emergency and Public health emergency
  - Federal level:
    - · Public health emergency
    - Stafford Act emergency or major disaster
    - National Emergencies Act

# Governor's Declaration of State of Emergency

- Activates emergency plans and authorizes deployment and use of personnel
- May allow suspension of certain laws and regulations
- · Triggers special powers, such as:
  - To protect persons and control property
  - To request and obtain mutual aid from other states

# Declaration of a State Public Health Emergency (PHE)

· May be a:

Health-related disaster declaration

or

A separate PHE declaration

or

The states may have no PHE declarations or laws

Does your state have a public health emergency declaration?

# Declaration of a State Public Health Emergency (PHE)

- PHE declarations may differ from disaster declarations
  - Authority to declare may be given to state health officer
  - May allow suspension of certain laws and regulations only during the PHE
  - · May trigger special powers only for use in the PHE, such as:
    - Quarantine citizens or mandate testing and vaccinations
    - · Issue mandatory health orders for general population
    - · Prioritize the supply, distribution, and use of medical products
  - Or the declaration may not do anything different than a disaster declaration

## State Declaration of Public Health Emergency

#### State law determines:

- · What powers are conveyed
- · Who can declare
  - Generally, governor or state public health officer
  - · City/county council or mayor
  - · Local public health officer
- · Procedure/information required for declaration
- Duration of declaration
  - e.g., 60 days unless renewed

# Declaration of Public Health Emergencies: State Example

Monkeypox outbreak - June 2003

- Disease spread to humans through contact with exotic pets (giant Gambian rats, prairie dogs)
- Illinois declared a public health emergency and Wisconsin issued an emergency order
  - To contain the outbreak through increased disease reporting and animal control measures

Example of using a declaration to control something that poses a public health threat.

#### **Declaration of Public Health Emergencies**

#### 2012–2013 Seasonal Flu Epidemic

- Seasonal flu reached epidemic proportions in early January.
- The State of New York and the City of Boston each declared a public health emergency
  - To contain the outbreak through increased vaccination and other disease control measures
    - New York declaration: suspended laws to allow pharmacists to give flu shots to patients between ages 6 months and 18 years old
    - Boston declaration: served to warn the public about the severity of the season's flu and encourage vaccination

These exemplify how declarations can be used to alter existing occupational laws or serve as public announcements

#### **Past State/Local Declarations**

- · Natural Disasters
  - Hurricane Katrina (2005)
  - Joplin Missouri Tornado (2011)
  - Superstorm Sandy (2012)
  - Georgia Snowpocalypse (2014)
- Terrorist Attack
  - 9/11/2001
- · Public Health Emergency
  - H1N1 (2008–2009)
  - West Nile (Dallas, TX 2012)
- Pre-event declarations
  - "Pre-landfall" for hurricane evacuation



Northridge Earthquake (1994)

#### **Tribal Emergency Declarations**



- Cherokee Code § 166-9.
  - "b) ...the Principal Chief is hereby authorized and empowered to issue a
    public proclamation declaring to all persons the existence of such a state
    of emergency, and, in order to more effectively protect the lives and
    property of people within the Cherokee Indian trust lands, to place in
    effect any or all of the restrictions hereinafter authorized."
    - · Authorizes suspension of tribal laws to aid in response.
- · Recent declaration:
  - 2014 emergency declaration by the Yurok Tribe due to drought

#### **Federal Public Health Emergency**

- Secretary of HHS can declare "Public Health Emergency" under Section 319 of the Public Health Service Act
  - Emergency lasts for 90 days, unless earlier terminated, or extended, by Secretary
  - May be declared when disease or disorder presents a public health emergency, or a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists
- Under declaration, Secretary "may take such action as may be appropriate to respond to the public health emergency"

#### **Emergency Waiver of Regulations**

- Section 1135 of the Social Security Act authorizes the Secretary of HHS to waive or modify certain requirements of CMS, CHIP, and HIPAA. Requires:
  - 1. Presidential disaster declaration and
  - Section 319 public health emergency declaration by the Secretary.
- · Example: EMTALA waiver
  - Emergency Medical Treatment and Active Labor Act (EMTALA) requires hospitals to:
    - Screen all individuals in ER to determine condition
    - Stabilize individuals before transferring or discharging
  - May be waived by Secretary for up to 72 hours (or longer in a pandemic)

#### **The Federal Stafford Act**

- Principal discretionary federal authority to assist state and local governments in responding to catastrophic events
- · Activated by a declaration of either:
  - · A major disaster
  - Natural catastrophe or "any fire, flood, or explosion"
  - An emergency
  - "Any occasion" where federal assistance is needed to save lives, protect property, public health and safety, or to lessen a catastrophe
- Provides both authorities and funds for federal response and assistance to state/localities
  - Note: Private sector generally not eligible for assistance

#### Stafford Act Authorities

- Authorizes the President to order any agency of the federal government to take emergency actions
- Federal government can directly provide emergency measures, or can provide grants to reimburse costs incurred by governments for
  - Search and rescue
  - Emergency medical care
  - Emergency mortuary services
  - Emergency mass careEmergency shelter
  - Temporary facilities for schools and other essential community services
  - Provision of food, water, medicine, and other essential needs, including movement of supplies or people

#### **Stafford Act Declaration Procedure**

- Governor or tribal leader must first request declaration
- · Request must state
  - Situation beyond capability of state and local governments
  - State's emergency plan activated
  - Specific nature of federal assistance requested
- DHS/FEMA makes recommendation to President based on severity
  - · President alone decides

# **Example of State Request for Federal Emergency Declaration**

- In Hurricane Katrina, Governors of Alabama, Louisiana, and Mississippi each made requests:
  - Pre-landfall Federal emergency declaration for evacuation and other measures
    - · This occurred more recently during Hurricane Sandy
  - Post-landfall For Major Disaster Declaration
- · Requests stated:
  - Capacity to respond had been exceeded
  - · State emergency plan activated
  - · Need for food, shelter, emergency supplies

# Stafford Act Unilateral Federal Powers

- · Ability of federal government to act unilaterally
  - President CAN declare an emergency without request of state Governor IF:
  - "Primary responsibility rests with the United States because the emergency involves a subject area for which, under the laws of the United States, the United States exercises exclusive or preeminent authority."
- Examples: Federal facilities, nuclear materials, WMD/national defense

# **Example of Unilateral Federal Declaration of Emergency**

Oklahoma City Federal Building bombing – 1995



- <u>Initially</u> a unilateral federal emergency declaration because federal facility was attacked and destroyed
- Governor requested the President to issue a major disaster declaration for the state

#### **National Emergency Act**

- Authorizes president to declare a national emergency, which activates emergency powers contained in other federal statutes
  - September 11, 2001
  - H1N1
- Unlike the Stafford Act, it does not provide any specific emergency authority on its own. Instead, it allows for other statutory authorities to be activated as specified in the declaration.
  - Example: An 1135 waiver could be issued if a NEA declaration is issued in conjunction with a 319 PHE declaration.
- · Must be published in the Federal Register
- Terminates automatically after one year (unless renewed within 90 days of the anniversary)

## **Objective 1.3**

Identify the basics of state and federal emergency declarations

#### Question:

What is one example of the effect an emergency declaration can have on the legal landscape?

#### **Unit 1 Summary and Key Take-Aways**

- 1. Attention to "public health legal preparedness" and the role of agency attorneys has intensified substantially.
- 2. The legal aspects of emergency management reside within our complex federal system.
- 3. States, tribes and localities should be "legally prepared."

# Public Health Emergency Law Minimum Competency: Domain 1

Domain 1: Systems Preparedness and Response

- 1.1: Act within the scope of federal, state, tribal, and local statutory and regulatory authority during emergency situations, 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, other health agencies, and other government agencies during planning, drills, and actual emergencies.
- 1.3: Identify limits to legal knowledge, skill, and authority and 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.

View the Competencies at:

 $\underline{www.cdc.gov/phlp/publications/topic/phel-competencies.html}$ 

#### End: Unit 1

For additional information on public health law and legal preparedness, visit the CDC Public Health Law Program



www.cdc.gov/phlp

# Lunch! See you in 1 hour!

## **Public Health Emergency Law**

CDC Foundational Course for Front-Line Practitioners Version 4.0

Unit 2
Emergency Powers:
Protection of Persons, Volunteers,
and Responders

#### Unit 2: Emergency Powers: Protection of Persons, Volunteers, and Responders

Unit 2 aligns with Public Health Emergency Law Minimum Competency Domain 3:

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, 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.

#### The Unfolding Story...

- A case appears in a hospital ED
- Public health officials are notified
- Health officials urge the Governor to declare emergency
- Laboratory tests confirm the diagnosis of smallpox for the first patient. More patients begin to appear in EDs, throughout the city, with signs of smallpox.
  - Public health personnel want to learn the identities of the persons with whom the cases had contact
  - Public health personnel want to examine those persons

## The Unfolding Story...

- · A case appears in a hospital ED
- Health officials are notified and urge the Governor to declare an emergency
- Laboratory tests confirm; more patients appear
- There are now 10 confirmed cases in the city and another 5 cases in other areas of the state
  - More people are demanding vaccination
  - Some people, who appear to be ill, are refusing treatment
  - Some people who are believed to have been exposed to smallpox are refusing vaccination

## The Unfolding Story...

- A case appears in a hospital ED
- Health officials are notified and urge the Governor to declare an emergency
- · Laboratory tests confirm; more patients appear
- Agencies within the state and federal governments, including public health and safety agencies, want information regarding persons who are ill
- 10 confirmed cases in city; 5 in other areas
- Public health officials recommend the use of isolation and guarantine
  - Some object to being isolated or quarantined
  - Family members do not want to be separated
  - People fear that their needs will not be met in isolation or quarantine

## The Unfolding Story...

#### Practical Question #1:

Can we declare a public health emergency?

#### **Practical Question #2:**

Can we investigate contacts?

#### Practical Question #3:

Can we examine and test people?

#### Practical Question #4:

Can we treat/vaccinate people?

#### Practical Question #5:

Can we isolate/quarantine people?

## **Unit 2 Objectives**

By the end of this unit, participants should be able to:

- Describe limits of mandatory controls and other social distancing measures
- Identify legal issues regarding mass evacuations, re-opening evacuation areas, special populations, and related issues
- Understand legal issues applicable to emergency volunteers, including liability, credentialing, and workers' compensation issues

## Objective 2.1

Describe limits of mandatory controls and other social distancing measures





Mandatory Controls & Social Distancing: Balancing the Public's Health with Individual Liberty Interests

Collective actions for the common good

Public Individual liberties

# Quarantine and Isolation: Constitutional Requirements



- Basic due process for guarantine and isolation
  - · Right to notice
  - Right to counsel (depends on state law)
  - · Right to hearing on request
  - · Rational/reasonable basis for detention

# SOCIAL DISTANCING AND THE LAW

Socrates H. Tuch, MA, JD, CPM Senior Counsel/Privacy Officer Ohio Department of Ohio July 2016

#### Overview

- · Public Health: the juncture of medicine and law.
  - · Medically informed exercise of legal authority.
  - · Enforceable medical judgments.
  - · 1918
- · Great deference.
  - · Jacobson v. Massachusetts, 197 U.S. 11 (1905).
    - The infected or suspect infected person's freedom of movement is subject to the greater good.
  - D.A.B.E., Inc. v. Toledo-Lucas Combined Health District. (2002), 96 Ohio St.3d 250.
  - $\bullet \ \ \text{Need: Administrative Authority and Subject-matter Jurisdiction}$
  - See R.C. 3709.20 / 3709.21 and R.C. Chapter 3707.

#### Isolation and Quarantine

- · Same authority for both isolation and quarantine.
  - R.C. 3707.07, 3707.08, and 3701.13
- Board of Health is the source of authority but Health Commissioner can act for the Board.
  - R.C. 3707.34
- ODH is the ultimate authority on isolation and quarantine.
  - R.C. 3701.13

#### Elements

- · Dangerous disease.
- LHD is notified (R.C. 3707.06); or
- LHD discovers (R.C. 3707.07).
- · Declared "Quarantine-able".
  - R.C. 3707.08; see Ohio Adm. Code 3701-3-13
- Threat to the public's health medically necessary.
- · Public health can control ingress and egress.
  - R.C. 3707.07; see R.C. 3709.20 (orders & regulations for public health emergencies).
- Public health must provide for the necessities of life.
  - R.C. 3707.14

#### Necessities of Life

#### Included?

- Definitely
  - Food, fuel, water, shelter
    Medical care, including
  - Medical care, including medications.
- · Maybe, to be polite
- · Non-related medications
- Some means of communication

#### Not Included?

- · Probably Not
- Entertainment expenses (cable TV. etc.)
- Clothing
- · A "but for..." test?
  - · But for the order
  - · Would the individual
  - Still have
  - The expense?

## The Person's Duty

- · Isolated or guarantined person must obtain the written permission of the Board of Health to leave designated
- R.C. 3707.08
- · Isolated or quarantined person shall not attend public gatherings, including school.
  - Organizer of gathering or school has duty to exclude.
- R.C. 3707.16

#### Enforcement

- Second degree misdemeanor to:
  - · Knowingly spread a contagion;
  - · Recklessly let someone spread a contagion (must be in the person's care); or
  - · Negligently let someone exposed to a contagion use a common carrier or public accommodation.
    - · R.C. 3701.81 and 3701.99
- · Person may be subject to different penalties for violations of R.C. 3707.01 through 3707.53.
  - R.C. 3707.48 and 3707.99(B) minor misdemeanor on first offense, fourth degree misdemeanor on each subsequent offense

# Keeping People Out

- · The board may close any school and prohibit public gatherings for such time as is necessary:
- During an epidemic or threatened epidemic,
- · When a dangerous communicable disease is unusually prevalent, or
- · For any other imminent public health threat as determined by the
  - R.C. 3707.26(A)
- · No definition of "public gathering."
  - "Public" = Of, affecting, or concerning the community or the people
    - Webster's II New College Dictionary, p. 895 ("public")
  - "Gathering" = An assembly: meeting....
  - · Id. at 463.

# Keeping People Out - The Big One

- · No explicit authority for a cordon sanitaire.
- · However, R.C. 3707.05 says that a board of health shall
  - · close public highways or prohibit travel thereon,
  - · interfere with public officers in the discharge of their official duties who are not afflicted with or directly exposed to a contagious or infectious disease, or
  - · establish a quarantine of one municipal corporation or township against another municipal corporation or township,
  - · without first getting permission from ODH and under regulations established by ODH.

#### Enforcement

- · Virtually all public officials are required to carry out the isolation and quarantine orders of ODH and rules ODH adopts.
- R.C. 3701.56
- Any official listed in R.C. 3701.56 can seek an injunction or other appropriate relief.
- Compare R.C. 3707.48 (no person shall violate an order of the LDH under penalty of law).
- Note: Board of Health can employ as many people as is necessary to carry out its orders, including hiring quarantine guards.
  - R.C. 3707.09

#### **MISC**

- · Board of Health can require a person be buried within 24
  - · Can also prohibit a funeral and restrict attendance.
  - R.C. 3707.19
- ODH can issue order related to conveyance of bodies.
  - · R.C. 3701.13

#### **MISC**

- Boards of Health can also seize suitable vacant buildings to use as quarantine hospitals.
- R.C. 3707.31
- · May establish field hospitals and hire staff.
- R.C. 3707.32
- · May build a hospital on land it purchases.
  - · R.C. 3707.29

# A word about Privacy....

- · HIPAA does not invalidate or limit:
  - · Disease or injury reporting;
- · Child abuse reporting;
- · Birth and death reporting;
- · Public health surveillance; or
- · Public health investigations or interventions.
  - · 42 U.S.C. 1320d-7(b)
- R.C. 3701.17 applies to public health activities.
- Incorporates the conceptual privacy standard of HIPAA.
- "Protected Health Information" is defined similarly.
- More "restrictive" than HIPAA fewer exceptions.
- · Have to evaluate situation/circumstances.

# **Privacy Definitions**

- "Protected Health Information" or "PHI" means:
- information, in any form, including oral, written, electronic, visual, pictorial, or physical
- · that describes an individual's past, present, or future
- · physical or mental health status or condition,
- · receipt of treatment or care, or
- purchase of health products.
- PHI factors The information must:
- · Identify the individual who is the subject of the information; or
- Could identify of the individual,
- · Either by using the information alone or with other information
- · That is available to
- Predictable recipients of the information.

Questions?

# **Objective 2.1**

Describe limits of mandatory controls and other social distancing measures

#### Question:

What four requirements usually constitute due process for quarantine and isolation?

# **Objective 2.2**

Identify legal issues regarding special populations, mass evacuations, re-opening evacuation areas, and related issues





# **Special Populations**

- · FEMA defines "special populations" as:
  - "A population whose members may have additional needs before, during, and after an incident in functional areas, including but not limited to: maintaining independence, communication, transportation, supervision, and medical care."
- · Groups included in special populations are:
  - · Older adults
  - · Persons with disabilities
  - · Pregnant women and children
  - · Transportation disadvantaged
  - · Non-English speaking

# Duty to Include Special Populations in Emergency Plans

Persons with disabilities:

- Communities Actively Living Independent and Free v. City of Los Angeles
  - In 2011, US District Court held that Los Angeles had violated state disability laws and the Americans with Disabilities Act for not considering persons with disabilities in city emergency plans.
- Brooklyn Center for Independence of the Disabled v. The City of New York
  - In November 2013, after a jury trial, it was found that the City of New York had not adequately prepared for persons with disabilities in the city's disaster response plans, particularly with regard to evacuation and messaging.

# Duty to Include Special Populations in Emergency Plans

- · Children and "at-risk individuals"
  - Recipients of Pandemic All-Hazards Preparedness Act funds must account for children and other at-risk individuals in their All-Hazards Public Health Emergency Preparedness and Response Plan.
- · Older adults
  - CDC planning guide: Identifying Vulnerable Older Adults and Legal Options for Increasing Their Protection During All-Hazards Emergencies: A Cross Sector Guide for States and Communities.

#### **Evacuation Powers**

- The purpose of evacuation is to remove people from a location that is an imminent threat
- Examples:
  - Florida Keys as a hurricane approaches
  - Area around a chemical tank car after train crash
  - · Area downstream of a dam about to collapse
- Every state/locality may exercise this fundamental police power to protect public health and safety

# **Questions for Evacuation Planning**

- When ordering an evacuation, the following issues must be considered:
  - · Is evacuation mandatory or voluntary?
    - If mandatory, how will it be facilitated and enforced?
  - · How to protect property in evacuated areas?
  - How to precisely identify areas to be evacuated?
  - How to safely evacuate special populations and pets?
  - How to ensure that mandatory evacuation zones are given priority over voluntary self-evacuation zones?
  - How to provide food, medical care, and shelter to the displaced (including persons with special needs)?

#### **Evacuation Powers**

State disaster authorities have specific provisions to order evacuation in "declared" emergencies:

#### Colorado Example

In a (state-) declared emergency, the Governor may:

"(e) Direct and compel the evacuation of all or part of the population from any stricken or threatened area within the state if the governor deems this action necessary for the preservation of life or other disaster mitigation, response, or recovery;

"(f) Prescribe routes, modes of transportation, and destinations in connection with evacuation"

# **Reopening an Evacuation Area**

- In general: The agency that issued the evacuation or closure order
  - Determines when the area or facility no longer poses a threat to public health and that the situation is "safe" or "acceptable"
  - · Issues an administrative order rescinding the closure order
- Note: Multiple agencies may have a role (e.g., US or state Environmental Protection Agency, in case of certain contaminants)
- Reopening is easier IF the criteria for reopening were considered BEFORE the closure

# **Evacuation Issues:** Considerations for Re-entry

- If evacuation is based on finding that an area was unsafe:
  - What standard is required to determine whether area is safe for people to return?
    - Condition causing evacuation was safely resolved? OR
    - Compliance with all appropriate environmental and health standards?
  - · Who decides?
    - The authority ordering the evacuation?
    - · A different government body?
  - Thinking ahead is vital

# **Evacuation Issues: Special Populations**

- Post-Katrina Emergency Management Reform Act requires:
  - Procedures in place to inform people with disabilities or other special needs of evacuation plans
  - Disability Coordinator appointed to ensure their needs are properly addressed
  - Information must be made available in form understandable by all population groups affected by a major disaster





# **Evacuation Issues:** The Pet Dilemma

- · Hurricane Katrina lessons learned:
  - "People won't leave their pets"
- · 62% of US households have pets
- 85% want to take pets with them in an evacuation
- · Implication: immediate logistical difficulties



# Pets Evacuation and Transportation Standards Act of 2006 (PETS Act)

- Requires that state and local evacuation plans "take into account the needs of individuals with household pets and service animals prior to, during, and following a major disaster or emergency"
- Requires the provision of "rescue, care, shelter, and essential needs" to individuals and their household pets and/or service animals

# **Objective 2.2**

Identify legal issues regarding special populations, mass evacuations, re-opening evacuation areas, and related issues

#### **Question:**

Is there a legal requirement to plan for persons with disabilities during emergencies?

## The Unfolding Story...

- A case appears in a hospital emergency department
- Public health officials are notified and they urge the Governor to declare emergency
- · Laboratory tests confirm; more patients appear
- 10 confirmed cases in city; 5 in other areas
- Isolation and quarantine recommended by public health
- Healthcare personnel become scarce, and workers and volunteers express concerns about liability

#### **Practical Question #6:**

Can we use non-governmental personnel?

#### **Practical Question #7:**

Are we liable?

## **Objective 2.3**

Understand basic legal issues applicable when government recruits and manages emergency volunteers, including liability, credentialing, and workers' compensation issues



# PROFESSIONALS AND THE LAW

Socrates H. Tuch, MA, JD, CPM Senior Counsel/Privacy Officer Ohio Department of Ohio July 2016

# **OFFICIALS**

Let's talk about you...and me.

# Sovereign Immunity

- · The Sovereign.
  - For discussion purposes "Sovereign" means the governmental entity with jurisdiction.
  - Local health districts are political subdivisions of the state created by R.C. 3709.01.
  - The Sovereign acts through its agents.
- · Can't sue the "Sovereign."
  - Without permission See R.C. Chapter 2743.
- "Yeah! I can't be sued!"
  - Whoa...slow your roll...no one said that.

## Qualified Immunity

- · Can't be personally liable for discretionary act unless:
- · Act is manifestly outside the scope of authority/employment.
- Act is done maliciously, in bad faith, wantonly or recklessly.
   R.C. 2743.02(F)
- Put another way, you are not liable for civil damages unless:
- · Your actions violate a clearly established right; and
- · You knew or should have known you would violate a right.
- · Translation:
  - You did your job, and only your job.
  - · What you did was informed and reasonable in the circumstances.
- · What you did, didn't violate anyone's right.

# **VOLUNTEERS**

If you disaster they will come.

# Some Background

- · Ohio licensure is general.
- · Generally license practioners not specialists.
- Exceptions do exist for public policy purposes.
- · Insurance is specific.
- · It's a contract.
- · What you do, when you do it, and where.
- · It's about distributing risk.
- · Malpractice is specific.
- · It's a "tort."
- ${\mbox{\footnote{h}}}$  What you should have done, what you did, when, and why.
- · Actions are measured against the standard of care.

#### "Good Sam"

- · Spontaneous volunteer.
- · Organized does not mean spontaneous?
- But if the government is involved...
  - Isn't the volunteer a government actor?
- If the volunteer gets anything in return is he or she still a volunteer?
- Can a volunteer be "instructed?"
- How responsible is government for the volunteer?
- · Look to R.C. 5502.281 and R.C. 3701.04(B)

# Enter R.C. 5502.281(C)

- · A registered volunteer
- is not liable in damages to any person or government entity
- in tort or other civil action, including an action upon a medical, dental, chiropractic, optometric, or other health-related claim or veterinary claim, for injury, death, or loss to person or property
- · that may arise from an act or omission of that volunteer.
- The immunity applies only if the volunteer was providing services:
  - Within the scope of the volunteer's responsibilities during an emergency or in disaster-related exercises, testing, or other training activities; and
  - The act or omission does not constitute willful or wanton misconduct.

#### **Definitions**

- · "Registered Volunteer"
- Means any individual registered as a volunteer pursuant to procedures established under this section and
- $\bullet \ \ \mbox{Who serves without pay or other consideration},$
- other than the reasonable reimbursement or
- allowance for expenses actually incurred or the provision of incidental benefits related to the volunteer's service, such as meals, lodging, and child care.
- Volunteer registration, training, and deployment is a joint public health/emergency management responsibility.
- · "Political subdivision"
  - Means a county, township, or municipal corporation in this state.

#### **Public Record Note**

- · That someone is a volunteer is public record.
  - · So is any summary, statistical, or aggregate information.
  - R.C. 5502.281(B)(1)
- A volunteer's responsibilities, assignment, or deployment plans are security records and not public.
  - R.C. 5502.281(B)(2)
- A volunteer's personal information, including that of family members or dependents, is not a public record.
  - R.C. 5502.281(B)(3)

# Limitations

- · Volunteers from Ohio are not eligible for EMAC.
  - · Volunteers are not "state actors."
  - · Not obligated to participate.
- Professional volunteers must be licensed if license is required in Ohio.
  - · Does not substitute for a required professional license.
  - Does not set or alter the standards of practice.
  - Does not set or alter the scope of practice.
  - · Does not address foreign licenses.
- · Volunteers are not immune from criminal charges.

#### Limitations

- · Ohio law on volunteers does not prohibit lawsuits.
- A person who has engaged in subversive activities is ineligible to be a volunteer.
  - · No person shall be associated with an EMS agency
- Who advocates or has advocated the forceful or violent change in government or convicted thereof.
- R.C. 5502.34
- R.C. 5502.281 and R.C. 3701.04(B) do not address Workers' Compensation questions.

## Workers' Compensation

- Volunteers are not generally covered because they don't get paid.
  - Public employers are required to carry workers' compensation coverage for the volunteer emergency service personnel they engage.
  - Examples of volunteer emergency service occupations requiring coverage would be:
  - · Volunteer firefighters;
  - Volunteer police officers;
  - Volunteer emergency medical technicians
- If an employer controls the working hours, selection of materials, traveling routes and quality of performance, an employer-employee relationship exists and the employer is required to provide workers' compensation coverage.

## Workers' Compensation

- Coordination is not control.
- Volunteer are free to ignore requests
- Volunteer can "unvolunteer" at any time.
- · What is the volunteer's level of responsibility?
- · Could the volunteer be an "independent contractor?"
- · Bottom line:
  - · Not sure.
  - Have to carefully walk through the situation with your legal counsel to decide your level of risk.

#### Questions?

## **Objective 2.3**

Understand basic legal issues applicable when government recruits and manages emergency volunteers, including liability, credentialing, and workers' compensation issues

#### Question:

If malpractice is alleged, will a healthcare provider be judged according to the emergency circumstances, or as a provider during normal non-emergency circumstances?

#### **Unit 2 Summary and Key Take-Aways**

- Constitutional framework for protection of people during emergencies includes clear role for the police power
- Quarantine and other social distancing powers are circumscribed by basic procedural protections that are contained in the Constitution, laws, regulations, and public policies

#### **Unit 2 Summary and Key Take-Aways**

- 3. The exercise of mass evacuation powers in an emergency is significantly improved by
  - Advance anticipation of the legal implications of using evacuation powers
  - Determination of re-entry criteria in advance
  - Careful consideration of special populations and pet evacuation issues

#### **Unit 2 Summary and Key Take-Aways**

- There are many legal issues applicable to emergency response personnel and volunteers, including
  - Liability
  - Credentialing
  - Workers' compensation issues

# Public Health Emergency Law Minimum Competency Domain 3

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, 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.

View the Competencies at:

 $\underline{www.cdc.gov/phlp/publications/topic/phel-competencies.html}$ 

# **End: Unit 2**

For additional information on public health law and legal preparedness, visit the CDC Public Health Law Program



www.cdc.gov/phlp

## **Public Health Emergency Law**

CDC Foundational Course for Front-Line Practitioners Version 4.0

Unit 3:

Emergency Powers: Property and Supplies

## Unit 3: Emergency Powers: Property and Supplies

Unit 3 aligns with Public Health Emergency Law Minimum Competency Domain 2:

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 and materiel 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.

#### The Unfolding Story...

- · A case appears in a hospital ED
- · Public health officials are notified
- · Health officials urge the Governor to declare emergency
- · Laboratory tests confirm; more patients appear
- Agencies within the state and federal governments, including public health and safety agencies, want information regarding persons who are ill
- 10 confirmed cases in city; 5 in other areas
- · Isolation and quarantine recommended by public health
- Healthcare personnel become scarce; workers and volunteers worry about liability
- · Facilities and supplies become scarce

#### **Practical Question #8:**

Can we obtain facilities and supplies?

# **Unit 3 Objective**

 By the end of this unit, participants will understand basic legal principles applicable when government takes control of, uses, and allocates privately owned facilities, equipment, materials, and supplies

# **Unit 3 Objective**

Understand basic legal principles applicable when government takes control of, uses, and allocates privately owned facilities, equipment, materials, and supplies



# Range of Government Powers Over Property

- In appropriate situations, local, state, and federal agencies can:
  - Close/prohibit access to structures, land, and airspace
  - Confiscate and destroy property, including animals, birds, and crops
  - Commandeer and use facilities, equipment, and supplies
  - Regulate the use of property

# Range of Government Powers Over Property (cont.)

#### BUT:

- These measures may only be authorized by certain officials in certain levels of government
- Specific legal procedures must be followed when exercising these powers
  - · Due process
  - · Special statutory procedures
  - Compensation, in some circumstances

# Constitutional Limits on Government Interference with Property Rights

- · US Constitution, 5th Amendment
  - Due Process Clause: "nor be deprived of life, liberty, or property, without due process of law"
  - Takings Clause: "...nor shall private property be taken for public use, without just compensation"
- · US Constitution, 14th Amendment
  - Bill of rights made applicable to the states
  - Due Process Clause: "nor shall any <u>State</u> deprive any person of life, liberty, or property, without due process of law"
- · Apply both during and absent a declared emergency

# Property Measures: Emergency Seizure for Government Use

- What constitutes a "taking" that requires compensation?
  - Physical seizure and eminent domain
  - Regulatory taking that deprives an owner of the full economic use of their property
- What about regulations to protect public health and safety?
- · What about dangerous property?

#### **Emergency Use of Healthcare Facilities**



- Some states have specific provisions covering use of healthcare facilities in emergencies:
- Georgia Example
  - 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."

## **Emergency Use of Personal Property**

#### **Georgia Example**

- Georgia law also covers any materials required during an emergency
  - "The Governor may...(4) Commandeer or utilize any private property if he finds this necessary to cope with the emergency or disaster."



# Acquiring Private Property: Key Issues for <u>Federal</u> Powers

- Federal government also can take property in emergencies - subject to "due process" and "just compensation" [RARELY USED POWERS]
- · Condemnation under Stafford Act Title VI:
  - Power to condemn; with right to take immediate possession
  - For purposes of preparedness, response, recovery
- · Defense Production Act: "priority contracting"
  - Can apply to preparedness, response, recovery
  - Federal priority can be accorded to state or local acquisition contracts

# Emergency Reallocation of Resources: Federal Powers

- As a matter of policy, HHS frequently requests voluntary reallocation of private resources (vaccines, medications, ventilators) to protect public health
  - Voluntary re-routing of influenza vaccine in Fall 2004
- HHS also can reallocate government-owned supplies:
  - Vaccines
  - · Strategic National Stockpile



## Federal Powers Regarding Medical Products and Supplies

- · FDA can issue special authorizations
  - Investigational New Drug (IND)
    - · Use requires informed, written consent
    - Occurred during the meningitis outbreak at Princeton University in 2013
  - · Emergency Use Authorization (EUA)
    - Used with actual or potential emergencies involving chemical/biological/radiological/ nuclear agents
  - Emergency Dispensing Order (EDO)
    - New authority. Draft guidance is here: www.fda.gov/RegulatoryInformation/Guidances/ucm125 127.htm

## Public Readiness and Emergency Preparedness (PREP) Act Immunity

 PREP Act 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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Declaration Under the Public Readiness and Emergency Preparedness Act

September 28, 2009.

AGENCY: Office of the Secretary (OS),
Department of Health and Human
Services (HHS).

ACTION: Notice.

SUMMARY: Declaration pursuant to section 319F-3 of the Public Health Service Act (42 U.S.C. 247d-6d) to provide targeted liability protections for pandemic countermeasures based on the Secretary's finding under the Act that

Applies to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of countermeasures

#### **PREP Act Immunity**

- Applies to approved countermeasures: medicine, medical devices, technology, etc.
- · Does NOT cover "willful misconduct"

of the Public Readinees and Emergency Preparedums. At for the Influenza Preparedums. At the The Influenza Secretary Charles of Public Health Secretary Charles Dobason determined under section 310 of the Public Health Act, and the Charles of the Public Health Secretary Charles of Public Health emergency exists antionwide involving the Swinson Act, That a public health emergency exist antionwide involving the Swinson Charles of the Public Health Suite and Section 2009—18(1) influenza" that affects or has significant potential to affect the Australia of the Public Health Service Act, 162 U.S.C. Whereas, on the July 24, 2009. Secretary Kathleon Sebelius renowed the of the Public Health Service Act, 162 U.S.C.

Whereas, the extent of immunity under section 1910–210 of the Act Development of the Conference of the

either with respect to? [1] Present of agreements, grants, laistergenery agreements, grants, laistergenery agreements, grants, laistergenery or memorands of understanding travelving consumerances that are used and declaration, and [2] activities unthorized and consumerances of the Athentity Having Intrinsification to presently Having Intrinsification to presently dispusses the Coverde Construences and medical responses of the Athentity and Athentical Construences, as defined as excited NC below. It also dispusses the Coverde Construences are declarated as the construence of the Athentity of the Construence of the Athentity of the dispusses the Coverde Construences and the planters, the immunity specified in effect to the action by delian Coverde Countermonaums through voluntary densities. The construence of the Athentical Construence and Countermonaums through voluntary densities.

# **Unit 3 Objective**

Understand basic legal principles applicable when government takes control of, uses, and allocates privately owned facilities, equipment, materials, and supplies

#### Question:

What are some ways government officials can control the use of privately owned property?

#### **Unit 3 Summary and Key Take-Aways**

- Each level of government has general powers to deny access to or take control of virtually any facility or property if necessary to protect the public's health
- Government actions affecting private property are subject to "due process" procedural rights and, if government takes property for public use, to payment of compensation
- 3. Exercising statutory authorities over property in emergency requires pre-emergency planning, training, and advance contracting

# Public Health Emergency Law Minimum Competency Domain 2

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 and materiel 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.

View the Competencies at:

www.cdc.gov/phlp/publications/topic/phel-competencies.html

#### **End: Unit 3**

 For additional information on public health law and legal preparedness, visit the CDC Public Health Law Program



www.cdc.gov/phlp

# Break! See you in 10 minutes!

# Legal Issues in a Public Health Emergency: A Case Study



#### DISCLAIMER

These course materials are for instructional use only and are not intended as a substitute for professional legal or other advice. While every effort has been made to verify the accuracy of these materials, legal authorities and requirements may vary from jurisdiction to jurisdiction. Always seek the advice of an attorney or other qualified professional with any questions you may have regarding a legal matter.

#### The Unfolding Story...

- A case appears in a hospital emergency department (ED)
  - A 30-year-old man presents with fever and pustules
  - He has waited in ED for a few hours before being seen by a physician
  - Patients and staff in ED have come and gone in the interval
  - When seen, the physician suspects smallpox

# Legal Issues in a Public Health Emergency:

#### **8 Practical Questions**



#### **Legal Issues in a Public Health Emergency**

- 1. Can we declare a public health emergency?
- 2. Can we investigate contacts?
- 3. Can we examine and test people?
- 4. Can we treat and vaccinate?
- 5. Can we isolate and quarantine?
- 6. Can we use non-governmental personnel?
- 7. Are we liable?
- 8. Can we obtain facilities and supplies?

#### The Unfolding Story...

- · A case appears in a hospital emergency department
- · Public health officials are notified
  - They close the ED, telling those present that they may not leave
  - Preliminary confirmation of the diagnosis of smallpox is made by the other ED physicians
  - The media pick up the story of a local case of smallpox and widely report it
  - The public begins to show signs of panic, and the local health resources are stressed

#### Legal Issues in a Public Health Emergency

♦ Can the governor declare an emergency?

State Law (Ohio)

R.C. § 5502.21 Definitions

Depends on definition of an "emergency" & "chief executive"

- (E) "Disaster" means any imminent threat or actual occurrence of widespread or severe damage to or loss of property, personal hardship or injury, or loss of life that results from any natural phenomenon or act of a human.
- (F) Except as provided in section 5502.41 of the Revised Code, "emergency" means any period during which the congress of the United States or a chief executive has declared or proclaimed that an emergency exists

#### Legal Issues in a Public Health Emergency

• Can the governor declare an emergency?

State Law (Ohio)

"chief executive"

R.C. § 5502.21 Definitions

(I) "Hazard" means any actual or imminent threat to the survival or overall health, safety, or welfare of the civilian population that is caused by any natural, human-made, or technological event. "Hazard" includes, without limitation, an attack, disaster, and <a href="mailto:emergency">emergency</a>.

#### Legal Issues in a Public Health Emergency

 Can he/she declare an public health emergency?
 Depends

State Law (Ohio)

R.C. § 5502.21 Definitions

(C) "Chief executive" means the president of the United States, the governor of this state, the board of county commissioners of any county, the board of township trustees of any township, or the mayor or city manager of any municipal corporation within this state.

#### The Unfolding Story...

- A case appears in a hospital ED
- · Public health officials are notified
- Laboratory tests confirm the diagnosis of smallpox for the first patient. More patients begin to appear in EDs, throughout the city, with signs of smallpox
  - Public health personnel want to learn the identities of the persons with whom the cases had contact
  - Public health personnel want to examine those persons

#### The Unfolding Story...

- · A case appears in a hospital ED
- · Public health officials are notified
- Given the nature of smallpox, health officials urge the Governor to declare an emergency
  - -Anxiety among the public increases
  - People begin to demand more information.
     Some demand vaccines.

#### Legal Issues in a Public Health Emergency

• Should he/she declare an emergency?

State Law (Ohio) Yes

R.C. § 5502.21 Definitions

(E) "Disaster" means any imminent threat or actual occurrence of widespread or severe damage to or loss of property, personal hardship or injury, or loss of life that results from any natural phenomenon or act of a human.

(F) Except as provided in section 5502.41 of the Revised Code, "emergency" means any period during which the congress of the United States or a chief executive has declared or proclaimed that an emergency exists

#### Legal Issues in a Public Health Emergency

◆ Can localities declare an emergency?

State Law (Ohio)

Yes

R.C. § 5502.21 Definitions

(C) "Chief executive" means the president of the United States, the governor of this state, the board of county commissioners of any county, the board of township trustees of any township, or the mayor or city manager of any municipal corporation within this state.

#### Legal Issues in a Public Health Emergency

◆ Can localities declare an emergency?

Local Law (Columbus, Ohio)

Yes

701.13 - Emergencies.

(A) Whenever the director finds that an emergency exists which requires immediate action to protect the health and safety of any person, he or she may issue an oral or written order reciting the existence of such an emergency and requiring that such action as he or she deems necessary be taken to meet the emergency. Notwithstanding the other provisions of this code, such order shall be effective immediately and complied with immediately.

#### Legal Issues in a Public Health Emergency

◆ Can localities declare an emergency?

Yes

Local Law (Upper Arlington, Ohio)

§ 1583.06 - EMERGENCIES.

(A) Whenever the health commissioner finds that an emergency exists which requires immediate action to protect the health and safety of any person, he or she may issue an oral or written order reciting the existence of such an emergency and requiring that such action as he or she deems necessary be taken to meet the emergency. Notwithstanding the other provisions of this Code, such order shall be effective immediately and complied with immediately.

#### Legal Issues in a Public Health Emergency

◆ Can localities declare an emergency?

#### Local Law (Cincinnati, Ohio)

Yes

Sec. 5. - Proclamation of Emergency.

When the mayor, or in the absence of mayor the vice-mayor, or in the absence of both the mayor and the vice-mayor, the city manager determines that a public danger or emergency as defined in this article exists, the mayor shall forthwith proclaim in writing the existence of the same and the time of its inception and shall issue proclamation thereof to the public through the news media and such other means of dissemination as deemed

#### Legal Issues in a Public Health Emergency

♦ Can we investigate the contacts?

Yes

#### State Law (Ohio)

R.C. § 3701.04 Powers of director of health

- (A) The director of health shall:
- (1) Require reports and make inspections and investigations that the director considers necessary;

#### Legal Issues in a Public Health Emergency

♦ Can we investigate the contacts?

#### State Law (Ohio)

Yes

R.C. § 3701.14 Special duties of director of health

(A) The director of health shall investigate or make inquiry as to the cause of disease or illness, including contagious, infectious, epidemic, pandemic, or endemic conditions, and take prompt action to control and suppress it.

#### Legal Issues in a Public Health Emergency

◆ Can we examine and test people?

Possibly

State Law (Ohio)

R.C. § 3701.14 Special duties of director of health

(A) The director of health shall investigate or make inquiry as to the cause of disease or illness, including contagious, infectious, epidemic, pandemic, or endemic conditions, and take prompt action to control and suppress it.

# The Unfolding Story...

- A case appears in a hospital ED
- Public health officials are notified
- · Health officials urge the Governor to declare emergency
- · Laboratory tests confirm; more patients appear
- There are now 10 confirmed cases in the city and another 5 cases in other areas of the state
  - More people are demanding vaccination
  - Some people, who appear to be ill, are refusing treatment
  - Some people who are believed to have been exposed to smallpox are refusing vaccination

#### Legal Issues in a Public Health Emergency

◆ Can we treat/vaccinate people? Possibly

#### State Law (Ohio)

R.C. § 3701.14 Special duties of director of health

(A) The director of health shall investigate or make inquiry as to the cause of disease or illness, including contagious, infectious, epidemic, pandemic, or endemic conditions, and take prompt action to control and suppress it.

#### Legal Issues in a Public Health Emergency

• Can we treat/vaccinate people? Unlikely

R.C. § 3701.13 Powers of department; quarantine and isolation; immunization; orders or rules; shared services agreements; accreditation

The department may approve methods of immunization against the diseases specified in section 3313.671 of the Revised Code for the purpose of carrying out the provisions of that section and take such actions as are necessary to encourage vaccination against those diseases.

R.C. § 3313.671 = school vaccination requirements

## The Unfolding Story...

- · A case appears in a hospital ED
- Health officials are notified and urge Governor to declare emergency
- · Laboratory tests confirm; more patients appear
- · 10 confirmed cases in city: 5 in other areas
- Public health officials recommend the use of isolation and quarantine
  - -Some object to being isolated or quarantined
  - Family members do not want to be separated
  - People fear that their needs will not be met in isolation or quarantine

#### Legal Issues in a Public Health Emergency

◆ Can we isolate/quarantine people?

Yes

State Law (Ohio)

State Law (Ohio)

R.C. § 3701.13 Powers of department; quarantine and isolation; immunization; orders or rules; shared services agreements; accreditation

The department of health shall have supervision of all matters relating to the preservation of the life and health of the people and have ultimate authority in matters of quarantine and isolation, which it may declare and enforce, when neither exists, and modify, relax, or abolish, when either has been established.

#### Legal Issues in a Public Health Emergency

◆ Can we isolate/quarantine people?

Yes

State Law (Ohio)

OAC 3701-3-13 Isolation requirement

A person infected with one of the following specified diseases or conditions shall be isolated as set forth in this rule:

(Y) Smallpox: a person with confirmed or suspected smallpox shall be placed in airborne isolation in a facility designated by the director. The patient's release from the facility can occur when all scabs have fallen off.

#### Legal Issues in a Public Health Emergency

◆ Can localities isolate/quarantine people? Yes

#### Local Law (Upper Arlington, Ohio)

§ 1583.01 - AUTHORITY OF BOARD OF HEALTH.

...The board of health has primary authority to enforce the provisions of ORC §§ 3707.04 to 3707.32 regarding quarantine and isolation. In accordance with ORC § 3707.34, the health commissioner shall act on behalf of the board of health in administering the provisions of ORC §§ 3707.04 to 3707.32 regarding quarantine and isolation when circumstances have rendered a meeting of the board of health to be impractical or impossible or delaying the action until a meeting of the board of health would compromise the public health.

#### Legal Issues in a Public Health Emergency

 Can the federal government isolate/quarantine people?

Yes

#### **Federal Authority**

- 1) Secretary's Authority: 42 U.S.C. §§ 264, 266
- Public Health Service to cooperate with and aid State and local authorities in the enforcement of their quarantine and other health regulations. 42 U.S.C. §243
- Director of CDC may take "reasonably necessary measures" to prevent spread between States if local efforts are "insufficient". 42 C.F.R. §70.2 (2002)
- Secretary may require permits for interstate travel; individuals with specified diseases may be detained. 42 C.F.R. §§ 70.5, 70.6 (2002)

#### The Unfolding Story...

- A case appears in a hospital ED
- · Public health officials are notified
- · Health officials urge the Governor to declare emergency
- · Laboratory tests confirm; more patients appear
- 10 confirmed cases in city; 5 in other areas
- Isolation and quarantine recommended by public health
- Healthcare personnel become scarce

#### Legal Issues in a Public Health Emergency

◆ Can we use non-governmental personnel?

#### State Law (Ohio)

Yes

R.C. § 5502.281 Statewide volunteer system; public records: immunity

(A) The executive director of the emergency management agency, jointly with the director of health, shall do both of the following:

(1) Advise, assist, consult with, and cooperate with agencies and political subdivisions of this state to establish and maintain a statewide system for recruiting, registering, training, and deploying the types of volunteers reasonably necessary to respond to an emergency declared by the state or a political subdivision;

#### Legal Issues in a Public Health Emergency

◆ Can we use out-of-state personnel? Yes

State Law (Ohio)

R.C. § 5502.35 Powers, duties, privileges, and immunities of all

Notwithstanding any inconsistent provisions of law, persons engaged in emergency management activities, members of emergency management agencies in this state, and members of the emergency management agencies of other states or of the federal government or of another country or of a province or subdivision thereof performing emergency management services at any place in this state pursuant to agreements, compacts, or arrangements for mutual aid and assistance, to which the state or a political subdivision thereof is a party, shall possess the same powers, duties, immunities, and privileges they would ordinarily possess if performing their duties in the jurisdiction in which normally employed or rendering services.

#### The Unfolding Story...

- A case appears in a hospital ED
- · Public health officials are notified
- · Health officials urge the Governor to declare emergency
- Laboratory tests confirm; more patients appear
- 10 confirmed cases in city; 5 in other areas
- Isolation and quarantine recommended by public health
- Healthcare personnel become scarce
- Workers and volunteers worry about liability

#### Legal Issues in a Public Health Emergency

◆ Are registered volunteers liable? No

#### State Law (Ohio)

R.C. § 5502.281 Statewide volunteer system; public records; immunity

(C) A volunteer registered under this section is not liable in damages to any person or government entity in tort or other civil action, including an action upon a medical, dental, chiropractic, optometric, or other health-related claim or veterinary claim, for injury, death, or loss to person or property that may arise from an act or omission of that volunteer. This division applies to a registered volunteer while providing services within the scope of the volunteer's responsibilities during an emergency declared by the state or political subdivision or in disaster-related exercises, testing, or other training activities, if the volunteer's act or omission does not constitute willful or wanton misconduct.

#### Legal Issues in a Public Health Emergency

Are volunteer, state, or out-of-state personnel liable?
 State Law (Ohio)

R.C. § 5502.30 Immunity from liability while in performance of emergency management (x,y)

(A) The state, any political subdivision, any municipal agency, any emergency management agency thereof or of the federal government or of another country or province or subdivision thereof performing emergency management agency thereof or of the federal government or of another country or province or subdivision thereof performing emergency management services in this state pursuant to an arrangement, agreement, or compact for mutual aid and assistance, or any agency, member, agent, or representative of any of them, or any individual, partnership, corporation, association, trustee, or receiver, or any of the agents thereof, in good faith carrying out, complying with, or attempting to comply with any state or federal law or any arrangement, agreement, or compact for mutual aid and assistance, or any order issued by federal or state military authorities relating to emergency management, is not liable for any injury to or death of persons or damage to property as the result thereof during training periods, test periods, practice periods, or other emergency management operations, or false alerts, as well as during any hazard, actual or imminent, and subsequent to the same except in cases of willful misconduct. As used in this division, "emergency management volunteer" means only an individual who is authorized to assist any agency performing emergency management during a hazard.

#### Legal Issues in a Public Health Emergency

Are volunteer, state, or out-of-state personnel liable?
 State Law (Ohio)

R.C. § 3701.048 Development of protocols regarding authority to administer, deliver, distribute, or dispense drugs during certain public health emergencies

(F)(1) An individual who administers, delivers, distributes, or dispenses a drug or dangerous drug in accordance with one or more of the protocols implemented under division (E) of this section is not liable for damages in any civil action unless the individual's acts or omissions in performing those activities constitute willful or wanton misconduct.

(2) An individual who administers, delivers, distributes, or dispenses a drug or dangerous drug in accordance with one or more of the protocols implemented under division (E) of this section is not subject to criminal prosecution or professional disciplinary action under any chapter in Title XLVII of the Revised Code.

#### The Unfolding Story...

- · A case appears in a hospital ED
- · Public health officials are notified
- · Health officials urge the Governor to declare emergency
- · Laboratory tests confirm; more patients appear
- 10 confirmed cases in city; 5 in other areas
- Isolation and quarantine recommended by public health
- · Healthcare personnel become scarce
- Workers and volunteers worry about liability
- Facilities and supplies become scarce

#### Legal Issues in a Public Health Emergency

♦ Can we obtain facilities and supplies?

Yes

#### State Law (Ohio)

R.C. § 125.061 Suspension of purchasing and contracting requirements during an emergency

(A) During the period of an emergency as defined in section 5502.21 of the Revised Code, the department of administrative services may suspend, for the emergency management agency established in section 5502.22 of the Revised Code or any other state agency participating in response and recovery activities as defined in section 5502.21 of the Revised Code, the purchasing and contracting requirements contained in Chapter 125. and any requirement of Chapter 125. and any requirement of Chapter 153. of the Revised Code that otherwise would apply to the agency. The director of public safety or the executive director of the emergency management agency shall make the request for the suspension of these requirements to the department of administrative services concurrently with the request to the governor of the president of the United States for the declaration of an emergency. The governor also shall include in any proclamation the governor issues declaring an emergency language requesting the suspension of those requirements during the period of the emergency.

#### Legal Issues in a Public Health Emergency

◆ Can we seize facilities and supplies?

Yes

State Law (Ohio)

Statutes are silent... but recall eminent domain!

#### **Questions, Comments, Thoughts?**



The "first tool of public health" is epidemiology.... "The second public health tool might well be the law."

William H. Foege, MD, MPH (Director, CDC, 1977-1983),
"Redefining Public Health," *Journal of Law, Medicine and Ethics*,
Dec. 2004



#### For more information on PHLP visit: http://www.cdc.gov/phlp

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The Sedient and combining in this count are those of the author and do not account the countries.

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