Public Health Law 101

A CDC Foundational Course for Public Health Practitioners

Public Health Law Program
http://www.cdc.gov/phlp
PUBLIC HEALTH LAW 101
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- Unit 1: Key Concepts of U.S. Law in Public Health Practice
- Unit 2: Ethics and the Law
- Unit 3: Administrative Law
- Unit 4: Role of the Legal Counsel
- Unit 5: Law of Public Health Surveillance, Investigations, and Emergencies
- Unit 6: Privacy and Confidentiality
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Unit 7
Infectious Diseases
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Infectious Diseases: Public Health Law Issues

- As a public health official, what can you do under the law …
  - … if a group of parents refuses to have their elementary school children vaccinated because of fears of unsubstantiated severe side-effects?
  - … if cases of listeriosis are diagnosed in emergency rooms in four cities around your state?
  - … if a TB patient, after 5 days of treatment, leaves the hospital in your jurisdiction and disappears?
Unit 7 Objectives

By the end of this unit, you should:

1. Understand the balance between an individual’s right to refuse vaccination and a state’s basis for requiring vaccination.
2. Recognize how food regulation and food-borne disease prevention are shared responsibilities of local, state, and federal governments.
3. Be familiar with the basis for a state’s authority to restrict the freedom of an individual to prevent the spread of some communicable diseases.

• Instructor: this is an essential slide, as the objectives frame the order of content included in this unit.
Federalism and Allocation of Public Health Powers

- The Constitution divides powers between the states and the federal government
- Federal Powers in public health
  - Interstate commerce
  - Foreign trade and travel
  - National security
- State Powers
  - All powers not given to the federal government
  - “Police powers” – Powers exercised by the states to enact legislation and promulgate regulations to protect public health, welfare, and morals, and to promote the common good
Federalism and Disease Control Authority

- State and local governments carry out most communicable disease control under the police power
- Federal government provides lead role in controlling diseases related to goods in interstate commerce, such as food
- Federal and state governments cooperate when:
  - Communicable disease threats cross state lines
  - Federal and state authority overlap, as in food safety
Objective 7.1
Understand the balance between an individual’s right to refuse vaccination and a state’s basis for requiring vaccination.
Vaccination History: Introduction of Immunizing Agents

- 1798  Smallpox
- 1885  Rabies
- 1897  Plague
- 1923  Diphtheria
- 1926  Pertussis
- 1927  Tetanus
- 1935  Yellow Fever
- 1955  Polio (inactivated)
- 1962  Polio (oral)
- 1964  Measles
- 1967  Mumps
- 1970  Rubella
- 1981  Hepatitis B
- 1995  Hepatitis A
- 1995  Varicella
Federal Vaccination Laws

Milestones in U.S. Food and Drug Law History
http://www.fda.gov/opacom/backgrounders/miles.html
Vaccination History: State Vaccination Laws

- States began requiring smallpox vaccinations in the 1800s
- These laws were upheld in an opinion written by Justice Harlan in *Jacobson v. Massachusetts*, 197 U.S. 11 (1905)
- The Supreme Court held that submitting to public health measures is a duty of those living in society

Justice Harlan
The Legal-Scientific Basis for Mandatory Vaccination Laws

- Herd Immunity
  - A primary purpose of mandatory vaccination laws is to slow or prevent spread of disease in the community
  - The proportion of vaccinated persons is inversely related to the likelihood that an infected person will transmit disease
  - Vaccines that do not provide complete protection for individuals can still reduce the spread of disease in the community
- It is community (not individual) protection that justifies mandatory vaccinations
Contemporary Vaccination Laws

• Most vaccine laws are state and local laws
  – With few exceptions, there are no federal vaccination requirement laws
    • Exceptions include: foreign travel restrictions and OSHA laboratory worker requirements
  – Federal guidelines encourage vaccination

• Target populations
  – Children
  – Special populations and settings
Childhood Immunization Laws

- Enforcement is through school exclusion
  - Children must be vaccinated to attend school
  - Requirements monitored and enforced by schools

- Many states have extended these requirements to related settings
  - Private pre-school and day-care settings
  - Colleges
  - Home schools
Example of School Vaccination Requirements: New York Education Law Sec. 914

• Effect of this law:
  – Each school must require of every child entering or attending proof of immunization against poliomyelitis, mumps, measles, diphtheria, rubella and varicella.
Requirements for Special Populations: Adult Health-Care Workers

Code of Massachusetts Regulations, Title 105, Chapter 130.00 (Hospital Licensure)

• “(F) Personnel assigned to maternal and newborn areas shall have:
  – (1) Demonstrated immunity to rubella either via rubella titer or physician-documentated rubella vaccine received on or after 12 months of age.
  – (2) Demonstrated immunity to measles (rubeola) either via measles titer, physician-diagnosed disease or physician-documentated live measles vaccine received on or after 12 months of age.”
Federal Role in Vaccine Guidelines

• CDC-sponsored Advisory Committee on Immunization Practices (ACIP) develops recommendations for vaccinations
  – States typically consider these recommendations in their decisions about vaccination mandates
  – Recommendations may be incorporated into administrative regulations
  – Private employers and health care providers also rely on these recommendations
Medical Exemptions

• Contraindications to vaccinations
  – Persons with immunocompromised conditions may be at risk for serious complications from live virus vaccines
  – Persons with hypersensitivity to certain vaccine components

• All states allow medical exemptions
  – Generally must be certified by a physician
  – Some states have tried to limit improper physician certifications through actions such as allowing hearings
Constitutional Issues and Vaccination: Religious Exemptions

- Exemptions to vaccination requirements based on religious grounds are not required by the U.S. Constitution
- Constitutional Issues
  - States cannot choose which religions qualify
  - State laws that only allowed exemptions for organized and recognized churches have been held unconstitutional
  - Many states now allow exemptions for both philosophical and religious reasons
Impact of Vaccination Exemptions

• Reduces herd immunity
  – Increases spread of disease within community
  – Increases risk to individuals with medical contraindications to vaccination

• Issue:
  – Some states allow suspension of exemptions during an emergency to allow for faster mass immunizations
  – Should exemptions apply in emergencies (e.g., during a smallpox outbreak)?
Compensation for Vaccine Injuries: History

- Smallpox vaccine was the first effective human vaccine
  - Historically, the vaccine was often contaminated and dangerous
  - The Supreme Court recognized this risk in *Jacobson v. Massachusetts*
- Risks of smallpox vaccination were considered part of life and there was no compensation for injuries
Compensation for Vaccine Injuries: Changing Expectations

- Events contributing to public expectations for compensation for injuries caused by vaccinations
  - The "Cutter Incident"
    - As a result of production errors, some early batches of polio vaccine were contaminated with live virus and caused polio
    - Courts allowed claims for damages in 1960
  - Restatement of Torts 2nd, Sec. 402a (1965)
    - Introduced strict liability for products, including vaccines
  - Swine Flu Act (1976)
    - Vaccine manufacturers sought protection from strict liability claims before they would manufacture the vaccine
    - Allowed government compensation for first time


- Swine Flu - Unthank v. United States, 732 F.2d 1517 (10th Cir. 1984)


Compensation for Vaccine Injuries: National Childhood Vaccine Injury Act

- By 1980s, vaccination litigation claims were driving manufacturers from the market
- National Childhood Vaccine Injury Act of 1986
  - Established National Vaccine Injury Compensation Program (VICP)
  - Provides no-fault, government compensation for injuries associated with routinely administered childhood vaccines
  - Shifts monetary costs of vaccine injuries away from vaccine recipients and manufacturers
  - Specifies compensation process and gives HHS Secretary discretion to revise list of compensable injuries
Issues in Vaccine Compensation and Emergency Preparedness

- Smallpox vaccination campaign of 2002
  - Targeted health care workers and first responders
  - Some people indicated that absence of an injury compensation program affected their decision not to participate

- There are no provisions for compensating adults who are vaccinated during public health emergencies
  - Claims against manufacturers have been limited by new laws
  - Will this affect public participation?
  - What is government’s role in providing compensation?
Objective 7.2

Recognize how food regulation and food-borne disease prevention are shared responsibilities of local, state, and federal governments.
The International Food Network

- Where does your food come from?
  - Eggs from a local farm
  - Beef from the Midwest
  - Shrimp from Louisiana
  - Apples from New Zealand
  - Raspberries from Central America
  - Grapes from Chile
  - Fish from Vietnam

- Ensuring safety of the food supply involves local, state, and federal agencies
Federal Authority to Regulate Food Safety

• Domestic food supply
  – Interstate commerce clause
  – National security powers for bioterrorist threats to food

• International food imports
  – Federal government has exclusive authority over international trade
  – Federal government may enter into treaties with other counties over trade
Federal Enforcement Agencies: Agriculture

- U.S. Department of Agriculture (USDA) is a dual role agency:
  - Helps farmers produce and sell more food
  - Has primary role in assuring that food is produced and processed safely
- USDA inspectors work with food processing facilities, including direct oversight of meat packing and enforcement of standards
- USDA plays important role in protecting food supply from plant and animal disease outbreaks
Federal Enforcement Agencies: FDA

- FDA regulates type and amount of drugs used in farm / food animal production
- FDA regulates food labeling
  - Nutritional content
  - Safe handling information (e.g., cooking eggs)
  - Deceptive labeling (as to content or health value)
- FDA regulates food additives and ingredients
Federal Non-enforcement Agency: CDC

• Activities
  – Publishes guidelines and best practices for food sanitation and food-borne illness prevention
  – Provides epidemiologic assistance to states during large or novel outbreaks
State Authority to Regulate Food Safety

• The Police Powers
  – Broad powers
  – Allow the state to license, inspect, and close businesses that do not meet the food sanitation codes

• Limitations
  – May not conflict with federal laws
  – May not be used as a barrier to interstate commerce by favoring local businesses over out-of-state businesses
State Agencies

- State and local health departments
  - Establish food safety standards through regulations
  - Conduct restaurant inspections
  - License local food processors
- State agriculture departments
  - Regulate grocery stores in some states
  - Regulate food production
Routine Inspections

- Cornerstone of food safety is routine inspection of businesses involved in producing, shipping, and serving of food
- Federal, state, and local agencies issue licenses and permits to regulated businesses that require:
  - Compliance with applicable regulations as a condition of operation
  - Allow warrantless, surprise inspections during regular business hours
- Businesses that do not comply can be closed
Surveillance for Food-borne Outbreaks

- State and local laws require reporting of potential food-borne illnesses
  - Starting point for investigations
  - Reporting sources: physicians, emergency rooms, laboratories
- Voluntary reporting
  - Persons not required to report an illness may make a voluntary report
  - Individuals may report their own illness
Issue:
Overlapping Authority and Jurisdiction

• Federal Jurisdiction and Authority
  – Federal government has not preempted state and local regulation in many areas of food safety
  – Federal government depends on state and local regulation in some areas of food safety (e.g., restaurant inspections)
• State governments cannot act across state lines
• Local governments cannot act outside their jurisdiction
Federal, State, and Local Cooperation

- Multi-jurisdictional outbreaks
  - Food-borne outbreaks can involve more than one locality or even several states
  - State and local officials will work together and with federal agencies to assure cooperation
- Overlapping authority
  - FDA may regulate food processing in a factory, and may generally inspect without a warrant or consent
Legal Actions to Protect the Public

- Emergency closure orders for suspected businesses
- Halting local and interstate shipments of the affected food
- Barring imports of suspect food
- Seizure of potentially contaminated inventory
- Recall of packaged food
- National consumer warnings
Special Regulatory Issues

- Exemptions from the permitting process
  - Some states exempt non-profit groups such as churches
  - Large family gatherings do not need permits
- Investigation of exempt businesses and individuals
  - No right of warrantless entry and search
Punishment and Compensation

- Administrative actions
  - Fines
  - Quality control requirements
- Lawsuits in tort
  - Private lawsuits for damages
  - Public health inspectors may be called to testify
  - Public health records and laboratory information may be used for evidence
- Criminal prosecution
  - Rarely used, usually for repeat offenders
  - Corporate executives may be held liable
Objective 7.3

Be familiar with the basis for a state’s authority to restrict the freedom of an individual to prevent the spread of some communicable diseases.
Communicable Disease Control: Example of Tuberculosis (TB)

- Why TB is a good model for exploring legal issues in communicable disease control:
  - A well-understood disease that still poses risks in the U.S.
  - A serious and potentially fatal disease spread by person-to-person contact
  - Control is through individual restrictions and treatment, rather than vaccination
    - Control sometimes requires use of isolation
  - Provides a useful model for some other non-vaccine preventable diseases, such as SARS
  - Most TB control law is state-level law with considerable variation in legal regimens by state
Legal Issues in TB Control

• Who can the health department screen?
  – Is screening voluntary?
  – What if someone refuses?

• Refusing treatment
  – Can a patient be detained to compel compliance?
  – Can a patient be physically compelled to accept medication?

• Isolation
  – What are the patient’s rights?
  – Can patients be isolated indefinitely if they remain contagious?
TB Testing and Screening Issues

- Routine TB Screening
  - Once conducted at population level
  - Now limited to persons at risk, such as:
    - Persons in contact with others sick with TB
    - Health care workers
    - Refugees and other immigrants

- What if someone refuses screening?
  - Potentially infectious workers can be excluded from employment
  - Persons can be required to submit to screening
  - Involuntary screening *generally* requires a court order
Active (Infectious) TB Cases

Mandatory public health testing does not violate freedom of religion - Washington v. Armstrong, 39 Wash. 2d 860, 239 P.2d 545 (Wa. 1952)

http://biotech.law.lsu.edu/cases/reporting/wa-armstrong.htm
Issues Related to Treatment

• What if a patient who is infectious, or is presumed infectious, refuses treatment?
  – While court orders for testing are routine, there is limited precedent for physically compelling treatment outside of selected special populations such as prison inmates
  – Most state laws allow for involuntary hold only after less restrictive measures are exhausted
  – Persons may be isolated until they are proven non-contagious
  – Some states require patients to be released when they are non-contagious, even if treatment is not complete
Issues Related to Compliance with Treatment

- It is recommended that all persons with active TB undergo directly observed therapy (DOT)
  - Whether DOT must be used depends on state law
  - Some laws require that all persons undergo DOT to ensure uniform enforcement
- For patients who refuse or do not cooperate with DOT:
  - Isolation may be imposed until they adhere
  - A court may be asked to order adherence
Louisiana Tuberculosis Control Law:
LA RS 40:4

(c) Control the spread of tuberculosis by:

(vii)(aa) Requiring the isolation and/or quarantine for directly observed therapy (medication taken in the presence of a health care provider) of any person with tuberculosis in a communicable state who has failed to comply with a daily self-administered course of chemotherapy for tuberculosis prescribed by a Louisiana licensed physician.

(bb) Requiring a more restrictive isolation and/or quarantine environment specified by the state health officer or by court order for any person who fails to comply with directly observed therapy under isolation and/or quarantine as provided in Subitem (aa) of this Item.
Hearing Requirements for Isolation Orders

• U.S. Constitution allows for “post-deprivation” hearing in emergencies
  – Many states have adopted pre-hearing requirements
  – Persons who are isolated or otherwise held by the state are generally entitled to a hearing after detention

• Right to appointed counsel
  – Some states provide appointed counsel
**Habeas Corpus**

- The U.S. Constitution gives every detained person the right to a *habeas corpus* hearing
- Habeas corpus requires:
  - The person to be brought before a judge
  - The government to show the legal authority for the detention
  - The government to show the factual basis for the detention
- If state's isolation law does not provide due process, *habeas corpus* may be available if the state's isolation law does not provide adequate due process
Is There A Right to the Least Restrictive Alternative for Isolation?

- "Least restrictive alternative" relates to government's use of the least restrictive means that will accomplish a legitimate government objective
- Possible examples:
  - Home isolation using electronic monitoring bracelets
  - Isolation in a private hospital with full services rather than a state hospital with limited facilities
- Constitutional requirements
  - Some state laws explicitly require least restrictive alternative
Paying for and Implementing Public Health Restrictions

- TB isolation and treatment is expensive
  - Covered by private health insurance?
  - What if the person is homeless?
  - Usually is an obligation of the jurisdiction that orders the restriction
- Costs may cause smaller health departments to be reluctant in ordering restrictions
- Isolation facilities are limited
  - Large outbreak could overwhelm facilities
  - Home isolation orders are difficult to enforce
Cooperation with Other Institutions

• Hospitals
  – OSHA requires hospitals to follow infection control practices, including patient isolation of persons with infectious TB
  – Hospitals have no legal authority to keep patients in their rooms
  – Health department must order and oversee enforcement of restrictions on hospital patients

• Jails and prisons
  – Jails and prisons can impose restrictions
  – Public health departments may assist in managing and investigating cases
  – Infectious prisoners can spread disease into community when released
Immigration-Related Issues

- TB is common worldwide
  - Refugee camps facilitate spread of TB
  - Immigrants may be infected
- Legal issues
  - Should new immigrants be screened?
  - How are cases investigated in the undocumented immigrant community?
  - What agencies should be involved?
Airline Travel: Multi-Jurisdictional Considerations

- A passenger with active TB poses risk to other passengers
- Airlines are regulated by Federal Aviation Administration
- Airport safety is regulated by the Transportation Safety Administration
- Both agencies may be involved in investigation of airline- and airport-associated transmission
- Notification and screening of exposed passengers may involve the airline, CDC, and state and local health departments
Interstate Disease Investigation and Management

- Persons with infectious TB who travel interstate may be subject to federal isolation
- State departments also can assist each other in tracking disease carriers who leave the state
- Law enforcement may be asked to help find individuals who have left treatment while still infectious
- CDC, through DHS, may prevent persons with infectious TB from boarding commercial flights via a "Do Not Board" order
Conclusion:
Unit 7
Summary: Unit 7

- Vaccination policy depends on a delicate balance between individual rights and the state's power to require vaccination to protect the public's health
- Food sanitation and outbreak investigation is one of the most legally complex public health activities, crossing local, state, and national boundaries
- States have broad powers to investigate communicable diseases and to restrict infected, potentially infected, and exposed individuals who do not cooperate with necessary public health measures
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