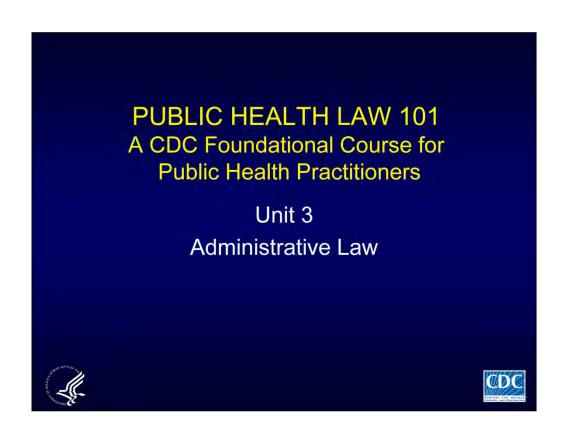


# PUBLIC HEALTH LAW 101 A CDC Foundational Course for Public Health Practitioners

- 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
- Unit 7: Infectious Diseases
- Unit 8: Environmental Public Health, Occupational Health, and Injury
- Unit 9: Chronic Diseases and Birth Defects





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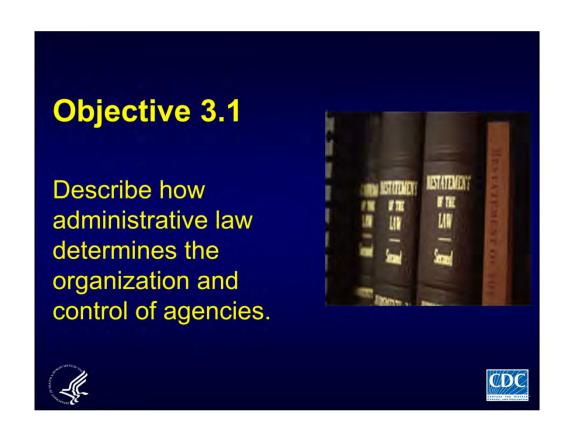
### **Unit 3 Objectives**

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

- 1. Describe how administrative law determines the organization and control of agencies.
- Discuss the administrative law process and tools for public health enforcement.
- 3. Understand the basis for challenges to administrative agency actions in public health and how the courts review such challenges.







## **Administrative Law**

- Administrative law governs:
  - Powers that legislatures can delegate to government agencies
  - Formation and organization of government agencies
  - Functioning and oversight of government agencies
  - Agencies' abilities to make law by way of rulemaking procedures
  - How courts review the actions of government agencies





Note - there is no single source of administrative law. It is drawn from statutes, regulations, and the constitution. Like many areas of jurisprudence, such as national security law, it is a functional definition.

## What is an Agency?

 Most parts of the government are agencies for the purpose of administrative law (exceptions: the legislature, courts, the executive officer [e.g., the President and governors]), and the military)





## Public Health as Early Administrative Law

- The colonial governments provided public health services that were taken over by the states after independence.
- Public Health Service hospitals and quarantine stations were established by the first U.S. Congress.
- City and state Boards of Health were among the first government agencies.





## Types of Agencies

- Agencies are divided into three types, based on their authority and organization:
  - Enforcement agencies
  - Independent enforcement agencies
  - Non-enforcement agencies
- Agencies in each category protect the public's health
- Some agencies have both enforcement and non-enforcement components





## **Enforcement Agencies**

- Can impose and enforce rules mandating or prohibiting certain behaviors
- Have powers to enforce laws through: civil actions, other administrative enforcement mechanisms (e.g., issuing, suspending, or revoking licenses or permits), and/or criminal penalties
- Examples:
  - Food and Drug Administration (FDA)
  - State health departments
- Federal enforcement agencies must be directly or indirectly controlled by the executive branch (President)
- State enforcement agencies are controlled by the governor or other elected officials





### **Independent Enforcement Agencies**

- Independent enforcement agencies are organized to limit the day-to-day control of the executive branch:
  - Overseen by commissioners who are appointed by the executive for fixed terms
  - Head can only be replaced for cause or when their term expires
- Examples:
  - Consumer Product Safety Commission
  - Some state and local health departments
- State commissioners may be appointed by the governor or other officials or the legislature

#### Note to instructor:

State separation of powers doctrines vary. Some resemble the federal government and see the governor as the primary executive, others see the governor and other elected officials as co-equal, and some allow the legislature more latitude in the control of enforcement agencies.

You might want to explain what cause is.

## Non-Enforcement Agencies

- Non-enforcement agencies may:
  - Do research and publish reports
  - Educate
  - Propose voluntary guidelines and standards
  - Disburse grant funds
- Examples:
  - Congressional Budget Office
  - Most units of the Centers for Disease Control and Prevention





## Public Education: Non-Enforcement Agencies

- Public education is a major vehicle for carrying out public health policy
  - Not legally binding
  - May be directed to public, professionals, or regulated parties
  - Can be provided by both enforcement and non-enforcement agencies
  - May be developed by agency or quasi-private groups
- Examples
  - CDC: "Parents' Guide to Childhood Immunization"
  - CDC: Recommendations of the Advisory Committee on Immunization Practices (note: because of their widespread dissemination to and adherence within the medical community, these recommendations may also establish the immunization standard of care)
  - Georgia Department of Resources: "The Georgia Epidemiology Report"





## Legislative Control in Establishing an Agency

- Federal agencies: established by acts of Congress
- Most state agencies: established by acts of the state legislature
  - Some states have agencies specified in the state constitution
  - Such agencies depend on the legislature for their specific powers
- Local agencies: may be established by the state legislature or local governing body

## The Enabling Act: Establishes an Agency

- The enabling act for an agency specifies the agency's:
  - Reason for being created
  - Powers
  - Organization
  - Funding sources
- The agency budget is established through appropriations bills
  - The legislature can establish agency priorities through the money it allocates for different agency functions





## Legislative Delegation of Broad Powers to the Agency

- General grants of power
  - Delegation of broad powers with limited specific direction
  - Allows agency flexible response to new problems
  - Allows executive branch to set direction of agency
  - Note: Implementation of general policies usually requires rule-making procedures
- Example
  - State health departments were established with broad grants of power





## Legislative Grants of Specified Powers to the Agency

- Specified grants of power
  - Delegation of specific and limited powers
  - Allows legislature to control the direction of agency to achieve specific goals
  - Limits changes in policy based on changing circumstances
- Example: National Childhood Vaccine Injury Act
  - Established National Vaccine Injury Compensation Program (VICP)
  - Gives HHS responsibility only to define which adverse events related to vaccine use are presumptively compensable





## Legislative Grants of Contingent Powers

- Contingent powers
  - Delegation of either broad or limited powers
  - Powers are available only when triggered by a specific event
- Powers may be trigged by:
  - Declaration by the President or governor
  - Fiscal event (e.g., budget shortfall)
  - External event (e.g., disease outbreak)





## **Executive Control of Agencies**

- Appointment of agency director
  - The executive's (e.g., President, governor, mayor) main control over an agency is through selection or replacement of the director
  - Independent agency commissioners can be replaced only at the end of their terms, limiting executive control
- Executive orders
  - Orders from the executive to change agency policy
  - Must be within legislated limits
  - Especially important in emergencies





#### Examples to discuss:

The federal response to the terrorist attacks on September 11, 2001 was directed by executive orders, such as the order to shutdown commercial and private aviation.

At the state level, the response to events such as hurricanes is shaped by executive orders from the governor and president.

## Separation of Powers in Local Government Agencies

- Most large municipalities have three branches of government
  - Agencies are part of the executive branch, headed by the mayor
- Smaller cities and counties may consolidate their government into two branches or even one branch
  - The separation of powers blurs





## Political Control of Agencies

- Agencies' directions and priorities may be key issues in elections
  - The voters can try to control agencies indirectly through the ballot box
- Interested parties contact legislators and the executive to change policy
- Examples of political control in public health practice
  - State and local tobacco use limitations
  - Seatbelt laws
  - Exceptions to mandatory childhood immunization laws

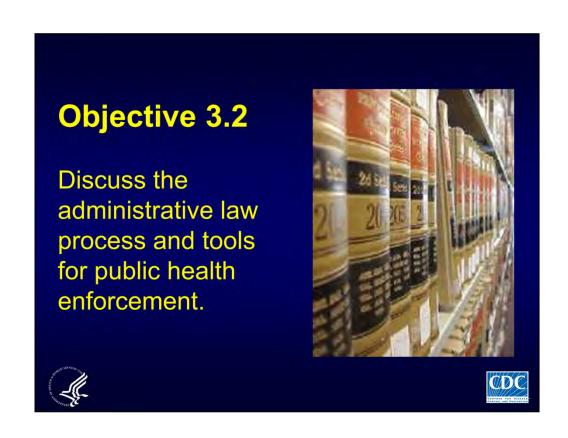


## Intergovernmental Control of Agencies

- Federal control of state and local government
  - When exercising Constitutionally-delegated powers, Congress can preempt state and local laws to assure uniform national policy
  - In public health, most federal control is exercised through funding (or defunding) certain projects
- Examples of federal preemption:
  - FDA regulations on medical devices
  - National Childhood Vaccine Injury Act
- States' approaches to local public health oversight may vary
  - Some state health departments control local departments, while in others, local departments are highly independent
  - In most states, the state health department can override local health departments' decisions and actions







## Administrative Law Process: Rules and Regulations

- The terms "rule" and "regulation" mean the same thing and are used interchangeably in administrative law
  - Legislature must delegate this power to the agency
  - Regulations are legally binding: they have the same effect as a statute passed by the legislature
- Examples
  - Occupational Safety & Health Administration: Bloodborne pathogens regulations (29 CFR 1910.1030)
  - Regulations promulgated under the New York City Smoke-Free Air Act





## Why Make Rules?

- Rules provide detail to implement broad grants of authority
  - Giving an agency rule-making authority allows the legislature to defer to the agency's expertise in the regulated area
  - Rules help the public understand the law
- Rules can incorporate voluntary standards, giving them the force of law – examples:
  - National building codes
  - Agency guidelines on food sanitation
  - General recommendations of the Advisory Committee on Immunization
- Courts defer to standards that are incorporated into rules

## Rules Governing Rulemaking

- Encompassed by administrative procedures acts
- Federal and state laws that specify how executive branch agencies make rules, adjudicate disputes, and handle petitions
- Example: law that specifies for requirements and the process for public participation in rulemaking





## Public Participation in Rulemaking

- Rulemaking generally requires public participation
  - Allows the public to directly affect policy
  - Proposed rules and any information they are based on must be published for public comment
  - Exception: promulgation of emergency rules
- Public comments
  - Agency receives written comments from all interested parties
  - Legislature also may allow oral comments through public hearings for certain rules
  - Agency reviews and considers the comments
  - Agency explains why it did or did not modify proposed rule as suggested by comments





## Administrative Law Tools: Permits and Licenses

- Permits and licenses: key tools in assuring compliance with public health standards
  - Applicants must meet regulatory standards before being issued permit or license
  - Applicants must agree to cooperate in quality assurance through inspections and/or re-certification
- Must be issued fairly
  - Requirements must be clear
  - All qualifying applicants must be treated equally
- Examples:
  - Restaurant license
  - Dog license
  - Permit to ship seafood interstate





## **Public Health Inspections**

- Inspections are examinations of residences and businesses
  - Random inspections are used to assure that permit and license holders are complying with regulatory standards
  - Inspections may be made in response to citizen complaints
  - Inspections may be done on periodic basis to assess health risks
- Examples:
  - Restaurant sanitation inspections
  - Rodent inspections in warehouses
  - Investigations of complaints about dangerous dogs





## **Administrative Searches**

- Inspections are a type of administrative search
  - Administrative searches are conducted to find and eliminate threats to the public
  - Administrative searches are not used to find evidence of criminal behavior to be used for prosecuting crimes
- Other examples of administrative searches
  - Surveillance of pharmacy records for antiviral prescriptions
  - Pet store inspections to identify animals with potential infectious conditions





### Warrant Requirements for Administrative Searches

- Persons operating pervasively regulated businesses generally are subject to warrantless inspections
  - In other situations, warrants are not required if the resident or business owner consents to entry, or if exigent circumstances exist
- Administrative warrants do not require probable cause
  - Administrative warrants must only show a reasonable plan for inspections
  - Administrative warrants are required to prevent unauthorized access or harassment
- Administrative warrants may not be used for criminal investigations





### **Administrative Orders**

- If a violation is found:
  - First step in enforcement is to issue an inspection report explaining the violation and how to correct it
    - This puts party on notice of the violation
  - Parties comply with the order
- If the target of the order does not comply, then the department must seek a court order to enforce compliance
  - Most agencies cannot make arrests or use force
- Violation of a court order allows the court to use its compulsion powers, which include fines, injunctions, and imprisonment for contempt



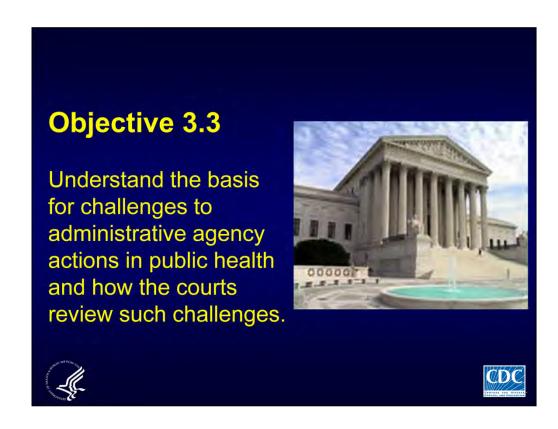


### **Court Orders**

- Injunctions
  - Orders to prevent an activity (e.g., operating a hazardous waste facility)
  - Temporary injunctions can be issued in emergencies when time does not allow for a full hearing
  - Permanent injunctions require notice to affected party and an opportunity to be heard in court
- Personal restriction orders to prevent danger to others
  - May require treatment (e.g., participating in directly observed TB treatment)
  - May limit activities (e.g., preventing a typhoid carrier from working in food service)







## **Contesting Agency Actions**

- Most administrative agencies provide an internal review process for parties wanting to contest an agency action
- If the party contesting the action is not satisfied with the appeal, then party may go to court
- In some circumstances, a party may challenge an allegedly illegal agency action by going directly to court



### Procedural Requirements for a Court Challenge: Exhaustion of Remedies

- Many agencies provide an internal appeals or review process for agency decisions
  - This process usually is addressed in a state's administrative procedure act
  - Courts require that persons who want to challenge agency actions in court first must exhaust all steps required by the agency
- The court does not require exhaustion of the agency process if the agency is acting unconstitutionally or otherwise unlawfully





#### Constitutional Requirements for Public Health Actions

- Does the public health action provide adequate procedural due process?
  - When is a hearing necessary?
  - Was the hearing fair?
- Does the action violate equal protection?
  - Does the action treat people differently because of race, ethnicity, sex, or other characteristics that may not be related to public health needs?
- Does the action deprive a person of his/her property (i.e., a "taking") without proper compensation?





### Must a Party Obtain a Hearing Before the Agency Acts?

- North American Cold Storage v. Chicago, 211 U.S. 306 (1908)
  - The freezer failed, spoiling 47 barrels of chicken
  - The chicken was seized and destroyed without a hearing
- Is there a Constitutional right to a hearing before the health department acts?
  - The court ruled that the health department could act without a hearing
  - The business was entitled to a hearing afterward to contest the action and ask for damages if the action was unwarranted



### When Must the Agency Compensate the Owner for Seized or Destroyed Property?

- Must the state pay for the chicken?
  - The state must pay for property seized for state or public use, but not for property that is a threat to the public (because the property has no value)
- What if the regulation reduces the value of property posing a threat to public health?
  - The state does not have to pay for the costs of regulation
- Some states are trying to change their laws to require payment for regulatory costs





#### Note to Instructor

What if the health department seizes and destroys a valuable pet dog that is in violation of the leash law? This would not be a taking, and the dog is not entitled to due process. The owner could contest the destruction of the dog in court, and could be compensated if the department acted illegally in seizing and destroying the dog.

Discuss the effect on public health practice if the state had to pay for all costs related regulations, such requiring standing water to be drained to prevent the growth of mosquitoes.

### Constitutional Due Process for Seizing or Restricting Individuals

- The Constitution generally does not require a hearing before restricting an individual who is a threat to the public's health
- The Constitution guarantees a habeas corpus hearing to anyone being held by the state
- A habeas corpus hearing requires the state to:
  - Bring the person before a judge
  - Show the legal authority for the restriction
  - Show the factual basis for the restriction
  - Explain why the restriction is necessary
- If the state cannot make these showings, it must release the person





### Legislative Restrictions on Public Health Authority

- Congress and state legislatures can impose stricter limits on public health authority than are mandated by the U.S. Constitution
- Some states have placed limits on traditional public health powers, including:
  - Requiring hearings before public actions
  - Requiring that the agency provide a lawyer to regulated persons
  - Increasing due process requirements when emergency powers laws are in effect
- The courts will require the agency to follow these restrictions, even if they are not Constitutionally mandated

## If the Action is Constitutional, Is it Otherwise Lawful?

- Does the agency's activity violate:
  - The state constitution?
  - Federal or state laws, including court decisions?
  - The agency's own rules?





### Courts Defer to Agency Policy Decisions

"It is not the function of a court to determine whether the public policy that finds expression in legislation of this order is well or ill conceived. The judicial function is exhausted with the discovery that the relation between means and end is not wholly vain and fanciful, an illusory pretense. Within the field where men of reason may reasonably differ, the legislature must have its way." (*Williams v. Mayor of Baltimore*, 289 U.S. 36, 42 (1933))





### Why Do Courts Defer to Agencies?

- Expertise
  - Legislatures do not have the expertise to draft detailed directions for the health department
  - Broad authority lets the agency use its own expertise
- Flexibility
  - Health departments must deal with new conditions and emergencies that were not anticipated by the legislature
- Speed
  - If courts required specific laws for all actions, the legislature would have to pass a new law for every new problem





### Judicial Deference and Emergencies

- State and local health departments historically have broad emergency powers
  - Courts recognize that public health powers must be construed broadly in an emergency
  - Unless limited by the legislature, emergency actions do not require special laws
- Limits on Emergency Actions
  - Emergency actions must be grounded in good public health practice
  - Large-scale restrictions (e.g., evacuations or quarantine) depend on public cooperation





### The Legislature Sets Standards for Judicial Review

- Legislatures set standards courts use for judicial review
- If the legislature does not set a standard, then courts defer to agencies by application of deference standards established by courts
- In some instances (e.g., the Smallpox Compensation Fund), the legislature does not allow judicial review of the agency decision





Standards for Judicial Review

De Novo Review

The court ignores the agency decision

Review on the Record

The court uses the record of the agency proceeding but makes an independent review Deference to the Agency

The court upholds the agency decision unless it is arbitrary and capricious

This is the usual standard for review

#### No Review

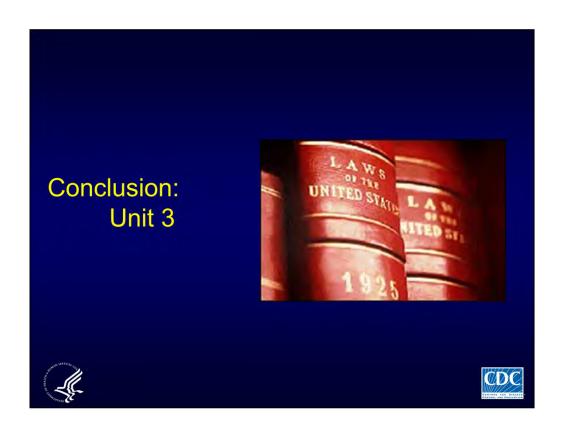
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## Can the Court Change the Agency Decision?

- If the court finds the agency action is illegal, it can order the agency to comply with the law:
  - By not acting
  - By acting when the law does require action
- Courts may reverse an agency decision for lack of sufficient supporting evidence
- Federal courts can only order the agency to reconsider its action, they cannot replace the agency's action with their own ruling
- Some state courts can substitute their rulings for the agency's ruling







#### Summary

- The people set public health policy through their elected officials: as administrative law agencies, health departments are delegated their responsibilities and powers by elected legislative bodies.
- Public health agencies' broad powers to protect the public's health incorporate open processes to make rules, and include a spectrum of lawbased tools and other interventions.
- The courts require public health agencies to abide by the constitution and legislation, but do not interfere with otherwise legal public health policy.





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