# PUBLIC HEALTH LAW

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#### **Chapter Overview**

This chapter will provide a survey of how pubic health law, rules and regulations function under agencies and administrative procedures. Understanding both federal and state administrative law gives insight into how the United States public health system functions.

## **Objectives**

On completion of this chapter, the reader should be able to:

- 1. Explain how public health is governed by government agencies.
- 2. Explain the concept of administrative law.
- 3. Understand how agencies carry out public health policy.
- 4. Understand the difference between health law and public health law.

## Health Law vs. Public Health Law

Defining health law and public health law depends on whom you ask. Health law is concerned with the legal aspects of promoting the quality, organized delivery, cost effective, access to health care, while protecting the human rights of those who are provided care within the health care system. "Public health law is the study of the legal powers and duties of the state to assure the conditions of people to be healthy (e.g., to identify, prevent, and ameliorate risks to health in the population) 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."<sup>1</sup> James Tobey said, that "[Public health law] should not be confused with medical jurisprudence, which is concerned only in the legal aspects of the application of medical and surgical knowledge to individuals. . . . [P]ublic health is not a branch of medicine, but a science in itself, to which, however, preventive medicine is an important contributor. Public health law is that branch of jurisprudence, which treats of the application of common and statutory law to the principles of hygiene and sanitation science."<sup>2</sup> Perhaps Lawrence Gostin said it best, "Public health law is the study of the legal powers and duties of the state, in collaboration with its partners (e.g., health care, business, the community, the media, and academe), to ensure the conditions for the people to be healthy (to identify, prevent, and ameliorate risks to health in the population), and of the limitations on the power of the state to constrain for the common good the autonomy, privacy, liberty, propriety, and other legally protected interests of individuals. The prime objective of public health law is to pursue the highest possible level of physical and mental health in the population, consistent with the values of social justice."<sup>3</sup> Social justice and the common good refer to the ethical and moral issues of health care.

## Public Health Law Historical Context

The first public health laws in the United States were enacted in the colonies where communicable diseases such as malaria, cholera, yellow fever, and smallpox were widespread.<sup>4</sup> These laws were for the abatement of nuisances, quarantine for communicable diseases, and regulation of the sale of food and drink. The colonial governments provided public health services that were taken over by the states after independence. The first US Congress established public health service hospitals and quarantine stations. City and state Boards of Health were among the first government agencies.

The constitutions of the federal and state governments established the structure of government. Through these documents, a separation of powers was established. While state governments all follow the three-branch model, their organizations differ significantly. Before an agency, such as the department of health, can be established, an agency enabling statute<sup>5</sup> must be enacted. This statute establishes the agency's powers and duties, organization, funding, and standards of review of the agency's actions. Some state agencies are established by the state constitution or later constitutional amendments.

## **Constitutional Basis for Public Health Law**

"Public health has historically constrained the rights of individuals and businesses so as to protect community interests in health."<sup>6</sup> The Articles of Confederation left all of the powers to the states. The Constitution divided powers between federal and state governments but the police powers were reserved to the states. The federal government is a government of limited power whose acts must be authorized by the Constitution to be valid. The states, in contrast, retain the power they possessed as sovereign governments before the Constitution was ratified.<sup>7</sup> The US Constitution gives the federal government direct powers to regulate interstate commerce, foreign trade, war, civil rights (by way of the 13<sup>th</sup>, 14<sup>th</sup>, and 15<sup>th</sup> amendments), and tax income. The Necessary and Proper Clause found in Article I, §8, Clause 18 of the Constitution permits Congress to employ all means reasonably appropriate to achieve the objectives of the enumerated national powers. This "implied powers" doctrine has enabled the federal government to expand greatly the network of public health regulation.

The tenth amendment enunciates the plenary power retained by 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." This "reserved powers" doctrine holds that the states may exercise all the powers inherent in government. Two specific inherent state powers are the police power (protecting the health, safety, morals, or general welfare of the community) and the *parens patriae* power (protecting the interests of minors and incompetent persons). The US Supreme Court has ruled that there is no federal police power. Therefore, public health is a state and local function. The Centers for Disease Control, a federal agency, only gets involved at the state's invitation. The state police power is very broad. State constitutions are used to limit that power. However, the Congress may preempt, or supersede, a state in its regulation of public health, by way of the Supremacy Clause found in Article VI of the Constitution.

The authority for the federal regulation of public health is rooted in its ability to tax and spend (Art. 1, §8, Clause 1) and to regulate interstate commerce (Art. 1, §8, Clause 3<sup>8</sup>). Most federal regulation of public health is by way of the "commerce clause." Congress also has the authority "to promote the Progress of Science and useful Arts."<sup>9</sup> Intellectual property protection (Art. 1, §8, Clause 8) provides incentives for scientific innovation, such as vaccines, pharmaceuticals, and medical devices. The presidential ability "to make treaties" (Art. 2, §2, Clause 2) with the advice and consent of the Senate has public health significance in areas of tobacco, infectious disease, and global warming.

"Public health powers can legitimately be used to restrict human freedoms and rights to achieve a collective good, but they must be exercised consistently with constitutional and statutorily constraints on state action. Individual rights to autonomy, privacy, liberty, property, and other legally protected interests limit the inherent prerogative of the state to protect the public's health, safety, morals, and general welfare. The right of privacy is generally adhered to by a liberal view of the word liberty in the preamble to the Constitution. Achieving a just balance between constitutionally protected rights and the powers and duties of the state to defend in advance, the public's health poses an enduring problem for public health law. Any theory of public health law presents a paradox. Government, on the one hand, is compelled by its role as the elected representative of the community to act affirmatively to promote the health of the people. On the other hand, government cannot unduly assault individuals' rights in the name of the communal good."<sup>10</sup>

*Jacobson v. Massachusetts* (1905)<sup>11</sup> is believed to be the most important judicial decision in public health. It is within this case that the state police power is recognized. The court held that an individual may be required to receive a vaccination against disease, even if his religion prohibits such procedures. An individual raising the Free Exercise<sup>12</sup> claim has generally lost when the health or welfare of others was at issue, but has usually won where only his own health or well-being would be jeopardized by an exemption. *Jacobson* gave rise to the Social Compact Theory of public health deference. This means 1) a state can regulate individuals and businesses to protect health and safety;<sup>13</sup> 2) liberty interests can be limited by the sate;<sup>14</sup> 3) questions of policy and science are for the legislature, not the courts;<sup>15</sup> and 4) the State can delegate police powers to agencies.<sup>16</sup> However, *Jacobson* established a floor<sup>17</sup> where public health powers were constitutionally permitted only if they were a pubic health necessity, the law or regulation used in response to the public health threat was fair, reasonable, proportional, and did not pose a harm to the subject to which the law or regulation was intended.

The Fifth and Fourteenth Amendments prohibit government from depriving individuals of "life, liberty, or property without due process of law." Due process is made up of procedural due process and substantive due process. Procedural due process requires notice and a fair hearing before an impartial decision

maker. Substantive due process requires that government have an adequate reason for its interventions. Adequate justification would be the state's police power, that is, the health, safety, morals, or general welfare of the community. The courts will use balancing tests to determine constitutionality. The government's purpose or reason for the intervention may be justified along several levels of need. The need follows along a sliding scale that may be constitutional, important, super important, or a compelling governmental interest. The means used by government to achieve that purpose should be the least restrictive means necessary. The means used is balanced against the purpose by determining if it is rational, reasonable, reasonably related, narrowly tailored, a real and substantial relation, or necessary. The level of judicial scrutiny applied to each level of governmental action will range from minor scrutiny for a compelling purpose/rational means test to the upper end of strict scrutiny for a compelling purpose/necessary means test.

## Public Health Law as Administrative Law

Administrative law governs the organization and functioning of government agencies, and how the courts review their actions. Public health law, and most health law, is carried out by government agencies. The principle federal agency is the Department of Health and Human Services (HHS). Within HHS are several other sub-agencies such as the Center for Disease Control (CDC), the National Disaster Medical System, the National Institutes of Health, the United States Public Health Service and the Food and Drug Administration. In catastrophic times, the Department of Defense may be called upon to assist with protecting the public's health. Each state has its own version of administrative law governing its own state agencies. The set of laws known as the Administrative Procedures Act (APA) in the federal and each state government specifies how agencies in that jurisdiction carry out their basic functions such as rulemaking, adjudications, and how citizens can petition the agencies.

The APA only applies if the legislature has made special rules for a given agency. The agency must follow the appropriate federal or state procedures as stated in the APA and agency-enabling acts when issuing rules. In *Vermont Yankee Nuclear Power Corp. v. NRDC* (1978), the Supreme Court ruled that the federal Administrative Procedures Act "establishes the maximum procedural requirements that Congress was willing to have the courts impose upon federal agencies in conducting rulemaking procedures."<sup>18</sup> The APA has two parts: a quasi-legislative part used to add to the law and a quasi-judicial part used to sanction. The focus of the APA is to require the agency to articulate their policies as rules.

The U.S. Constitution does not mention agencies. That is because the founders did not anticipate that there would be much federal government. Congress and the courts, within the constraints of the Constitution, have shaped administrative law doctrines. Through the late 1800s, the states did almost all the regulation. By the late 1800s, the US Supreme Court limited some state

actions by use of the interstate commerce clause, due process and equal protection.

Agencies are limited by legislation, the state, and the constitution. They are established, by legislation, under the executive branch and given a budget. They have the characteristics of the three branches of government. They may exercise legislative power to issue rules and regulations; executive power to investigate violations and sanction offenders, and judicial power to interpret legal norms and adjudicate disputes. Each power has its own duty to act in the public interest. Enforcement must be reasonable and without discrimination; rulemaking must be done fairly and publicly; and adjudication must provide procedural due process. The courts can review agency action because of our system of checks and balances.

The legal justifications for agencies are their expertise, efficiency, and flexibility. Agencies are meant to have expert staffs that manage complex problems. They have more efficient enforcement powers because they are not limited by criminal law protections. They can act without new legislation and can tap new expertise as needed. Agency heads are political appointees. Federal agency heads must undergo confirmation battles. Even so, talented people may still be placed at the top but it is very difficult to get real experts because of improper political pressure. There are even more problems recruiting at midlevel positions. In the states, salaries limit expertise in many positions.

Federal agencies fall under the President. Independent agencies<sup>19</sup> have appointed commissions. The states can have agencies falling under various independent heads in the executive branch. These may include the governor, insurance commissioner, attorney general, secretary of state, and others. The state may even have agencies under local government such as the County Health Department or County Hospital Board.

The legislature can give an agency broad power with little specific direction. This gives the agency flexibility. On the other hand, the legislature can give the agency very specific direction, power, and duties. This limits flexibility but assures that the legislative policy is followed. The legislature can also give the agency contingent grants of power triggered by specific events such as by a disaster declaration.

In the federal government, all enforcement agencies are in the Executive branch. Congress can only control agencies that do studies and investigations, such as the Congressional Budget Office. States have several elected executives that control agencies, not a single head like a president. The governor controls most agencies and the attorney general controls the legal office. Other state offices, like state auditor, also have elected heads. Boards or commissions run independent agencies. Members have fixed, staggered terms and can only be removed for bad conduct. The President appoints members to commissions and boards in the federal government. The Securities and Exchange Commission is an example. In the states, the governor or other elected officials appoint members. The boards may be statewide or local. Boards of Health are appointed to hire and supervise the health director to reduce political pressure on the agency. Agencies act as a vehicle for carrying out public policy. Their duties include enforcement policy and fiscal policy. The agency decides if a business will get a second chance or be closed or when to use quarantine and isolation. The agency will decide which diseases get investigated when there is limited staff and what programs to cut when there are budget cuts. Agency policy can by changed by the executive, legislature, or citizens. The executive can replace the agency director or use Executive Orders to direct agency policy. The legislature can change the enabling law or change funding for agency functions. In certain instances, the federal government can preempt state and local governments. Congress can preempt state laws to assure a uniform policy. Although Congress cannot pass a law to force a state to do something, Congress can make state funding, such as for roads, contingent on adopting certain policies. States have different models of local control. The legislature determines the allocation of powers. Some state health departments control the local departments, and some local departments are independent.

## Rulemaking

The main function of agencies is rulemaking. They make rules to particularize statutes and give the pubic guidance. An agency may not have a non-rule policy. Without rules, the public does not know what is required. The public is allowed to participate in the rulemaking process. The legislature can delegate the power to make rules to the agency however, not all agencies have rulemaking authority. Rules cannot exceed the authority in the agency's enabling legislation or the constitution. Properly promulgated rules have the same effect as statutes. To make rules, there must be public notice and the public must be allowed to comment. In this way, national standards can be adopted through agency rules, harmonizing practice across jurisdictions. These include national building codes, CDC guidelines on food sanitation, and recommendations of the Advisory Committee on Immunization Practices. Rules give the public and regulated parties guidance. They limit the issues that can be reviewed by the courts.

Rulemaking is presumed feasible.<sup>20</sup> A rule is an agency's statement of general applicability. They must be general and not specific to any one party. They generally grant rights or require compliance and have the force and effect of a law. Proposed rules must be published for public comment. The agency must take written comments and must review and consider the comments. To amend or repeal a rule requires the same process as that of rulemaking. Anyone substantially affected by a rule has the right (standing) and ability to challenge a rule. If an agency acts improperly in making a rule or goes too far it is known as an "invalid exercise of delegated legislative authority." On the other hand, if the legislature improperly delegates authority to the agency to make laws then it is known as an "invalid delegation of authority." Courts defer to agency decision-making on areas of agency expertise in fact finding and rulemaking.<sup>21</sup> However, agency rules may not be "vague, arbitrary or capricious." Rules must involve only one subject, be written in readable language and require the least costly alternative that accomplishes the statutory objective. They are often

accompanied with a statement of estimated costs. The courts do not defer to agency interpretations of law.

#### Enforcement

Another function of agencies is the enforcement of agency rules. Agencies have the power to directly regulate individuals, professionals, and businesses. Authorities set clear, enforceable rules to protect the health and safety of workers, consumers, and the population at large. However, agencies cannot act beyond the Constitution or their enabling legislation. A grant of rulemaking is necessary and a specific law must be implemented for an agency to function.

Only the legislature can make laws and that function cannot be delegated to an agency. The agency can implement or interpret the law but it cannot make laws. The legislature enacts the general policy and gives the agency the right to make rules. Once the legislature authorizes rules then the rule must follow the statute. Regulation of individual behavior reduces injuries and deaths (e.g., use of seat belts and motorcycle helmets).<sup>22</sup> Licenses and permits enable the government to monitor and control the standards and practices of professionals and institutions (e.g., doctors, hospitals, and nursing homes). Inspections and regulation of businesses helps to ensure humane conditions at work, reduce toxic emissions, and improve consumer product safety.

Agencies govern who gets licenses and permits. An applicant must show that they have met the standards set by law or regulation before obtaining a license or permit. The standards must be clear and must treat all applicants equally. The license or permit is conditioned on the applicant accepting the enforcement standards. The applicant must agree to be bound by the administrative rules, allow inspections during business hours, or face revocation without a court order.

What an agency does before it states an action against an individual is called free form. Free form is the investigation prior to the first letter.<sup>23</sup> The inspector or investigator determines the facts through an inspection or investigation. The defendant may present his/her case explaining the problem during the inspection. The inspector must provide a written record. Local governments often allow appeals to the city council. The courts will defer to the inspector's findings if the case is appealed to the courts.

License and permit holders may be inspected without a warrant but other inspections may require an administrative warrant. Requirements for administrative warrants, unlike criminal warrants, do not require probable cause. They require a list of the addresses to be searched and the reasons for the search. Administrative searches cannot be used when a criminal warrant is necessary. The first step in enforcement is to issue an order by the agency explaining the violation and how to correct it. Most persons comply with the order but if the person does not comply, the order proves that the person was on notice of the problem. In some cases, there may also be a fine for not complying with the order. If the target of the order does not comply, then the department must seek a judicial order to force compliance. Most agencies cannot make arrests or use force. Violating a court order allows the courts to use their powers, which include fines and imprisonment for contempt.

Court orders may also include injunctions and personal restriction orders. Injunctions are orders to prevent an action, such as operating a restaurant. Temporary injunctions can be issued in emergencies when there is not enough time for notice and a full hearing. Permanent injunctions require notice to the effected party and an opportunity for that party to be heard in court. Personal restriction orders require an individual to refrain from dangerous behavior, require treatment (such as participation in a directly observed tuberculosis treatment), or limit activities (such as preventing a typhoid carrier from working in food service).

Some agencies assume an advisory and consultative role. They do not have enforcement powers. Instead they do research and education. They shape policy by funding other agencies or private projects. The Centers for Disease Control is a non-enforcement agency. Its role is providing guidance to state and local health departments. Most guidance is voluntary, but it can be tied to the receipt of grant funds. State and local health departments with enforcement powers also have an important research and educational role. These include epidemiology, health education, and technical assistance to businesses such as restaurants.

State and local health departments historically have had broad emergency powers. The courts recognize that public health powers must be construed broadly in an emergency. Unless limited by the legislature, they may act without special laws. However, there are limits on emergency actions. Courts have made it clear that an agency's power is greatest when dealing with imminent danger to the public health and safety. The more the ability for a threat to harm a greater number of people, the greater is the agency's power to prevent harm. The courts tend to find reasons to support emergency public health actions rather than preventing action unless law specifically authorizes it. Knowing what to do is more important than the law. Emergency actions must be grounded in good public health practice. Having elaborate emergency laws in place will not substitute for good public health planning and adequate resources to carry out the plans.<sup>24</sup> Large-scale restrictions, such as evacuations or quarantine, depend on public cooperation.

## Adjudication

When an individual or business violates a rule, they are subject to enforcement sanctions. Everyone charged with a violation is entitled to due process. An agency makes decisions by adjudication. Adjudications differ from rules in that rules apply to everyone in the affected class. Adjudications decide questions in individual cases and only bind those parties.<sup>25</sup> Most state legislatures are more suspicious of agencies than is the US Supreme Court. States tend to give greater rights of judicial review. The states often require more agency (administrative) due process given the limited expertise of many state agencies. The standards differ for criminal law due process, administrative due process for restrictions of persons, and the due process for economic rights and government

benefits. Due process for economic rights is the most common issue in public health and in administrative law in general.<sup>26</sup>

Administrative due process requires notice (certified mail), a point of entry, a hearing, and judicial review. Parties to adjudication are entitled to be heard. Adjudications may include oral hearings or may be done through written documents only. An administrative law judge acts as the fact finder in the administrative law system.

Administrative law judges usually act as inquisitorial judges and try to assure that the case is fairly presented and decided. They act as the finder of fact and do not make final decisions but instead make recommended rulings to the agency. These judges act as referees and decide whether the lawyers are proceeding by the rules of procedure and evidence. If the attorney makes a mistake, such as neglecting important issues, the judge does not intervene. It is the attorney's job to present his/her case. The role of the judge is to make sure that the case is presented properly and that the result is just. The judge may ask guestions and review the evidence and can help an attorney to protect the client. Administrative law judges differ from civil and criminal court judges in the way they decide a case. Administrative law judges may use their own knowledge of the subject. Civil and criminal court judges can be disgualified if they know about the subject. The ethical responsibility in conflict of interest situations is different between the two types of judges. An administrative law judge often knows the parties and may have worked on the case. Civil and criminal court judges cannot know the case or the parties. As stated above, administrative law judges act as the fact finders of a case as opposed to a jury. They often follow Attorney General Opinions whereas, civil and criminal law judges decide legal questions on their own. The administrative law judge makes recommendations to the agency and it may be changed by the agency. Adjudication is not binding in other cases whereas; civil and criminal court cases are binding on lower courts. Only after one has exhausted all administrative remedies may one appeal to the courts. Where a statue gives an agency primary jurisdiction to consider or do something, the courts cannot take that away. The agency has the first right to decide.

# Public Health and Privacy

The core of public health activities is in five areas, they are: 1) disease reporting, 2) disease investigation, 3) mandatory treatment and restrictions, 4) environmental health and 5) vital statistics. In disease reporting there is no right of privacy or right to refuse reporting. An agency can inspect medical records, investigate child abuse, and investigate violent injury. Disease reporting can also be extended to medical procedures, occupational illnesses, the use of scheduled drugs, and other areas of public health concern. Disease investigation can involve contact tracing, partner identification, and investigations of business and food establishment. Public health data can be reported to the police, but it cannot be the basis of individual prosecution. Mandatory treatment and restrictions include vaccination law. There are no religious exceptions to

vaccinations and there are no free riders<sup>27</sup> (*Jacobson*). Public health laws concerning venereal disease, sexually transmitted disease, tuberculosis and others can require testing or treatment or hold someone in jail for refusing. There is a Habeas Corpus<sup>28</sup> remedy. However, many states have weakened these laws due to political pressure over AIDS. Environmental health involves food sanitation, drinking-water treatment, and wastewater disposal. Most public health orders are directed at environmental health problems. There are two central legal questions involving environmental health: when does the government owe compensation to the owners of regulated property and when can inspectors enter private premises to look for public health law violations? Vital statistics include birth and death records along with disease registries.

The actions taken by any agency are subject to judicial review to determine legality. Courts will review if the agency's activity violates the US constitution or a treaty, the state's constitution or the agencies enabling act, or if other laws prohibit the activity or even if the agency is following its own rules. The legislature sets the standards for judicial review of the facts. They are de novo,<sup>29</sup> review on the record, deference to the agency, or no review.<sup>30</sup> In de novo, the court ignores the agency's decision and starts anew. The court uses the record of the agency proceeding but makes an independent review. If a review is granted the most common method for judicial review, deference to the agency, upholds the agency decision unless it is arbitrary and capricious. Generally, no review is the usual standard for review. In some cases, such as the smallpox compensation fund, the legislature does not allow judicial review of the agency decision.

If the law is not clear, traditional public health laws give the agency board powers without detailed statutory guidance. Courts use a standard from an environmental law case, *Chevron v. NRDC*, to decide if the statute clearly prohibits the agency action. The first step is to determine if the law clearly prohibits the agency action. If the law would allow the action, then the second step is to decide if the agency action is reasonable in light of the objectives of the law. If the action is reasonable under the statute, then it is allowed. Courts defer to agencies because of efficiency, flexibility, and speed. Legislatures do not have the expertise to draft detailed directives for the health department. It is more efficient to give broad authority to the agency to use its own expertise. It is more flexible to let health departments deal with new conditions and emergencies that were not anticipated by the legislature. If the courts require specific laws for all actions, it would take months to years to get laws passed for new problems. Agencies act faster.

If a court finds an agency action illegal, it can prevent the agency from acting. A federal court cannot change an agency ruling, only block it by sending the case back (remand it) to the agency for reconsideration. Some state courts can change the agency ruling and substitute their new ruling. Before challenging agency actions, courts require that a person exhaust all internal appeals or review processes for agency decisions. The courts do not require exhaustion of the agency process if the agency is acting illegally. If the litigant goes directly to court and the court decides the action was legal, it will be too late to finish the agency process.

The Freedom of Information Act provides public access to information held by agencies. However, they have exceptions to protect trade secrets and information that will affect agency function or public safety. State and federal privacy laws to protect personal information have modified the Act. Government in the sunshine laws<sup>31</sup> provide for public attendance at agency governing body meetings, require public notice of meetings, and allow for closed meetings on personnel matters and other topics such as bids that require secrecy.

## Legal Liability for Public Health Professionals

Attorneys general, public health authorities, and private citizens possess a powerful means of indirect regulation through the tort system. Civil litigation can redress many different kinds of public health harms: environmental damage (e.g., air pollution or groundwater contamination), exposure to toxic substance (e.g., pesticides, radiation, or chemicals), hazardous products (e.g., firearms and tobacco), and defective consumer products (e.g., children's toys, recreational equipment, or household goods).

While tort law can be an effective method of advancing the public's health, like any regulation, it is not an unmitigated good. The system imposes economic and personal burdens on individuals and businesses. Litigation, for example, increases the cost of doing business, thus driving up the price of consumer products. Tort actions can deter not only socially harmful activities (e.g., unsafe automobile design) but also socially beneficial ones (e.g., innovation in vaccine development). Federal and state legislators have sharply limited tort liability in such controversial areas as consumer protection class actions,<sup>32</sup> medical malpractice lawsuits,<sup>33</sup> firearms and obesity litigation.<sup>34</sup>

#### Major Laws and Regulations of Public Health Importance

#### Surveillance

A mandatory reporting system for the healthcare industry exists in the states for various conditions and diseases. Healthcare practitioners, medical laboratories, and medical facilities are mandated to report to the local county health department diseases and conditions of public health significance. Enteric disease is a classification requiring a report. One enteric disease example, all too frequently encountered in daycare centers, is shigellosis, a type of dysentery caused by the shigella bacteria and spread by contact with human feces. Some other examples of reportable conditions include mercury and lead poisoning. The timeframe for reporting occurrences of a specified disease or condition varies from immediate to one business day. Clustering of symptoms or an outbreak of symptoms in humans caused by an unknown agent requires an immediate report. Symptoms potentially related to terrorism are required to be immediately reported to the local county health department by the discovering healthcare practitioner, laboratory, or healthcare facility.<sup>35</sup>

#### Nuisance Injurious To Health

Sanitary nuisance is broadly defined and includes any act or thing that threatens or impairs human health including disease-causing agents. Any item, which threatens the health or life of an individual or by which disease may be caused, is a sanitary nuisance and a condition injurious to health. The terms sanitary nuisance and nuisance injurious to health are interchangeable. These include improperly treated human waste, improperly built or maintained septic tanks, keeping diseased animals dangerous to human health, unclean slaughter houses, maintaining a situation capable of breeding flies, mosquitoes, or other insects capable of transmitting disease to humans. Statutorily specified per se<sup>36</sup> violations do not usually require expert testimony to establish a prima facie<sup>37</sup> case. Allegation of a per se violation also facilitates ex-pate<sup>38</sup> application for and issuance of orders to show cause. The health department on its own may investigate any situation where a nuisance injurious to health is suspect. Upon request of any proper authority or any responsible citizens, the health department is obligated to investigate a sanitary nuisance. If a sanitary nuisance is found, the health department will serve notice to abate upon the responsible parties, specifying the item or practice to be corrected and when this must be accomplished. Notice and opportunity to correct are the clear distinctions between the legal process of guarantine (see infra) and nuisance injurious to health.

#### Quarantine

Though the phrase "public health" does not appear anywhere within the US Constitution, public health authority is exercised under the state police power. There is no federal police power. The case most often cited as defining the authority of state government to exercise police power for the protection of public health is Jacobson v. Massachusetts, 197 U.S. 11 (1905). In Jacobson, an individual refused to be vaccinated for smallpox when a law had been passed requiring all individuals to be vaccinated due to an outbreak. Jacobson appealed the punishment. The US Supreme Court ruled that, "The possession and enjoyment of all rights are subject to such reasonable conditions as may be deemed by the governing authority of the country essential to the safety, health, peace, good order, and morals of community. Even liberty itself, the greatest of all rights, is not unrestricted license to act accordingly to one's own will." The Court went on to recognize that vaccination was an effective way in which to meet and suppress the harm of smallpox. The Court next reasoned that "If there is any such power in the judiciary to review legislative action in respect of the matter effecting the general welfare, it can only be when a statute purporting to have been enacted to protect the public health, morals, or safety, has no real or substantial relation to those objects." The Court upheld the statute as

constitutional. Specifically, the Court upheld the decision for Jacobson to pay the \$5 fine and established that an individual can be required to undergo vaccination against their will for the protection of the community at large.

State guarantine is the most dramatic and guick method of controlling threats to the public's health. Historically, quarantine was the detention and separation of persons suspected of carrying a contagious disease, especially travelers or voyagers before they were permitted to enter a country or town and mix with inhabitants.<sup>39</sup> In contrast, isolation is the separation, for the period of communicability, of *known* infected persons is such places and under such conditions as to prevent or limit the transmission of the infectious agent. Isolation may authorize confinement of infected persons on the basis of disease status alone ("status based") or the infected person's dangerous behavior ("behaviorbased").<sup>40</sup> Quarantine can mean isolation, closure of premises, testing, destruction, disinfection, treatment, and preventive treatment including immunization. It may apply to people, places, or things. A quarantine order is not a criminal proceeding and hence not bailable. "The constitutional guarantees of life, liberty, and property... cannot be deprived without due process of law, do not limit the exercise of the police power of the State to preserve the public health so long as that power is reasonable and fairly exercised and not abused."41

As stated in the August 16, 2006, Congressional Research Service Report for Congress: "Federal and state quarantine laws are subject to Constitutional due process constraints. The Fifth and Fourteenth Amendments prohibit governments at all levels from depriving individuals of any constitutionally protected liberty interest without due process of law. What process may be due under certain circumstances is generally determined by balancing the individual's interest at stake against the government interest served by the restraints, determining whether the measures are reasonably calculated to achieve the government's aims, and deciding whether the least restrictive means have been employed to further that interest."

"Federal quarantine authority derives from the Commerce Clause, which states that Congress shall have the power "(to) regulate Commerce with foreign Nations, and among the several states..." Thus, under section 361 of the Public Health Service (PHS) Act, 42 U.S.C. §264, the Secretary of Health and Human Services has the authority to make and enforce regulations necessary "to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from on State or possession into any other State or possession." While providing the Secretary with broad authority to promulgate regulations "as in his judgment may be necessary," this law limits the Secretary's authority to the communicable diseases published in an Executive Order of the President. The list of communicable diseases in Executive Order 13295 currently includes cholera, diphtheria, influenza, tuberculosis, plague, smallpox, yellow fever, viral hemorrhagic fevers, Severe Acute Respiratory Syndrome (SARS), and influenza caused by novel or reemergent influenza viruses that are causing or have the potential to cause a pandemic. State health departments or health officials typically have primary quarantine authority, though the federal government retains jurisdiction over interstate and foreign quarantine. The federal government may assist with or take over the management of an interstate incident if requested by a state of if the federal government determines local efforts are inadequate. Title 42 of the Code of Federal Regulations (CFR) divides quarantine into two parts. Part 71 deals with foreign arrivals and part 70 deals with interstate matters. The Secretary has delegated the authority to prevent the introduction of diseases from foreign countries to the Director of the CDC. The CDC maintains quarantine stations at eight major airports with quarantine inspectors who respond to reports of diseases from carriers. According to the statutory scheme, the President determines through Executive order which diseases may subject individuals to quarantine.

# EMTALA

The Emergency Medical Treatment and Active Labor Act is generally known as the anti-patient-dumping law.<sup>42</sup> The law places two principle obligations on hospitals participating in Medicare: 1) to screen any individual appearing in an emergency room to determine whether an "emergency medical condition exists," and, 2) to stabilize individuals determined to have an emergency medical condition before transferring or discharging the patient. Hospitals may not discriminate on ability to pay. The penalty for violation is loss of Medicare reimbursement elegibility. However, in a mass casualty event, hospitals may not be capable of screening or stabilizing everyone who arrives. But HHS has authority to waive EMTALA "screening" and "stabilizing" requirements under two conditions. A federal emergency must be declared and HHS must also declare a public health emergency.<sup>43</sup> An EMTALA waiver can be issued retroactively.<sup>44</sup>

## **Study Questions**

- 1. Define a rule and rulemaking.
- 2. What is the name of the legislative Act that governs how agencies function?
- 3. Explain administrative due process.
- 4. What does it mean to exhaust all administrative remedies before appealing to the courts?
- 5. Where in the US Constitution does the government get its authority to regulate public health?
- 6. What is EMTALA?

## Take Home Conclusions

- Agencies act as a vehicle for carrying out public policy. Their duties include enforcement, rulemaking, adjudication, and fiscal policy.
- The legislature must create an agency though an enabling act with rulemaking authority.

- An agency makes decisions by adjudication. An individual charged with a rule violation must be given due process by notice and a hearing.
- Hearings are held with an administrative law judge.
- One must exhaust all administrative remedies before appealing to the courts.

#### Acknowledgements

The author has no financial interests or conflicts of interest with any of the government agencies mentioned.

#### References

<sup>1</sup> Gostin LO, Public Health Law: Power · Duty · Restraint, University of California Press; 2008, 3.

<sup>2</sup> Tobey JA, *Public Health Law: A Manual of Law for Sanitarians* (Baltimore, MD: Williams and Wilkins; 1926, 6-7.

<sup>3</sup> Gostin LO, Public Health Law: Power · Duty · Restraint, University of California Press; 2008, 4.

<sup>4</sup> See Kreit A, Raich AM, *Health Care and the Commerce Clause*, 31 Wm, Mitchell L. Rev. 957,983 (2005) (noting that epidemics such as smallpox, yellow fever, typhoid, and malaria swept the east coast during the early nineteenth century).

<sup>5</sup> An enabling stature is a law that permits what was previously prohibited or that creates new powers; esp., a congressional statute conferring powers on an administrative agency to carry out various delegated tasks. *Black's Law Dictionary, Second Pocket Edition*, Garner BA, Editor in Chief, West Publishing Co.; 2001.

<sup>6</sup> Markel H, *When Germs Travel: Six Major Epidemics That Have Invaded America and The Fears They Have Unleashed* (New York: Vintage; 2005); Brandt AM, *No Magic Bullet: A Social History of Venereal Disease since 1880* (New York: Oxford University Press; 1987); Parmat WE, "Health Care and the Constitution: Public Health and the Role of the State in the Framing Era," *Hastings Constitutional Law Quarterly*, 20; Winter 1992; 267-334.

<sup>7</sup> "The Constitution gives nothing to the states or the people. Their rights existed before it was formed, and are derived from the nature of sovereignty and the principles of freedom." *Gibbons v. Ogden*, 22 U.S. 88, 98 (1992) (holding that a state law prohibiting vessels from navigating the waters of the state was repugnant to the Constitution and void).

<sup>8</sup> The commerce clause gives Congress the exclusive power to regulate commerce among the states, with foreign nations, and with Indian tribes.

<sup>9</sup> U.S. Const. Art. I § 8.

 $^{10}$  Gostin LO, Public Health Law: Power  $\cdot$  Duty  $\cdot$  Restraint, University of California Press; 2008, 11.

<sup>11</sup> Jacobson v. Massachusetts, 197 U.S. 11 (1905) (upholding state compulsory vaccination law).

<sup>12</sup> The free exercise claim used in this context refers to the freedom of religion. The right to adhere to any form of religion or none, to practice or abstain from practicing religious

beliefs, and to be free from governmental interference, as guaranteed by the First Amendment and Article VI, Section 3 of the U.S. Constitution.

<sup>13</sup> German Alliance Insurance Co. v. Hale cites Jacobson when asserting that "all corporations, associations, and individuals . . . are subject to such regulations, in respect of their relative rights and duties, as the state may, in the exercise of its police power, . . . prescribe for the public convenience and the general good." 219 U.S. 307, 317 (1911).

<sup>14</sup> Williams v Arkansas quotes Jacobson as saying, "The liberty secured by the Constitution . . . does not import an absolute right in each person to be at all times, and in all circumstances, wholly freed from restraint." 217 U.S. 79, 88 (1910).

<sup>15</sup> South Carolina State Highway Department v. Barnwell Bros. Cites Jacobson when saying that where the legislative action is "within the scope of {the police} power, fairly debatable questions as to its reasonableness, wisdom, and propriety are not for the determination of courts, but for the legislative body." 303 U.S. 177, 191 (1938).

<sup>16</sup> *Plymouth Coal Co. v. Pennsylvania* cite *Jacobson* when saying, "It has become entirely settled that {police powers} may be delegated to administrative bodies." 232 U.S. 531 (1914).

(1914).
<sup>17</sup> A floor is the lowest limit. A ceiling is the highest limit. *Black's Law Dictionary, Second Pocket Edition*, Garner BA, Editor in Chief, West Publishing Co.; 2001.
<sup>18</sup> Vermont Yankee Nuclear Power Corp. v. NRDC, 435 U.S. 519, 523-25 (1978).

<sup>19</sup> An independent agency is a federal agency, commission, or board that is not under the direction of the executive, such as the Federal Trade Commission or the National Labor Relations Board. *Black's Law Dictionary, Second Pocket Edition*, Garner BA, Editor in Chief, West Publishing Co.; 2001.

<sup>20</sup> Feasible, workable and have a reasonable likelihood of success. *Black's Law Dictionary, Second Pocket Edition*, Garner BA, Editor in Chief, West Publishing Co.; 2001.

<sup>21</sup> Chevron U.S.A., Inc. v. Natural Res. Def. Council. Inc., 467 U.S. 837, 844 (1984) ("We have long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer . . . .").

<sup>22</sup> Briggs NC, "Seat Belt Law enforcement and Racial Disparities in Seat Belt Use," *American Journal of Preventive Medicine*, 31; 2006 (showing that Blacks have a lower prevalence of seat-belt use compared with Whites but seat-belt use among both blacks and whites was more than 15 percent higher in states with primary, rather secondary, law enforcement, indicating that such preventive legal interventions increase seat-belt use and reduce motor vehicle crash morbidity and mortality); Houston DJ, Richardson, Jr. LE, "Safety Belt Use and the Switch to Primary Enforcement; 1991-2003," *American Journal of Public Health*, 96; 2006: 1949-54 (arguing that states with secondary enforcement laws could increase belt use by 10 percent by upgrading to primary enforcement). <sup>23</sup> The first letter is the letter sent to an alleged violator by the agency explaining that an

investigation is underway, what violation is being investigated and how to correct it.

<sup>24</sup> Richards EP, Peltier HA, *Public Health Law as Administrative Law*, (slides) (hypertext guide) Third Annual CDC Public Health Law Conference, Atlanta, June, 2004, Online Louisiana State University Law Center's Medical and Public Health Law site [Internet], http://biotech.law.lsu.edu/cphl/articles/index.htm.

<sup>25</sup> Online Louisiana State University Law Center's Medical and Public Health Law site [Internet] http://biotech.law.lsu.edu/Courses/study\_aids/adlaw/551.htm.

<sup>26</sup> Richards EP, "Public Health Law as Administrative Law: Example Lessons," *Journal of Health Care Law & Policy*, Vol. 10:61-88; 2007: 74. Online Louisiana State

University Law Center [Internet], http://biotech.law.lsu.edu/cphl/articles/index.htm.

<sup>27</sup> The term free rider refers to individuals who perceive that they can rely on herd immunity for protection against disease. The belief that, so long as, the majority of individuals are vaccinated it will protect the few who refuse.

<sup>28</sup> Habeas corpus is a writ employed to bring a person before a court, most frequently to ensure that the party's imprisonment or detention is not illegal. *Black's Law Dictionary, Second Pocket Edition*, Garner BA, Editor in Chief, West Publishing Co.; 2001.

<sup>29</sup> A court's nondeferential review of an administrative decision, usually through a review of the administrative record plus any additional evidence the parties present. *Black's Law Dictionary, Second Pocket Edition*, Garner BA, Editor in Chief, West Publishing Co.; 2001.

<sup>30</sup> Vermont Yankee Nuclear Power Corp. v. Natural Res. Def. Council. Inc. 435 U.S. 519, 555 (1978) ("[T]he role of a court in reviewing the sufficiency of an agency's

consideration of environmental factors is a limited one, limited both by the time at which the decision was made and by the statute mandating review.").

<sup>31</sup> Sunshine laws are statutes requiring a government department or agency to open its meetings or its records to public access. *Black's Law Dictionary, Second Pocket Edition*, Garner BA, Editor in Chief, West Publishing Co., (2001).

<sup>32</sup> Class Action Fairness Act of 2005, Pub. L. No. 109-2, 119 Stat. 4 (2005) (requiring class-action lawsuits with plaintiffs living in a state different from the defendant or those seeking more than \$5 million in damages be removed from state to federal courts).

<sup>33</sup> Comprehensive Medical Malpractice Reform Act of 2006, H.R. 4838, 109<sup>th</sup> Cong. (referred to committee on March 17, 2006) (proposing to limit noneconomic damages in medical malpractice suits).

<sup>34</sup> Protection of Lawful Commerce in Arms Act, 15 U.S.C. § 7901 (2005) (immunizing firearms manufacturers, wholesalers, and dealers from civil liabilities in lawsuits alleging that key recklessly or negligently supplied guns to criminals); Vernick JS, Mair JS, "State Laws Forbidding Municipalities from Suing the Firearm Industry: Will Firearm Immunity Laws Close the Courthouse Door?" *Journal of Health Care Law and Policy*, 4; 2000: 126-57.

<sup>35</sup> Levin LJ Editor, Buchanan JD Co-Editor, Editorial Board Health Law Section 2006-2007, Florida Practitioner's Health Law Handbook 2007, The Florida Bar Health Law Section.

<sup>36</sup> Per se means of, in, or by itself, standing alone, without reference to additional facts or as a matter of law. *Black's Law Dictionary, Second Pocket Edition*, Garner BA, Editor in Chief, West Publishing Co.; 2001.

<sup>37</sup> Prima facie means sufficient to establish a fact or raise a presumption unless disproved or rebutted. *Black's Law Dictionary, Second Pocket Edition*, Garner BA, Editor in Chief, West Publishing Co.; 2001.

<sup>38</sup> Ex parte means on or from one part only, usually without notice to or argument from the adverse party. Done or made at the instance and for the benefit of one party only or

relating to court action taken by one party without notice to the other usually for emergency or temporary relief (e.g. ex parte hearing or injunction). Black's Law Dictionary, Second Pocket Edition, Garner BA, Editor in Chief, West Publishing Co.; 2001. <sup>39</sup> Oxford English Dictionary, 2d ed.; 1989.

<sup>40</sup> Gostin LO, Public Health Law: Power  $\cdot$  Duty  $\cdot$  Restraint, University of California Press (2008), 429. <sup>41</sup> Varholy v. Sweat, 153 Fla. 571; 1943.

<sup>42</sup> 42 USC sec. 1395dd.

<sup>43</sup> 42 USC sec. 1320b-5.

<sup>44</sup> Id.