

2009 Chapter 13 Laws, Rules and Regulations

Before reading this material read the following set of 3 articles from JAMA's 2004 publications, written by Larry Gostin J D: Public Health Law in a New Century

[Part I:](#) Law as a Tool to Advance the Community's Health

[Part II:](#) Public Health Powers and Limits

[Part III:](#) Public Health Regulation: A Systematic Evaluation

Many good ideas to improve public health have failed or proved difficult to carry out because the local director and staff neglected to consider laws and regulations already enacted. State legislators enact most laws and regulations that affect health department programs but, sometimes, local laws (or ordinances) and regulations act as roadblocks to new programs. Laws are the result of legislative action. When the laws are placed into the appropriate section of the written and published books of laws they are known as codes. They provide an agency like the health department with the authority to perform an activity or control someone else performing an activity. Rules or regulations tell people affected by a law, or how an agency will carry out the intent of the law.

Regulations that affect local health departments may describe how to manage health care programs, or how to protect property or the environment. Federal regulations are the basis of local and state laws that control dispensing of controlled drugs, regulate the financial accountability required when using grants of money provided by federal agencies, or set standards such as those for hygienic food preparation and storage. Federal codes have usually been enacted because certain practices need to be uniform among the states.

State codes may be enacted to ensure that state and local agencies have the authority to write regulations allowing them to enforce federal laws. Typically, states set standards for operation of public utilities such as water and sewage plants. To receive money from the federal government states are required to enact laws that allow agencies such as health departments to set operating standards for the public utilities and ensure they operate in general conformity with federal regulations. Certain rights, known as police powers, are reserved to the states unless specifically preempted by the federal government. Authority to set standards regarding quarantine for people capable of transmitting diseases that are a hazard to the public, such as plague, tuberculosis or syphilis are set by state codes.

Local government, in most states, can only enact local laws or ordinances when state law has delegated agencies with the power to do. Such examples are the ability of local government to set their own standards for operations of restaurants or installing septic tanks, or to enact laws requiring pets to be immunized against rabies. In states such as Virginia, local government can set standards for maintenance of rental housing, including the ability to inspect housing before it is rented. Other states, such as Texas, have a constitution that confers an absolute right to use personal property thus a local government cannot control rental of individual dwellings but can charge fees for people who attend public health clinics.

To plan health and environmental programs, local health directors need to understand what laws and regulations they operate under in their states, and what delegated authority they have. In Virginia a local health director may think an individual should be quarantined. The state legislature, being concerned about removing individual's rights to move freely around the state without conviction by a court, have restricted specific authority to impose a quarantine to the state health director. A state may enact laws enabling localities to pass environmental laws that are more restrictive than the state, but allow the state to set up a mechanism to allow waivers to state regulations. This may cause a conflict for a local health director charged with enforcing both local and state law. It is important therefore to understand which laws supersede the other.

Many laws are enacted because citizens impress legislators with the need for change. If health directors do not monitor state legislatures, and city and county elected officials, laws that might appeal to the public, but have no scientific validity may be enacted. For example, in the last few years, with the discovery of AIDS, and the mass of information and misinformation provided in the various media some school superintendents have tried to pressure city councils and state legislators to require health departments to provide names of children infected with the human immunodeficiency virus (HIV) to them. Although such requests have been made of state legislators for several years, few have succumbed to public pressure. Most, as did the legislature in Virginia, accepted the scientific advice of health professionals and refused to pass such laws, although the discussion was bitter at times, and votes were close. Michigan actually enacted a law, against the advice of public health officials and medical society members, to require persons applying for marriage licenses to be tested for HIV. Fortunately this law was repealed at a future legislative session.

Many state and local laws are enacted in the wake of those made by the Congress. Federal agencies have to develop rules and regulations to carry out these laws, just as state and local governments do. Government has developed procedures on writing regulations, known as "administrative process" acts. The purpose of these acts is to give as many people as possible, including organizations and institutions directly affected by the laws, also interested members of the public and advocacy groups, the chance to take part in the development of the regulations, a process known as "rule-making." The federal and state governments have publications used specifically to advertise new regulations known as federal and state registers. Local government and some state agencies also publish their intent to make new regulations in the major newspapers, to give as widespread notice of new regulations as possible. All interested persons are given a set time to reply to the notice of new regulations. The agency producing the regulations then has to review the suggestions and state why they will or will not change the preliminary regulations to comply with the suggestions made during public hearings or in writing prior to the hearings. After this final notice the regulations are published in final form and if not challenged in court become law. Different states allow different time periods between the various steps and may require policy boards such as state boards of health to give the health department approval to adopt the regulations in final form. All the various steps are intended to ensure that regulations are not adopted in haste, and not put into action without an opportunity for the public to challenge them.

One would think, that once a law was passed none of this activity should be necessary, that the law should speak for itself. Unfortunately many laws are passed hurriedly, without dotting all the 'i's and crossing all the 't's. Some people, who will not agree with or want to keep these laws, will challenge them in court for many reasons. Some of the reasons given will be that the law conflicts with a previous one, that the law is unconstitutional, that the body enacting the law does not have the power to do so, or that a law made for one agency conflicts with one drawn up for another. The period used to develop the regulations, and the advertising and comment period provided for the preliminary regulations, allow agencies to clarify the intent of laws that are often vague, to explain the boundaries within which the agency will act, and clarify when other agencies have the right to intervene. Any misspelling or failure to clarify a law can result in a successful challenge in court.

Once the regulations have passed through each required administrative steps required by federal and state law they have the force of law and must be followed. It is important to provide flexibility for administration of regulations by responding to testimony given to an agency during the rule-making period. Failure to challenge the regulations during the period when the rules are being drawn up leaves no option except court action, which is expensive and may take months or years to reach resolution. For these reasons it is important that health directors and their staffs learn the basic elements of rule making and learn how to raise a successful challenge to clarify the intent of a law during the development of the regulations. A law that has come back to haunt many health departments is the Delaney Amendment to the Food and Drug Administration Act passed more than forty years ago. This amendment to FDA law states, simply, that the FDA may not approve any item for interstate sale that cause mutation in any living system. This law was put in by a lawmaker who read about research

performed by Dr. Bruce Ames on toxic products and ways of detecting them. The law was made with good intent but with little understanding of the underlying science. The law was not based on the major principles of toxicology, or with a complete understanding of biologic systems and their abilities to repair themselves. Dr. Ames has stated categorically that his research was not conducted for this purpose, and was taken out of context and applied improperly. Despite these facts the law has taken on a life of its own and efforts to repeal it have failed. The Environmental Protection Agency has used the Delaney Amendment to ban many products from commerce stating that these products were dangerous to people and likely to cause cancer. To this point few challenges to the EPA have been successful, although people are starting to understand some of the scientific judgment that should go into toxicological decision-making. Many scientists believed the Delaney Act should be amended. After almost 50 years, Congress removed the rule in 1998

Planning changes to laws:

For example:

- Judgment in application of rules and regulations.
- Specific Health Regulations.
- Vital data codes.
- Prostitution.
- Administrative Hearings.

As an alternative to using the courts one can write regulations that require hearings before a local policy board or a health director. For example, a local health director may be given the power to banish an animal from the community, or order it killed subject to court action stopping him from enforcing the order. Administrative hearings move faster than court hearings. If you choose this route always have a member of the city or county attorney's staff present as facilitators and legal advisors. Allow the other parties to bring lawyers if they wish. Administrative hearings are effective methods of problem solving. Strict rules of evidence don't apply, but everyone involved needs to learn how to present and interpret evidence, and how to explain compliance standards. I have had to dismiss actions against suspected violators when new staff members had not learned to present evidence clearly, consistently and without hesitating or stumbling or giving the impression of acting arbitrarily and without due process. Staff should not say "I think" or "I heard." They must have seen the incident themselves, or bring in someone who saw it. There is nothing more detrimental to credibility than having staff forget what they saw, and when. Refer to written notes if necessary. As standard operating procedures require staff to write down violations when seen, recommend actions and explain follow-up steps taken. Good staff work leads to good decisions.

Most local public health policies are developed for environmental control rather than for health services. Health department staff is often asked to help develop standards for rental housing, installation of personal sewage disposal systems, restaurants, and water wells. The most controversial are usually animal control laws.

Denial of Permits.

Besides violation of laws, there are potential violations that are appealed to the health director. An example is the denial of a permit to install a septic tank or open a restaurant for business. Such denials normally provide an opportunity to appeal the decision to the health director. This appeal requires a technical decision, but does not need the formality of an administrative hearing. One rarely has a legal problem when giving people what they want, unless they think you are showing favoritism. You are more likely to get into trouble when turning down a request, when denying people something they think they have a right to, such as a septic system on their property. Take the time to explain exactly why, in simple terms, the permit is not being given. Repeat it again if necessary. Explain why their request is

different from someone else's, and make sure they know if there is a further appeal mechanism. Don't wait for someone to find out, after denying a permit, that it was possible to appeal the decision. The health director should always be prepared to discuss a permit denial by a staff member. This is one way of backing the staff. It is also a learning experience for staff on the (hopefully) rare occasions you over-rule them.

They won't like it, but will accept your reasons with grace if you take the time to explain your reasons for overturning their decisions. When such occasional reversals of denial occur it improves the department's credibility in the community. Depending on the complexity of the issue, there are times when the department's attorney should chair a hearing on a permit denial, allowing the health director to sit only as the judge.

Local health directors carry out their activities in a fishbowl. They work in an environment bound by laws and regulations. Learn them, understand them, be able to explain them, administer them fairly, and you will make many friends for your agency.

Reading List:

1. Fallon LF JR. and Zgodzinski EJ – Public Health Management, Chapter 3, Legal Basis for health departments.
2. Turnock B.J.: Essentials of Public Health – Chap 4. Jones & Bartlett, 2007
3. Gostin, Lawrence O. Public Health Law - Power, Duty, Restraint. (California/Milbank series on health and the public) 2000.
4. Virginia State [Health Codes](#).
5. National Model Codes available through city and county attorneys.
6. County & City Ordinances.