



# The Legal Basis of Public Health

An Individual or Group Study Course in Ten Modules

## Module 7 Policy Development

SS0007



**CDC**  
CENTERS FOR DISEASE CONTROL  
AND PREVENTION

## ***The Legal Basis of Public Health***

SS0007 - Module 7, Policy Development

### **Continuing Nursing Education (CNE)**

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# *The Legal Basis of Public Health*

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## **Course Contents**

This course consists of the following ten modules and a Coordinator Guide, which includes suggestions for using the course materials.

<b>SS0001</b>	<b>Module 1, Introduction</b>
<b>SS0002</b>	<b>Module 2, Data Collection and Surveillance</b>
<b>SS0003</b>	<b>Module 3, Service Delivery</b>
<b>SS0004</b>	<b>Module 4, Licensing</b>
<b>SS0005</b>	<b>Module 5, Inspections</b>
<b>SS0006</b>	<b>Module 6, Enforcement</b>
<b>SS0007</b>	<b>Module 7, Policy Development</b>
<b>SS0008</b>	<b>Module 8, Negotiation</b>
<b>SS0009</b>	<b>Module 9, Communication</b>
<b>SS0010</b>	<b>Module 10, Responsibility and Liability</b>

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# About this module

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## Overview

Previous modules have described how protection of the public's health relies heavily on law and how the state police power gives legislative bodies wide latitude in enacting public health laws. But public health laws come into being only after a public health problem or need has been defined, a legislative or regulatory solution tailored, and a specific law or regulation drafted.

Laws and regulations need input from public health professionals to ensure that the problem, its solution, and the outcome are well-defined.

For public health laws and regulations to be effective, you as a public health professional must take part in developing them. In particular, you need to define the *problem* a proposed law or regulation is to solve and the *end* it is to achieve. When a law is drafted by people who do not practice public health or do not have the advice of public health experts, the law is less likely to achieve the desired ends and more likely to create unintended adverse consequences.

The four phases of developing new laws and regulations

There are generally four distinct phases in the development of new laws and regulations:

1. Identifying and defining a public health problem that needs attention
2. Determining whether laws or regulations are needed to help solve that problem and, if so, whether new statutory authority is required or only new regulations based on existing statutory authority
3. Drafting the proposed new statutes, ordinances, and/or regulations
4. Shepherding these drafts through the legislative or rulemaking process

This module discusses the role of the public health professional in each of these phases.

## Module components

This module consists of the following components:

- Text and self-study exercises to be completed individually. The exercises are meant to help you better absorb what you have just read and immediately apply the concepts. You may find it helpful to discuss the exercises with members of your learning group if you are in one.
- A review section that includes a review of terminology and self-check multiple-choice questions.
- Group exercises, including discussions of case studies. If you are not in a learning group, you can review these case studies independently.

## Goals

Keep these goals in mind as you study the module; they describe how it can help you in your job.

This module is intended to help you understand the complex process of drafting legislation and regulations, and the important role that public health professionals must play in order to enact clear, effective, and enforceable laws and regulations.

## Learning objectives

After completing this module, you should be able to:

1. Identify the issues you should consider when thinking about initiating legal solutions to public health problems.
2. Identify the types of information that you should contribute to the development of legislative and regulatory specifications.
3. Identify the ways you can help with the negotiating, drafting, reviewing, and advocating of regulations to implement new and existing statutes and ordinances; describe why your contribution is so important.
4. List the basic steps involved in the legislative process and the federal regulatory process and identify points where you can provide expertise to support an initiative.





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## Start by networking...

The material in this module will make more sense if you first locate an expert who can explain how the process works in your area. You should also find out who works on legislative and rule-making matters for your agency. Finally, you should determine whether your agency has a legislative office with primary responsibility to advocate for the department's legislative agenda. If so, find out whether it seeks advice or assistance from "content experts" such as yourself within the agency's program offices.

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# Introduction

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## Problem definition

Public health professionals must often find new ways to solve new problems.

When a new public health problem is identified or when there is dissatisfaction over how an old problem is being dealt with, those who work most closely with the problem may realize that existing laws and regulations are not working and a change is required.

Some new or newly recognized public health problems require new legal solutions. This was the case when anonymous HIV testing was needed but prohibited by existing laws. Needle exchange programs have faced the same barriers. New laws were required when the emergence of recalcitrant tuberculosis rekindled the need for forced isolation and treatment of patients, but the requisite legal authority was outdated. New laws have also been developed to provide more effective enforcement of prohibitions on the sale of tobacco to minors.

New laws are not the only solution.

Not every new public health problem requires legal action. Sometimes passing a new law or regulation is not politically feasible, or enforcement cannot be carried out. In some cases existing statutes and regulations are perfectly adequate, and what may be needed are more resources and funding, better management, different approaches to administration and enforcement, or new educational or consultative solutions.

Begin with a careful definition of the problem.

Before deciding on a legal solution, the specific public health need must be carefully and deliberately defined.

- What is the problem and what are the desired outcomes?
- What must be changed in order to mitigate the problem?
- Why are existing legal authority, prohibitions, or requirements not reliable or sufficient?
- Why are new laws or regulations the only solution?



**See Group exercise 7.1 at the end of the module.**

## Specifying a legal solution

Specific details are needed from the outset.

Once new legislation or regulations are deemed necessary and viable, the specifics of a new legal solution must be worked out.

- What types of prohibitions or requirements are needed?
- Exactly what should the new law require, prohibit, or permit?
- On what governmental authority would they be based?
- Do related laws exist in any form at present?
- Do any useful models already exist, such as laws in other jurisdictions or laws dealing with analogous problems?
- What enforcement mechanism, including sanctions, will be necessary to make new legal approaches work?

Regulations may be preferable to laws.

You will also have to decide whether to develop a new law or new regulations. Regulations have several advantages over legislation:

- They are more flexible.
- They do not require action by a legislative body.
- They are more easily crafted to address specific situations and conditions.
- Input from experts in the problem areas is more routine.

If new implementing regulations are what is needed, it should be kept in mind that regulations have the full force of the law. Even more than statutes and ordinances, they should be narrowly fitted to the task.

Public health professionals often initiate new laws and regulations.

New legal solutions are most often brought about by concerned public health professionals like yourself. Public health officials must aggressively identify the need for new laws, initiate their development, review proposed drafts, and help gain consensus on the specific statutory and regulatory language. These responsibilities fall within the scope of the second core function of public health agencies identified in the Institute of Medicine report, *The Future of Public Health*.<sup>1</sup>

Get input from all concerned.

You will need to begin working right away with attorneys, legislators, legislative staff, legislative reference bureau staff, academics, advocates, lobbyists, and other public health professionals. Their early input is needed to identify and avoid problems and weaknesses in the structure and wording

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<sup>1</sup> The three core functions are assessment, policy development and assurance.

# Drafting new laws and regulations

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## Collaboration between legal and public health departments

Legal counsel is needed to anticipate legal difficulties.

When it comes to legislative drafting, legal counsel is likely to take the lead role since lawyers are trained in the use of precise, clear, and consistent use of language, and the careful tailoring of legal remedies and sanctions. Legal counsel is concerned with making sure that the final result will work and will be able to withstand legal challenge. They are also able to anticipate problems regarding the validity of a proposed law, especially concerning issues of due process and equal protection, as discussed in Module 1, Introduction.

As a public health practitioner, you are more likely to be involved in drafting new regulations than in drafting new laws. Still, it is important for you to review and offer input and advice when new laws are being drafted.<sup>2</sup> As important as it is to anticipate possible legal difficulties, it is also important to anticipate possible practical and administrative difficulties. As William Curran points out:

Public health professionals anticipate practical and administrative difficulties.

“Many lawyers are trained to look to the courts for all guidance... consider the subject of legislative drafting as if only court interpretation and enforcement are to be expected. Yet literally thousands of statutes, many of them very important, never receive court interpretation. Lawyers are prone to see that a law means only what a judge says it means. Actually, most statutes and regulations mean what administrators of those make them mean. Even when judicial interpretation differs from administrative practice, the agency is often able to get the law changed to conform with its policy for future cases. In the drafting process, this means that it is often advisable to take a chance on contrary judicial interpretation rather than tie the hands of administration in a particular area.”<sup>3</sup>

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<sup>2</sup> Most states have a bill-drafting manual which may be obtained from the state’s legislative reference bureau.

<sup>3</sup> Curran, p.753.

## Gain consensus

Without a broad base of support, drafts go nowhere.

A critical first step is to gain general consensus among key policymakers on the need for a new piece of legislation or regulations. The historical development of the 1993 Chicago ordinance to prevent childhood lead poisoning provides a useful illustration of the need to gain broad support for new public health laws before introducing them.

### *Case Study: Development of a Municipal Lead Poisoning Prevention Code<sup>4</sup>*

Chicago lead poisoning prevention case study

In November 1986, in response to increasing public concerns and the release of new scientific information about the dangers of lead, the Mayor of Chicago created a City Task Force on Lead Poisoning, composed of community leaders and various city department heads. The group's findings and recommendations were published in a 1988 report.

Between 1988 and 1993, when a new lead ordinance was passed, the city's political, professional, and community leaders struggled to redefine and assess the need for a revised strategy to deal with lead poisoning. The events which occurred during this five-year period illustrate the many activities that may be required to successfully develop new public health legislation, and the pitfalls to be avoided.

A major force behind the 1993 ordinance was the director of the city health department's lead screening and environment program. She had already accelerated the rate at which enforcement actions were initiated against recalcitrant landlords. Tests were conducted in all units of a multi-unit building whenever a single case of childhood lead poisoning was detected in the building, a practice not authorized under the existing law.

Notwithstanding the new director's actions, lead poisonings continued to mount and a growing number of children remained exposed to a toxic environment. Having exhausted most of her administrative and programmatic options, the director turned to the city's legal department for assistance. The department prepared a revised lead ordinance which included many code provisions supportive of the director's goals and initiatives.

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<sup>4</sup> Public Health Institute, unpublished case study.

Unfortunately the law department failed to involve other city departments that would have joint responsibility for implementing some of the legal mandates. Nor did they seek input from the community organizations concerned about childhood lead poisoning. As a result, there was little political support for the draft ordinance and it went nowhere.

In 1991 a new effort was undertaken to deal with the lead poisoning problem. This time a number of steps were taken to gain support and avoid the mistakes made the first time around:

Ways to gain  
community support

- Community groups and other city departments were brought in to help reshape the language of the draft ordinance.
- Potential opponents of the ordinance were invited to negotiate its final language.
- A multimedia campaign was launched to make the public aware of lead hazards and to gain public support for the new legislation.
- A member of the mayor's staff lobbied the mayor's political network to gain crucial political support for the proposal.

By the time the ordinance was introduced in the city council, there was strong support from hundreds of people. Emotionally powerful testimony was presented in city council hearings by parents of lead-poisoned children. In November 1993, the health committee voted unanimously to pass the ordinance and the full city council approved it shortly thereafter.



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## Bringing it home...

Who are the constituents and stakeholders for the public health program(s) you implement?

How would they be affected (either positively or negatively) by any new laws or regulations you might develop?

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**See Group exercise 7.2 at the end of the module.**

## Legislative and regulatory specifications

Specifications describe how goals will be incorporated into the draft.

Once you have defined a problem and general consensus has been reached on the need for new legislation or regulations, you must refine the objectives before those responsible for drafting the legislation or regulations can begin their work. Refinement occurs through the process of preparing legislative or regulatory specifications. These specifications provide the drafter with an extensive narrative description of how policy goals are to be incorporated into the draft legislation. It is, in effect, a blueprint for the drafter.

Involve the person who will write the legislation from the outset.

It is a good idea for you to involve the drafter in developing the specifications. A drafter who is involved early on in policy deliberations will better understand your objectives and preferred legal solutions, and can then help identify specifications that are too vague to craft into law. Given only general guidance, the drafter may add concepts that inadvertently alter the intended effect of the legislation.

Laws designate who must obey them, who will enforce them, and how.

Surprisingly little has been written for the non-lawyer in recent years about the strategies and techniques of legal drafting. A 1964 article by William Curran in *Public Health Reports* still stands up well as one of the best discussions of this topic. He reviews the structure of statutes and ordinances, including titles, preambles, definitional material, and legal commands, explaining that a law must a) designate the persons or group who must obey it, b) designate the official who has the responsibility of enforcing it, and c) provide a means of enforcement, a penalty, or reward. Curran goes on to advise:

Avoid loopholes and assure uniformity of interpretation.

Be as precise and specific as you can in stating the substance of the law in the command to people to do something. Tell them what to do and don't leave too many loopholes, too many alternatives to interpretation... Isn't it an advantage to have flexibility? It is, of course, but please examine the result. The audience addressed cannot clearly understand or obey such laws or regulations, and the law cannot be fully self-executing, as nearly all public health laws must be. If the manner of compliance is left unclear, health department enforcement people must interpret and enforce laws in particular instances. This places great discretion in enforcement people, many of whom may not be adequately trained to assume this responsibility. Also, a lack of uniformity in interpretation and enforcement may result, depending on the inclinations of the enforcer.<sup>5</sup>



Specifications provide guidance to those who implement and those who interpret.

Drawing up clear legislative specifications requires disciplined thinking. Poorly drafted laws will produce weak, cumbersome, and ineffective enforcement. A poorly drafted law or regulation can be worse than none at all, for it can exacerbate a problem while creating the illusion of a solution.

In drafting a proposed law or regulation, both the public health problem to be addressed and the legislative or regulatory solution must be specified. You must picture how the proposal will be implemented and anticipate all contingencies. Specifications must not be drawn so narrowly that they apply only to an exact duplicate of the incident that led to the need for the new law, or so broadly that the law might be invalidated for being unconstitutionally vague or for going beyond the appropriate bounds of the police power. It should provide adequate guidance to the agencies that must implement it, as well as to the judges who must interpret it. The process of writing detailed specifications is almost certain to raise basic questions about the policy that had not been thought of earlier or that had been discussed in sketchy and unrealistic terms.

Donald Hirsch offers the following advice for developing legislative specifications: "...think through in detail the specific actions one would need to take to implement the proposal. Ask yourself, 'If this were a statute addressed to me, how exactly would I go about carrying it out?'"<sup>6</sup>

In short, specifications should clearly convey the following:

- The objectives of the proposed policy
- How the policy will be implemented
- What actions will be required for compliance

Neither the drafter nor the public should have to guess at what the law is calling for.

### **Review the draft legislation**

Review for clear language and practical implications.

Even when specifications seem well done, it is important for you to review the language of the proposed legislation to make sure that the law, if passed, will accomplish the desired public health objectives. When reviewing a lawyer's legislative or regulatory draft, you should not hesitate

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<sup>5</sup> Curran, p.751.

<sup>6</sup> Hirsch, p.5.



**See Group exercise 7.3 at the end of the module.**

Draft legislation should also be reviewed by public health program staff and by the program attorneys who will be responsible for implementing the provisions. These individuals often have unique insight into whether the provisions are practical and whether the new law will work as planned.

### **Negotiate the details**

Engaging all stakeholders in negotiations ensures wider acceptability.

Negotiation and compromise are essential to the legislative drafting process. It is important to consult with those who will be affected by a new public health law or regulations. These include:

- Public health officers who will be called upon to interpret and enforce the rule
- Persons who will be required to obey it
- The intended beneficiaries
- Any potential opponents

Concessions and trade-offs with stakeholders help gain their support.

Bringing together affected stakeholders at this early stage helps the public health agency gain crucial support for a proposed law, as was illustrated in the case study. It gives stakeholders the opportunity to negotiate provisions that are important to them and their constituents, provisions that may be of little value or concern to the public health agency, but which will make the proposal acceptable to a wider group of affected parties. Such concessions and trade-offs are often used by interest groups to sell an otherwise problematic law to their constituents. Module 8, Negotiation discusses principles and strategies of negotiation in more detail.

An initial outline of the major provisions in the law can provide a focal point for discussion. Although extensive consultation may seem unnecessarily time-consuming, it will make it more likely that the law will be enacted and less likely that it will be challenged in court.



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## Bringing it home...

Whom would you involve in negotiating a new childhood lead poisoning prevention ordinance in your area?

The City of Chicago included the following persons and organizations:

- Initial proponents, including key staff from the Health Department and community advocacy groups
  - Other affected city departments, including the Law Department, Department of Buildings, Department of Human Services, Department of Consumer Services, Board of Education, and the Mayor's Office
  - Potential opponents, including a property owners' association, and other representatives of the real estate industry
-

## Advocacy for approval of legislation

The drafting process occurs within a highly political environment. Support for any proposed legislative measure should not only be sought early on in the process, but continue after the measure is finally signed into law. Your expertise as a public health professional can be a supportive factor in gaining the votes needed to enact a piece of legislation or to ensure the promulgation of a regulation.

The Hatch Act does not limit government employees from providing expert testimony.

Because public health professionals are government employees, they are limited by law in how involved they can become in political advocacy. Despite the specific prohibitions on participation in partisan politics contained in federal and state statutes, such as the Hatch Act (see below), this area of law is murky. But a public employee is free to provide information, including expert testimony to legislators, legislative committees, legislative reference bureaus, and other participants in the legislative process. Module 9, Communication provides useful information about testifying before such bodies.

## The Hatch Act

### Federal Hatch Act

Under the 1939 Hatch Act, federal employees, employees of the District of Columbia government, and certain state and local government employees faced significant restrictions on their ability to participate in political activities. [The regulations define “political activity” as an activity directed toward the success or failure of a political party, candidate for partisan political office, or partisan political group. [See 5 CFR 734.101] Congress amended the Hatch Act in 1993 to permit more political activity by federal and D.C. government employees....

*Ref: 5 U.S.C. chapter 73, subchapter III, as amended; 5 C.F.R. Part 733; 5 C.F.R. Part 734 as amended (61 Fed. Reg. 35088, July 5, 1996)*

### State and Local Hatch Act

The Hatch Act also applies to the political activity of certain state and local government employees. Covered employees under the act are persons principally employed by state or local executive agencies in connection with programs financed in whole or in part by federal loans or grants. The act does not apply to the political activity of persons employed by educational or research institutions or agencies supported in whole or part by (a) states or their political subdivisions, or (b) religious, philanthropic or cultural organizations.

It should be noted that some statutes make Hatch Act provisions applicable to other categories of individuals as well--e.g., persons employed by private, non-profit organizations that plan, develop, and coordinate Head Start and certain other types of federal assistance.

*Ref: 5 U.S.C. 1212 (f), and chapter 15*

### State and Local Hatch Act Do's

Covered state and local employees may:

- run for public office in nonpartisan elections
- campaign for and hold office in political clubs and organizations
- actively campaign for candidates for public office in partisan and nonpartisan elections
- contribute money to political organizations and attend political fundraising functions

### State and Local Hatch Act Don'ts

Covered state and local employees may not:

- be a candidate for public office in a partisan election
- use official authority or influence to interfere with or affect the results of an elections or nomination
- directly or indirectly coerce contributions from subordinates in support of a political party or candidate

[U.S. Office of Special Counsel, <http://www.gpo.gov/osc/> October 3, 1996]

The next two sections provide a textbook description of how the legislative and federal regulatory processes work. The information will give you the requisite foundation to track public health initiatives through the legislative or rule-making process. The narrative also describes key points within the process where you might provide expert testimony or otherwise lend support to an initiative.

In reality, legislative and regulatory processes rarely unfold according to the textbook description. Additional references at the end of this module provide essential insight into selecting bill sponsors, parliamentary maneuvers, lobbying tips, and other information about the inner workings of the legislative and regulatory processes.



### **It's time to network...**

Who are your best sources of support for getting a bill passed in the state legislature?

Congressional representatives and senators

Lobbyists and special interest groups

Media

Others?

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**See Group exercise 7.4 at the end of the module.**

# The legislative process

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The legislative process consists of seven basic steps, although processes in the jurisdiction served by your agency may vary.<sup>7</sup> Below we discuss each step,<sup>8</sup> and follow the discussion with a flow chart (Figure 7a).

## Step 1

**Introduction of bill and first reading.** The process begins when an individual, group or administrative unit such as a health department persuades a member of a state legislative body, county commission, or city council to author a bill. The legislator sends the idea for the bill and any proposed language to the legislative office responsible for drafting the idea into legislative language. If the bill's proponents have gone through the legislative specification and advocacy steps outlined above, the bill is more likely to move forward successfully than if the idea is simply dropped into the legislative hopper.

When a bill is introduced formally for the first time, the clerk announces or reads the bill number, the name of the author, and the descriptive title of the bill on the floor of the sponsor's chamber. Health officials can play a crucial part by helping shape a bill's language early in the process.

## Step 2

**Committee assignment.** Following the first reading, the committee on assignment, the rules committee, or the legislative leader assigns the bill to the committee or subcommittee that normally considers bills in that general subject area.

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<sup>7</sup> Public interest groups and trade associations frequently develop materials to help their constituents participate effectively in the legislative and regulatory processes.

<sup>8</sup> Adapted from the *Manual for Public Interest Lobbying in Illinois*.



**Step 3**                    **Committee action.** Upon assignment to a committee, the bill is studied by a committee staff analyst who issues a report to the committee members on what the bill will do if enacted into law, who supports it, and who opposes it. When the report is complete, the bill is posted for hearing.

At the hearing, testimony is considered and committee members vote on the bill, recommending either passage in its current form, passage with specific amendments, further hearing by subcommittee or committee, or no further consideration. The expert testimony of health officials is often persuasive in helping committee members decide whether to vote to pass the bill as is, pass it as amended, or vote to defeat it.

**Step 4**                    **Second reading.** Bills approved by committee are read a second time on the floor of the house of origin. In some jurisdictions, amendments to the bill are debated and voted on at this stage. A second bill analysis may be prepared before the bill advances to its third reading.

**Step 5**                    **Third reading.** The third reading is the passage stage, in which the bill is debated and voted on by the full chamber. A bill generally may not be amended on third reading, but may be returned to second reading for purpose of amendment. Passage is often by roll call vote.

**Step 6**                    **Resolution of differences and concurrence.** In a bicameral legislative body, such as most state legislatures, the final version of the bill passed in its chamber of origin then proceeds to the other chamber where the process is repeated. If a bill is amended in a second chamber, it must be returned to the first chamber for agreement. If concurrence is denied, the second chamber votes on whether to recede from its amendments. If the second chamber fails to recede, the bill is usually sent to a conference committee to attempt to work out a version agreeable to both chambers. If compromise is reached the bill is returned to both chambers for a vote.

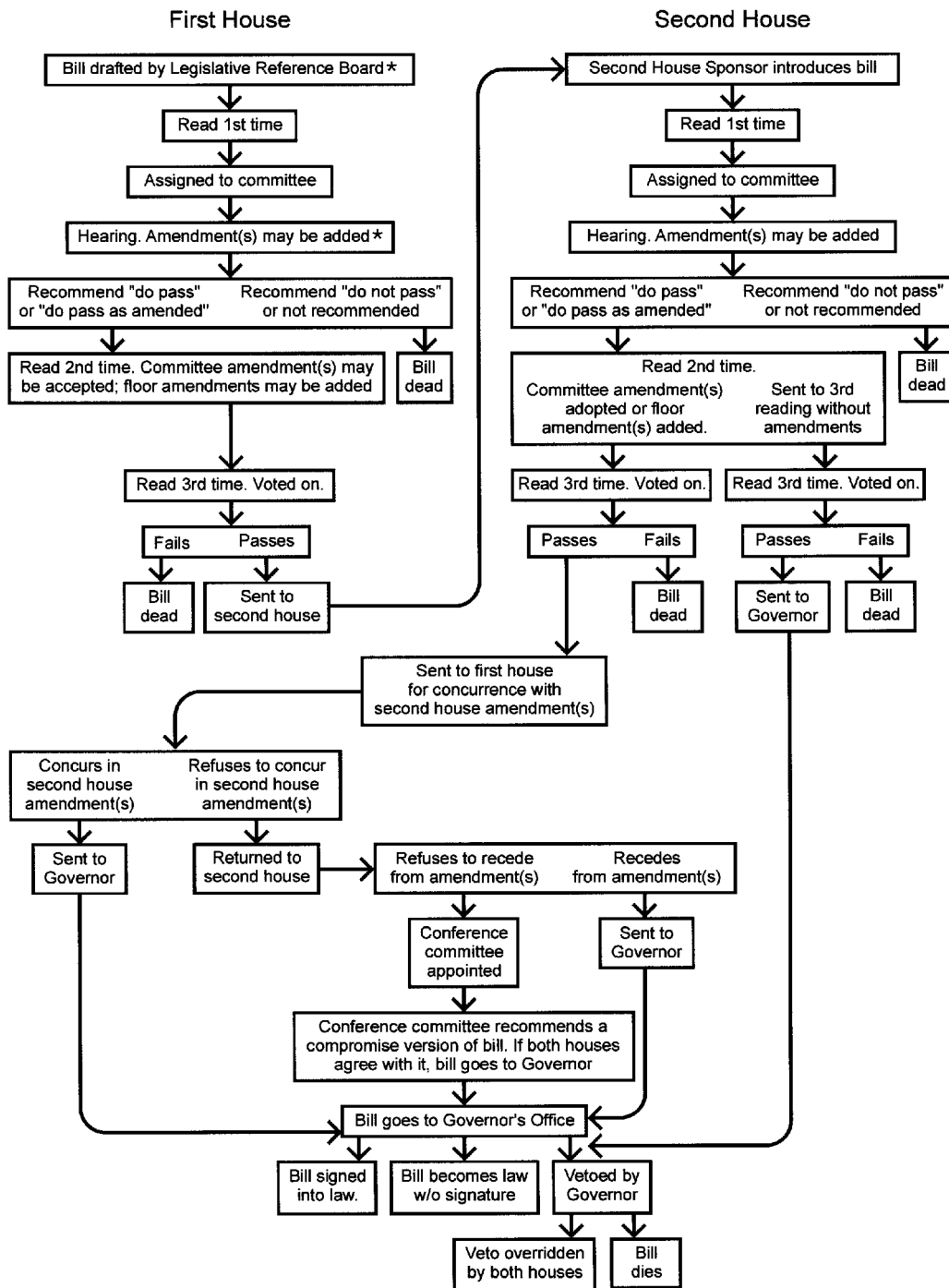
**Step 7**

**Chief executive's action.** The bill then goes to the governor or to the mayor, who has three alternatives:

- Sign the bill into law
- Allow the bill to become law without signature
- Veto the bill

In some states a governor or mayor may revise the bill by an amendatory veto, and in some states an appropriations bill can be reduced by a line item veto. The state legislature or city council may override the veto. In some states it takes a two-thirds majority and in others it takes a three-fifths majority to override a veto. If the veto is overridden, the bill passes; otherwise it dies.

**Figure 7a. How a Bill Becomes Law**





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## Bringing it home...

What do you know about the legislative processes in your state and local jurisdictions?

At what steps in this process are public health professionals allowed to provide input?

What type(s) of input might public health professionals provide?

You probably don't know everything you want to know about this process in your state. These are questions to discuss with your study group or with colleagues.

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# The federal regulatory process

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The Administrative Procedure Act guides rulemaking activity and promotes public input.

Figure 7b illustrates the procedural steps that federal agencies follow when developing new federal regulations.<sup>9</sup> State and local governments usually have similar but often less formal regulatory processes. The federal procedures are required by the Administrative Procedure Act (5 U.S.C.551, et seq.). The Administrative Procedure Act was enacted in 1946 in response to the proliferation of regulations that were developed by the many new federal agencies created at that time. Before its passage there were no procedural rules governing the promulgation of federal regulations, virtually no public oversight of the process, and no central publication system, making it difficult for the public to learn about regulations which affected them. The primary goals of the Administrative Procedure Act were to promote public involvement in rule-making activities and to make the process clear, open, and non-arbitrary.

The *Federal Register* publishes new and proposed regulations.

In 1978 these goals were further enhanced by a presidential executive order that required federal agencies to publish an agenda of significant regulations under development or review within their agency. The agenda is published in the *Federal Register* at least semi-annually. It provides state and local health officials early warning of possible new regulations which may affect their work, giving them an opportunity to prepare expert advice and comments on the proposed action.

## Step 1

**Initiation of process.** In most cases the process is triggered by one of two events:

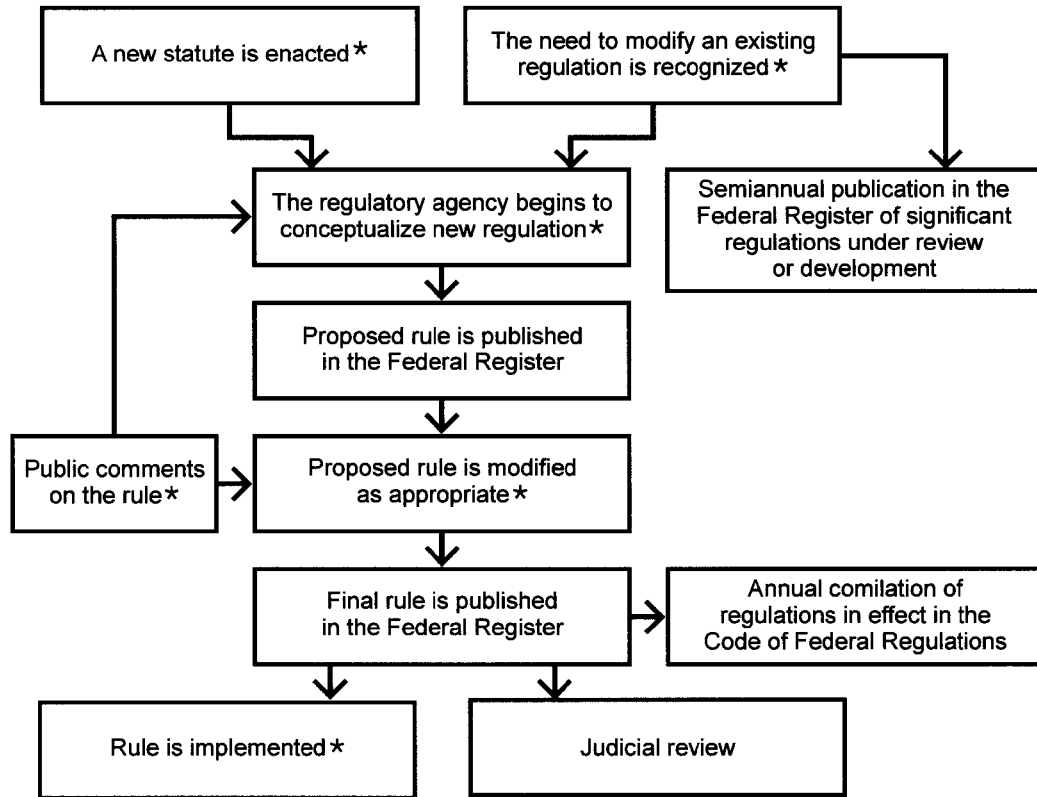
- The passage of a new law that requires regulatory action
- An agency's recognition that new regulation is needed or that an existing regulation needs to be updated, changed, clarified, or rescinded

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<sup>9</sup> Adapted from *Regulations and Health: Understanding and Influencing the Process*.

- Step 2**            **Conceptual formulation.** The agency identifies the general goals and the factual information it needs in order to write a useful regulation. Ideas are shaped by talking with relevant constituents and conducting background research. The agency also estimates the expected impact of the regulation. As ideas are crystallized, specialists begin drafting the formal regulatory language. State and local health officials may help shape federal regulatory developments that affect their programs.
- Step 3**            **Publication in the *Federal Register*.** The agency publishes a notice of the proposed regulation in the *Federal Register*. (The *Federal Register* is published several times a week and provides notice of all federal regulatory developments having general applicability and legal effect.)
- Step 4**            **Public input and modification.** Interested parties may submit written comments on the proposed regulation during the public comment period. In some instances public hearings are held to accept written and oral testimony. Agencies must consider the comments received during the public comment period when drafting the final regulation. Health officials can often provide valuable information about the impact of the federal rules on their state or local programs thus helping to influence the final language of the regulation.
- Step 5**            **Final publication in the *Federal Register*.** The final regulation is published in the *Federal Register* with a discussion of the comments the agency received and why these were accepted or rejected. The Final Rule must be published in the *Federal Register* at least thirty days before it is to take effect.
- Step 6**            **Inclusion in the *Code of Federal Regulations*.** The regulation is included under one of the fifty titles of the Code of Federal Regulations (CFR), according to the subject matter. The CFR is revised annually and contains all federal regulations in force.
- Step 7**            **Implementation or challenge.** The regulation is implemented. It may also be challenged in court on the basis that it is not consistent with the enabling statute, that there were procedural errors, or that the rule is not supported by facts in the administrative record. If the court agrees with the challenge, it will invalidate the regulation and send it back to the agency for further consideration.

**Figure 7b. Steps in the Development of a Federal Regulation**



\* Indicates step in process where health official may get involved.



## Stop and think...

How do your state and local regulatory processes differ from the federal process?

Which process seems better? Why?

During which steps in the regulatory process might a public health professional participate?

What types of input might the public health professional provide?

[If you cannot fully answer these questions or if you want to know more, you can use your networking sources or discuss them in your study group.]

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**See Group exercise 7.5 at the end of the module.**



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## Review of terminology...

Not all of these are strictly legal terms, but you may want to think about how they are used in the process of developing laws and regulations. Add additional useful terminology if you wish.

Administrative Procedure Act

Advocacy

Code of Federal Regulations

Federal Register

Hatch Act

Legislative specifications

Stakeholders

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# Self-check review

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Check your knowledge of the preceding material by answering the questions below. Circle the letter of the correct response.

1. The responsibility of legal counsel in drafting new laws is to
  - A. Make sure issues of due process and equal protection are covered
  - B. Make sure all the stakeholders' views are represented
  - C. Anticipate possible administrative difficulties
  - D. Ensure that the public health problem is clearly defined
  
2. It is most important to involve stakeholders when
  - A. Deciding whether to introduce a new law
  - B. When negotiating details in the wording of the law
  - C. When advocating for approval of legislation
  - D. All of the above
  
3. Specifications should
  - A. Only be drawn up by lawyers
  - B. Closely mirror the specific situation that led to the need for the new law
  - C. Be broadly stated to allow for wide application of the law
  - D. Anticipate questions about implementation and compliance
  
4. The Hatch Act
  - A. Allows government employees to be party candidates for office
  - B. Prohibits state and local employees from campaigning for party candidates
  - C. Covers employees of educational and research organizations
  - D. Prohibits public employees from giving expert testimony in the legislative process
  - E. None of the above

5. Amendments to bills are made
  - A. In committee or on the floor
  - B. Only in committee
  - C. Only on the floor
  - D. By the governor
  - E. Only with a two-thirds majority
  
6. Committees
  - A. Write legislation
  - B. Decide whether a bill should be sent to the floor for vote
  - C. Override the governor's veto
  - D. All of the above
  
7. The *Federal Register*
  - A. Sets rules for promulgation of new regulations
  - B. Contains all federal regulations in force
  - C. Informs the public about possible new regulations
  - D. Informs the public about court challenges to existing regulations

Answers:

1.A, 2.D, 3.D, 4.E, 5.A, 6.B, 7.C

# References

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*Manual of Public Interest Lobbying in Illinois*, Illinois Association of Schools Boards, 209 South Fifth Street, Springfield, Illinois, 62703.

Public Health Leadership Institute. Unpublished case study in policy development, Lead poisoning prevention: Enactment of a public health city ordinance. University of Illinois-Chicago, School of Public Health.

The Internet address for the *Federal Register* is:  
[http://www.access.gpo.gov/su\\_docs/aces/aces140.html](http://www.access.gpo.gov/su_docs/aces/aces140.html).

# Group exercises

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## Exercise 7.1      **Problem Definition**

### **Case Study: Development of a Municipal Lead Poisoning Prevention Code**

In November 1986, in response to increasing public concern and the release of new scientific information about the dangers of lead, the Mayor of Chicago created a City Task Force on Lead Poisoning, composed of community leaders and various city department heads.

The Task Force formed a Subcommittee on Legal Reform and Legislation, which was responsible for reviewing existing federal, state, and city policies and legislation. The subcommittee reported that:

- a. Virtually every lead poisoning case in housing court originated as the result of a child ingesting lead paint from peeling walls, doors, or windows.
- b. Court action seeking abatement of lead paint was dangerously slow due to insufficient utilization of the legal and equitable remedies available.
- c. Property owners were not always quick to respond.
- d. The main remedy available to the city against recalcitrant owners was to seek fines. Fines, however, were seldom assessed by judges or collected by the city.
- e. Remedies were needed to allow the city to seek swift action in those cases where it was evident that the owner was not prepared to act.
- f. Punitive sanctions did not go far enough to penalize recalcitrant owners.

- g. Residential properties were not being properly or fully inspected for lead-based paint.
- h. The public and potential purchasers of buildings affected by lead paint were given insufficient warning about lead-associated health hazards.
- i. Universal screening of all children under the age of six or before enrollment in a preschool program was not mandated.

### **Discussion questions**

How would you define the specific problem(s) at issue?

Do these findings call for new legislation or do the problems arise from inadequate resources, poor management, the need for different administrative and enforcement approaches, and/or new educational or consultative solutions?

What are the options for responding to the listed problems?

What would a new ordinance need to specify? List at least 10 specifications.

### **Exercise 7.2**

#### **Group discussion of the case study in the main text (page 7).**

Which activities do you think were instrumental in passing the amended ordinance?

What, if any, conduct was detrimental to the effort?

How does this compare to your own experience in public health policy development?

**Exercise 7.3      Legislative specifications**

The following memorandum was written by the Director of the City Health Department's Lead Poisoning Prevention Department to the City's Law Department:

**Memorandum**

Date:      March 3, 1996  
To:        Mr. Joe W. Drafter  
              City Law Department  
From:      Ms. B.J. Policymaker  
              Director, City Lead Poisoning Prevention Department  
Subject:    Specifications for City's Lead Poisoning Prevention Code  
              Amendments

As we've discussed, I would like to present a draft ordinance to the members of the City Council Health Committee by July 4, revising the municipal Lead Poisoning Prevention Code. Here are the specifications for the code amendments:

1. Clarify that the law is violated whenever lead-based paint poses some reasonable risk to a child, without requiring proof that a child has already been poisoned or is likely to be poisoned.
2. Require blood testing of all children (ages 6 months to 6 years) before they are admitted to daycare centers or schools.
3. Empower the city to inspect all buildings for lead hazards and, if tests prove positive, empower the city to order abatement and other appropriate measures.
4. Make it illegal to maintain a lead hazard that endangers the health of children in a building, school, or childcare facility.
5. Authorize the city to use administrative adjudication in cases involving lead hazards, to reduce court backlog and speed the process.
6. Authorize the city to charge those who can afford to pay for costs of testing and inspection.



Thank you for your assistance. Please send me the ordinance amendments to review once they are drafted.

**Discussion questions**

1. Which specifications, or portions thereof, require further explanation and greater detail? Why?
2. Which specifications, if any, are sufficiently clear and detailed to guide the city attorney? (The answer may depend on the knowledge and expertise of the city attorney.)
3. Would your law department have sufficient expertise in this area to draft the ordinance amendments based upon these specifications?

Hint: Picture how the code amendments will be implemented. Ask yourself, If this code were addressed to me, how exactly would I go about carrying it out?

**Exercise 7.4**

All of the examples in the module are about lead poisoning. As a group, decide on a public health problem other than lead poisoning that might benefit from new legislation or regulations. This can be far fetched or wishful thinking, since it is just for practice.

1. Define the problem and carefully specify a legal solution.
2. Figure out who your stakeholders are, who will interpret and enforce the new law or regulation, who will obey it, who will benefit, and who might oppose it.
3. Outline the proposed legislation or regulation, with specifications about objectives, implementation, and ensuring compliance.
4. Figure out which key policymakers need to add their support.
5. If your group proposed a regulatory response, determine which, if any, board or commission is responsible for the rule-making

**Exercise 7.5**

Discuss experiences members of your learning group have had with the legislative or rule-making process.

1. Did the actual process differ from the theoretical explanation presented in the module? If so, how?
2. What, if any, practical advice would you give your colleagues who are about to become involved with legislative or rule-making activities?

# To register for continuing education credit and to evaluate this module

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## Registering for Continuing Education Credit

To receive credit for this module you must submit course enrollment forms and the answers to the **Evaluation and Test** (located on the following pages) to CDC. There are several ways to complete this registration process:

### ***Complete the forms online.***

- U Go to the PHTN website [www.cdc.gov/phtn](http://www.cdc.gov/phtn) and complete the registration and evaluation online. Directions will be given at the website.

### ***Complete the forms on paper. There are two ways to obtain the forms from CDC. (If you plan to study additional modules, you may want to request enrollment materials for those modules also at this time.)***

- U Request the enrollment materials online by going to the following URL at the PHTN website <http://www.cdc.gov/phtn/legal-basis/req-form.htm> and completing the online request form. After the online form is submitted, an enrollment packet will be mailed to you with instructions.
- U Request the enrollment materials by calling **1-800-41-TRAIN** (1-800-418-7246). At the prompts, press 1, then 3. Please clearly speak your name, mailing address, daytime phone number, and the correct module name and number. The enrollment materials will be mailed to you with instructions.

If you are unable to register online, you will have to wait several weeks until your course enrollment materials arrive in the mail. If this is the case, you might want to complete the Evaluation and Test immediately after you finish the module by marking your answers directly on the following pages (or make a photocopy) and then, when the enrollment materials arrive, transfer your answers to the answer sheet included with the materials.

## Evaluating the Module

**If you are registering for continuing education credit**, you will be asked to complete an evaluation as part of that process.

**If you are not interested in receiving continuing education credit, we ask that you please take time to evaluate the module.** Follow the procedure specified above for getting continuing education credit, but indicate in the first question on the **Evaluation and Test** that you do not wish to receive continuing education credit. Although this is not required, your opinion of the module is important to us. By letting us know if this module was effective for you, we can improve future editions, as well as other PHTN courses.

**Evaluation and Test**  
***The Legal Basis of Public Health***  
***Module 7, Policy Development***  
**COURSE #SS0007**

**Objectives for *Module 7, Policy Development***

- g Identify the issues you should consider when thinking about initiating legal solutions to public health problems.
- g Identify the types of information that you should contribute to the development of legislative and regulatory specifications.
- g Identify the ways you can help with the negotiating, drafting, reviewing, and advocating of regulations to implement new and existing statutes and ordinances; describe why your contribution is so important.
- g List the basic steps involved in the legislative process and the federal regulatory process and identify points where you can provide expertise to support an initiative.

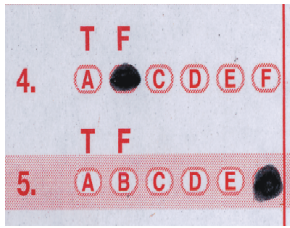
**N**Please use the red *CDC Answer Sheet* included in the enrollment materials to complete the following questions.

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***Tell us about yourself...***

- 1. What type of continuing education credit do you wish to receive?**
  - A. (CME) *Not Available for this Course*
  - B. Continuing Nursing Education (CNE)
  - C. Continuing Education Units (CEU)
  - D. do not want continuing education credit
  
- 2. Have you previously completed *Module 1, Introduction?***  
***(Completion of Module 1 is required before taking any of the other modules.)***
  - A. yes
  - B. no
  - C. I have just completed ***Module 1, Introduction.***
  
- 3. Are you a**
  - A. Nurse
  - B. Physician
  - C. None of the above

**Please note:** Question 5 is a continuation of question 4. Please answer each question, but choose only **ONE** occupation. Your answer to one of the these questions will be **F. None of the above**. For example, a Health Educator would answer as follows:



**4. Which of the following best describes your current occupation?**

- A. Epidemiologist
- B. Health Educator
- C. Laboratorian
- D. Pharmacist
- E. Physician Assistant
- F. None of the above

**5. Which of the following best describes your current occupation?**

- A. Field Inspector (nursing homes, restaurants, etc.)
- B. Manager/Supervisor
- C. Environmental Health Worker/Sanitarian
- D. Lawyer/Attorney
- E. Other public health professional
- F. None of the above

**6. Which of the following best describes the organization in which you work?**

- A. Academic
- B. Private health care setting
- C. Federal government
- D. State government
- E. Local government
- F. Other organization

***Tell us about the module...***

**7. How did you first learn about this module**

- A. State publication (or other state-sponsored communication)
- B. MMWR
- C. CDC website (not including PHTN website)
- D. PHTN source (PHTN website, catalog, e-mail, or fax announcement)
- E. Colleague
- F. Other

- 8. How did you obtain this module?**
- A. Purchased from the Public Health Foundation
  - B. Downloaded from the PHTN website
  - C. Borrowed or copied materials from someone else
  - D. Other
- 9. What was the most important factor in your decision to obtain this module?**
- A. Content
  - B. Continuing education credit
  - C. Request from supervisor
  - D. Previous participation in PHTN training(s)
  - E. Ability to take the course at my convenience
  - F. Other
- 10. I completed this module**
- A. As an individual learner
  - B. As part of a learning group that organized itself
  - C. As part of a learning group that was organized by someone outside of the group
- 11. My completion of this module included interaction(s) with an expert(s) (or reasonably experienced person) on the topic?**
- A. Yes
  - B. No
- 12. My interaction(s) with the expert(s) on this topic could be described as follows**
- A. I had no interactions with an expert
  - B. One or more sessions organized by someone outside of the group
  - C. One or more sessions organized by someone within my group
  - D. One or more informal consultations that I initiated on my own
- 13. How long did it take you to complete this module?**
- A. 1 - 2 hours
  - B. 3 - 4 hours
  - C. 5 hours or more
- 14. How many of the ten modules comprising the *Legal Basis of Public Health* have you completed?**
- A. 1 or 2 modules
  - B. 3 to 5 modules
  - C. 6 to 9 modules
  - D. All 10 modules

15. **How many of the ten modules comprising *The Legal Basis of Public Health* do you plan to complete?**  
A. 1 or 2 modules  
B. 3 to 5 modules  
C. 6 to 9 modules  
D. All 10 modules
16. **Please rate your level of knowledge prior to completing this module.**  
A. Had a great deal of knowledge about the content  
B. Had a fair amount of knowledge about the content  
C. Had limited knowledge about the content  
D. Had no prior knowledge about the content  
E. No opinion
17. **Please estimate your knowledge gain due to completing this module.**  
A. Gained a great deal of knowledge about the content  
B. Gained a fair amount of knowledge about the content  
C. Gained a limited amount of knowledge about the content  
D. Did not gain any knowledge about the content  
E. No opinion
18. **If this module is further evaluated through the use of focus groups or other methods (e.g., follow up questionnaires) would you be willing to participate?**  
A. Yes  
B. No

Please use the scale below to rate your level of agreement with the following statements about this module.

- A. **Agree**  
B. **No opinion**  
C. **Disagree**  
D. **Not applicable**

19. **The objectives were relevant to the purpose of the course.**
20. **I would recommend this module to my colleagues.**
21. **I believe completing this module will enhance my professional effectiveness.**
22. **The content in this module was appropriate for my training needs.**
23. **Reading the text on my own was an effective way for me to learn this content.**

24. The self-study questions contributed to my understanding of the content.
25. The group exercises contributed to my understanding of the content.
26. The Coordinator Guide contributed to my ability to have a learning experience appropriate to my (or my group's) needs.
27. Downloading the materials from the PHTN website was user-friendly.
28. Ordering the materials through the Public Health Foundation was user-friendly.
29. Ordering the materials through the 1-800-41-TRAIN phone number was user-friendly.
30. I am confident I can identify the issues I should consider when thinking about initiating legal solutions to public health problems.
31. I am confident I can identify the types of information that I should contribute to the development of legislative and regulatory specifications.
32. I am confident I can identify the ways I can help with the negotiating, drafting, reviewing, and advocating of regulations to implement new and existing statutes and ordinances; and describe why my contribution is so important.
33. I am confident that I can list the basic steps involved in the legislative process and the federal regulatory process and identify points where I can provide expertise to support an initiative.