How Do Health Departments Create Regulations, Policies, and Guidance Documents? Overview of Administrative Law: Part 2

Full Script

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Introduction & Presentation Overview

Slide 1

Welcome to the Public Health Law Academy's training addressing the question **How Do Health Departments Create Regulations, Policies, and Guidance Documents?** This training – Part 2 in a three-part series on administrative law – is tailored from a training that was developed by ChangeLab Solutions and the Public Health Law Program at the Centers for Disease Control and Prevention.

You might be asking, "Why do I need to take this course?" If so, we would ask, "Do you work in or with a health department? Are you involved in developing public health regulations or providing data or evidence to support development of regulations? Have you participated in drafting public health policies or guidance documents that explain licensing standards or other regulatory requirements? Or have you helped draft documents that set internal agency processes for public health practitioners to follow when implementing and enforcing public health programs?" This training focuses on the laws governing how public health practitioners carry out these common regulatory activities and discusses how practitioners can promote health equity in their day-to-day tasks. It's critical for public health practitioners to understand this area of law – which is called *administrative law* – because it touches nearly every aspect of modern life, and public health practitioners encounter it every day.

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Before we begin, one of the content developers, ChangeLab Solutions, wants me to remind you that the information provided in this training is for informational purposes only and does not constitute legal advice. ChangeLab Solutions does not enter into attorney-client relationships.

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Furthermore, the other content developer, the Centers for Disease Control and Prevention, wants me to remind you that while every effort has been made to verify the accuracy of these materials, legal authorities and requirements may vary from jurisdiction to jurisdiction. The contents of this presentation have not been formally disseminated by the Centers for Disease Control and Prevention and should not be construed to represent any agency determination or policy. Always seek the advice of an attorney or other qualified professional on any questions you may have regarding a legal matter.

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Before you take this training, we encourage you to watch Part 1 of this series, the training called **What Legal Powers Do Health Departments Have?** Part 1 covers basic concepts that lay the foundation for today's discussion. It defines *administrative law* and explores how health departments can work within the requirements of administrative law to shape equitable health outcomes. It also identifies some key limits on public health agencies' regulatory authority and discusses why it's important for public health officials to understand administrative law.

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Building on the basic concepts introduced in Part 1, today's training explores how administrative law principles guide two common activities carried out by public health agencies: creating regulations – also known as *rulemaking* – and writing policies and guidance documents. After reviewing an overarching framework for agency activities and other key concepts from Part 1, we will discuss the following new topics:

- First, we'll explore regulations, including what they are and when and how public health agencies can create them in line with administrative law principles. We'll also identify strategies for promoting health equity throughout the rulemaking process.
- Next, we'll discuss common legal challenges to public health regulations, and we'll explain why it's important for public health practitioners to be aware of these types of legal issues when creating regulations.
- We'll then explore what policies and guidance documents are, how they differ from regulations, and ways they can be used to promote health equity.
- Finally, we'll outline some best practices for issuing policies and guidance documents to ensure that the process is fair, equitable, and accessible to everyone.

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In Part 3 of this training series, we will continue our discussion of how administrative law principles guide day-to-day health department activities, including issuing permits and licenses, conducting investigations and inspections, and enforcing public health laws.

We note that tribal and territorial health departments also encounter administrative law in their day-to-day work; however, this training series is focused specifically on state and local administrative law.

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As you may recall from Part 1 of this series, the five activities we will discuss in Parts 2 and 3 fall along a continuum from making laws to implementing and enforcing them. The fact that agencies engage in such a broad spectrum of regulatory activities is one reason why administrative law – including its limits on agency authority – is important for public health practitioners to understand.

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Parts 2 and 3 of this training series will also explore how health departments can engage community members and promote health equity while carrying out these five common regulatory activities in line with administrative law requirements.

We'll try to use as many examples as possible throughout today's presentation, to bring these concepts to life, and we also encourage you to think of examples from your own work.

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To help you get started, we encourage you to think about how the regulatory activities that are the focus of today's discussion can incorporate the following equity-promoting strategies, which were introduced in Part 1:

- Engaging community members
- Building partnerships
- Inviting varying perspectives
- Considering how you use data to identify inequities or track unintended consequences
- Equitably directing resources
- Promoting systems thinking
- Evaluating outcomes and being accountable for decisions that affect the public

Finally, we note that the administrative law principles that govern the activities of public health agencies vary by jurisdiction, so it's always important to consult an attorney licensed in your state.

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Before we dive into new topics, let's take a moment to review some key concepts from Part 1 of this series. Our first question is . . .

What is health equity?

A. A state where everyone has a fair and just opportunity to be as healthy as possible

B. Applying public health interventions to everyone in the same way, irrespective of need

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If you selected A, you're correct! In Part 1, we introduced a frequently cited definition of health equity from Dr. Paula Braveman, one of the nation's leading experts on health equity and health disparities. She and her colleagues explain, "Health equity means that everyone has a fair and just opportunity to be as healthy as possible. This requires removing obstacles to health such as poverty, discrimination, and their consequences, including powerlessness and lack of access to good jobs with fair pay, quality education and housing, safe environments, and health care."

Part 1 of our training series also explained that equity is different from equality. An intervention focused on equality would apply the same one-size-fits-all solution to everyone, irrespective of need. This approach can sometimes leave people behind or even widen health disparities. An intervention focused on advancing health equity recognizes that the people who have the fewest resources require greater, not just equal help in order to equalize their opportunities.

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Part 1 of this training also explained that achieving health equity requires eliminating the fundamental drivers of health inequity. The drivers of inequity include structural discrimination, especially structural racism, which law professor Ruqaiijah Yearby has described as "the way our systems are structured to advantage the group in power and disadvantage racial and ethnic minorities." Some additional drivers of health inequity are income inequality and poverty, disparities in opportunity, disparities in political power, and governance that limits meaningful participation. This training will dive deeper into these concepts by providing examples of how public health practitioners can use their regulatory powers to address the drivers of health inequity.

Dr. Braveman's definition of health equity is an accepted and frequently cited definition, but it's one of many. Your idea of equity – and your colleagues' and community partners' idea of equity – might be different. The primary goal is for health equity efforts to be effective and to promote core principles such as fairness, justice, and opportunity to reach one's full health potential. Fairness is also one of the key principles of administrative law, which brings us to our next review question:

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Administrative law can be defined as . . .

A. The legal principles that govern the activities and organization of administrative agencies

B. The guardrails that agencies must stay within as they engage in regulatory activities

C. The law that applies to the legislative branch of government

D. Both A (the legal principles that govern administrative agencies) and B (the guardrails that agencies must stay within as they engage in regulatory activities).

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If you chose D, you're right! As we learned in Part 1, administrative law can be defined as the legal principles that govern the activities and organization of administrative agencies. An *agency* is an organization within the executive branch of government with authority to implement certain legislation. Public health departments are one type of administrative agency, encompassing the Department of Health and Human Services at the federal level as well health departments at state and local levels. Administrative law provides guardrails that agencies must stay within when engaging in their everyday regulatory activities, to ensure appropriate separation of powers, to promote fundamental fairness to regulated parties, and to ensure transparency and accountability to the communities that agencies serve.

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Our last review question is . . .

Why is administrative law important for public health?

A. Health departments are directly subject to administrative law.

B. Understanding administrative law can facilitate interagency collaboration.

C. Regulatory actions can profoundly affect public health practice and health equity.

D. All three: A (health departments are directly subject to administrative law); B (understanding administrative law can facilitate interagency collaboration); and C (regulatory actions can profoundly affect public health practice and health equity)

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If you selected D, you're correct! Part 1 identified three reasons that administrative law is important to the everyday practice of public health.

First, health departments themselves are administrative agencies and are therefore directly subject to the administrative law doctrines adopted in their jurisdictions. Understanding administrative law principles can promote good governance within health departments, including advancing the tenets mentioned in the previous question: fairness, transparency, and accountability to the public. Ultimately, applying these tenets helps health departments fulfill their mission of ensuring better health for all.

Second, understanding administrative law can facilitate interagency collaboration. Public health work relies on a wide range of agencies *other than* health departments, especially when the goal is addressing the social determinants of health and advancing health equity. For example, public health practitioners might want to partner with officials in labor departments who oversee occupational safety and wage standards or with officials in departments of social security who oversee public benefits programs. Understanding administrative law can help practitioners in health departments identify how they can influence or participate in the regulatory process of other agencies or collaborate directly with other agencies through a Health in All Policies framework or interagency work group.

Third, regulatory actions undertaken by administrative agencies can profoundly affect public health practice and health equity throughout the nation. A regulation, policy, or licensing or enforcement strategy pioneered by one health department can affect practices in health departments at higher or lower levels of government or can spread to other agencies at the same level of government, resulting in adoption of the policy throughout a state or the nation.

In summary, understanding public health agencies' regulatory powers and how to deploy them equitably – in alignment with administrative law principles – can significantly affect public health practice and improve population health outcomes.

Part 1: What are the steps for creating regulations?

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Now that we've finished our review, let's begin by exploring the steps for creating regulations.

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In this section of the training, we will answer three central questions related to regulations, to deepen our understanding of the rulemaking process.

- We'll begin by defining the term *regulation* and reviewing how regulations differ from legislation.
- Then, we'll explore *when* health departments can create regulations.
- Finally, we'll discuss *how* health departments create regulations and how the process can promote health equity.

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Creating regulations falls at the beginning of the continuum of agency activities because it relates to agencies' power to make laws.

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First, we need to define a few terms.

As you may recall from Part 1, a *regulation* is a law drafted and finalized by an administrative agency, such as a health department. In contrast, *legislation* is a law drafted and adopted by a legislative body.

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On the left side of this chart, you can see that the terminology for adopted legislation differs according to the level of government.

- At the federal or state level, legislation is known as a *statute*.
- At the local level, legislation adopted by a city council or county board of supervisors is known as an *ordinance*.

Typically, the terminology for laws created by administrative agencies does not vary according to the level of government. However, you might sometimes hear the term *rule* in addition to *regulation*. These terms mean the same thing and can be used interchangeably. In this training, we generally use the term *regulation*.

We'll provide examples to help distinguish between legislation and regulations later on. The key thing to remember at this point is that regulations created by administrative agencies have the effect of law, just like legislation, and can be enforced against individuals and private businesses. Whereas it is common for federal and state agencies to engage in rulemaking – that is, creating regulations – local agencies' authority to create regulations varies across jurisdictions, which is why you see the word *sometimes* on this slide. To learn more about the similarities and differences between legislation and regulations, as well as variations in the structure of public health governance and local authority to create regulations, refer to Part 1 of this training series or check out the Public Health Law Academy training called **Structure of Government**.

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So, when can health departments and other public health agencies make regulations?

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Part 1 of this training explained that the US Constitution vests "all legislative Powers" in Congress, meaning that only Congress has the authority to make federal laws.

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The same is true at other levels of government. State constitutions typically vest the power to make laws in the state legislature, as you can see in this example from the State of Washington.

And at the local level, county and city charters typically vest the power to make laws in the local legislative body. For example, the Seattle city charter vests all legislative powers in a mayor and city council. The charter further states, "Every legislative act of [the City of Seattle] shall be by ordinance," which must be adopted by a majority vote of the city council.

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However, a legislative body can *delegate* its power to make laws to administrative agencies in the executive branch of government. Note that administrative agencies do not have any inherent power to make laws. Therefore, an administrative agency – including a health department – can make regulations *only* when a legislative body has given the agency that authority.

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This limit on when an administrative agency can make regulations is rooted in the constitutional concept of separation of powers: the idea that government responsibilities are divided across the three branches of government – the legislative, executive, and judicial branches. Each branch is generally prohibited from exercising the responsibilities of the others. Agencies, which sit in the executive branch of government, generally have the power only to *enforce* laws passed by legislative bodies – unless legislative bodies delegate their lawmaking power to the agencies. Courts (the judicial branch) act as a check on agencies, making sure that agencies are not acting outside the scope of their delegated authority, which would infringe on the powers of the legislative branch. We will discuss this concept in greater detail when we provide an overview of common challenges to public health regulations.

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A delegation of authority from a legislative body to a specific administrative agency is typically spelled out in legislation. For example, this Florida statute, which was adopted by the state legislature, directs the state's department of health to "adopt and enforce sanitation rules consistent with law to ensure the protection of the public from food-borne illness." This is a fairly narrow and specific delegation of authority. It gives the state health department authority to adopt regulations spelling out the details of a food safety program but not, for example, to regulate food marketing and labeling, which would likely be outside the scope of this particular delegation of authority.

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A delegation of authority to an administrative agency may also appear in a state constitution or, at the local level, a city charter. Here's an example from New York City's charter, which creates a local board of health within the Department of Health and Mental Hygiene. The charter grants the local board of health the authority to make regulations "in regard to any matter contained in the health code." The health code is the section of the New York City municipal code containing ordinances about public health.

Compared with the Florida statute we just discussed, which granted a limited delegation of authority, this charter provision is very broad; it gives the local board of health the authority to make regulations on a wide range of issues addressed in the health code, from sanitary standards for food service establishments, to recordkeeping requirements for pet stores, to regulations implementing the city's Smoke-Free Air Act.

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A delegation of authority can either enable or limit a health department's ability to design and implement equity-promoting interventions – and may even do both at the same time! For example, in 2008, New York City launched a "green carts" initiative authorizing vendors to sell fresh fruits and vegetables in designated low-income neighborhoods. The New York City Council adopted ordinances amending the food vendor code to create the green cart program and specified the total number of green cart licenses that could be issued. The ordinances delegated authority to the New York City Board of Health to make regulations to implement the program. Based on their authority, the board of health created regulations that exempted green carts from equipment requirements applicable to other food vendors, such as the need to have dishwashing sinks and overhead structures, making the regulations less burdensome. The regulations also specified that the city would supply green cart vendors with distinctive umbrellas to help with marketing. Evaluations of the green cart program found that it successfully provided entrepreneurial skills and opportunities for both green cart owners and employees. In addition, evaluations found that the program increased fruit and vegetable consumption among customers, many of whom had low income. This example shows how legislation can create equity-promoting programs and how agencies can use their delegated authority to implement the programs in ways that further health equity – for example, by providing technical support or resources or by tailoring regulatory requirements to account for different circumstances.

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On the other hand, the legislation authorizing the green cart program did not give the board of health the authority to adopt regulations specifying what types of penalties would apply when green cart vendors violated their licenses. Instead, green cart vendors were subject to the same general penalties as all other food vendors – including criminal citations punishable by imprisonment or a fine of up to $1,000 for unlicensed vending, as well as civil penalties ranging from $25 to $500 for other types of violations. Fines like these may be especially burdensome for low-income entrepreneurs. A 2012 study found that New York City food vendors who were fined $399 or less paid the fine only 47% of the time. Other research found that fruit and vegetable carts in one Chinatown neighborhood, where the majority of vendors were immigrants, were subject to a disproportionate share of the citations issued to mobile food vendors citywide. The researchers found that the city's aggressive enforcement in this neighborhood drove fruit and vegetable vendors out of business, diminished the market for fresh foods, and reduced fresh food access for Chinatown residents. For example, one vendor – who had sold food for 11 years – reported that after receiving fines totaling $7,000, he was unable to renew his license, and his family had to go on public assistance. This story exemplifies a broader problem; outside of the food vending context, the US Department of Justice has written that fines for "minor offenses can generate crippling debts, result in jail time because of an inability to pay, and result in the loss of a driver's license, employment, or housing."

In short, the board of health's lack of authority to specify alternative, less punitive penalties for violations stemming from the green cart program had adverse consequences for health equity among some of the intended beneficiaries of the program – namely, entrepreneurial food workers looking for a path toward employment and economic stability. Alternative penalties could have included, for example, warnings, mandatory trainings, or community service. In Part 3 of this training series, we will go into greater detail on equitable enforcement approaches that health agencies can consider – such as alternatives to fines and fees or strategies to reduce the risk of disproportionate enforcement against people who are affected by structural drivers of inequity, like poverty and structural racism.

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As we wrap up this topic, some of you might be wondering why legislatures delegate their authority to make regulations to administrative agencies in the first place. Good question!

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There are three primary reasons:

First, legislative bodies – such as Congress, state legislatures, and city councils – do not always have the subject matter *expertise* to draft detailed directives in specific regulatory areas, including areas related to public health such as standards for drinking water, septic system design, hospital operations, and many others. Note that legislatures are not *required* to delegate authority to make regulations to administrative agencies; they can always work with their own staff to gather the information they need to draft detailed and accurate laws. However, delegating regulatory authority to expert agencies is one option that is frequently used to save time and effort – which brings us to our next point.

Delegating authority to administrative agencies can sometimes be the most *efficient* course of action. Legislatures may not have time to hammer out all of the details needed to address a problem or implement a particular program – especially if they are working on a tight timeline to get legislation passed. In this circumstance, it can be more efficient for legislatures to pass laws that set a general framework and then delegate authority to administrative agencies to figure out the most effective way to implement the legislation.

Finally, it's impossible for legislatures to anticipate all possible circumstances that may arise after legislation is adopted. Legislatures can amend laws, but the process can be time-consuming. Delegating authority provides *flexibility* so that administrative agencies can adopt regulations to address conditions or emergencies that the legislative body did not anticipate, which may save the legislative body time in the long run.

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For example, in 2020, the Maryland state legislature adopted a bill reducing the blood lead level that triggers environmental investigations of homes and medical case management for children. As a result, the level now conforms with CDC guidelines. Because state elected officials are not experts on the technical standards for conducting environmental investigations, the legislation directed the Maryland Department of the Environment to issue regulations. The Department of the Environment then used its scientific expertise, along with information and comments submitted by affected community members, to issue regulations consistent with best practices for reducing childhood lead exposure. Over time, the Department of the Environment may need to update and revise these regulations as the science and best practices evolve. Generally, delegated authority allows this flexibility.

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Before moving on, let's review what we've learned so far with a quick question.

True or false? State and local health departments have inherent authority to adopt regulations.

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The answer is "False." State and local health departments may adopt regulations *only* when a legislature has given them that authority. Members of the public can challenge health departments that adopt regulations without having received the necessary authority from the appropriate legislative body. For this reason, it's prudent for state and local health departments to confirm that they have been granted the authority to regulate in a particular issue area *before* starting to develop regulations. Consulting with the agency's attorney can be helpful.

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Now that we know *when* public health agencies can make regulations, let's address *how* they do it – and how they can do it equitably. As mentioned earlier, the process of making regulations is often called *rulemaking*, and we will use that term in the following slides.

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To see how rulemaking works in practice, let's meet Wendy.

- Wendy has a degree in public health and works for her state's public health department.
- The state legislature recently updated its retail food code to address food safety and sanitation for mobile establishments such as food trucks and produce carts, and Wendy's boss has asked her to lead the process of developing new regulations to implement the changes to the law.

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Although the example focusing on Wendy in Parts 2 and 3 of this training series is related to food safety, the basic concepts we'll cover are the same for public health professionals who work in different practice areas or have different types of expertise. In other words, the steps that public health professionals must follow – whether they are developing regulations to implement a new public health program or issuing licenses and inspecting facilities to ensure compliance – will always be rooted in the basic administrative law concepts and procedural steps we will outline in Parts 2 and 3. These concepts and steps need to be used in all areas of public health, whether you're developing regulations to ensure safe drinking water, licensing tobacco retailers, or inspecting child care facilities.

Administrative law is not limited to a specific regulatory topic or practice area. It is about the *process* of developing, implementing, and enforcing laws in general.

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Now that we have that context, let's return to our example. Wendy has already consulted with the state health department's legal team to confirm that the state retail food code delegates authority to the health department to make regulations addressing mobile food establishments. Wendy also learned from the legal team that her state's administrative procedure act sets forth certain steps that Wendy must follow when developing regulations.

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As you may recall from Part 1, every state has an administrative procedure act – or APA, for short – that sets out the rules and procedures that agencies must use to develop regulations. These are known as *rulemaking procedures*.

Rulemaking procedures are typically similar across states and are generally analogous to procedures in the federal APA, which applies to federal agencies such as the US Food and Drug Administration and the US Environmental Protection Agency. The basic rulemaking procedures outlined in state and federal APAs will be the focus of this part of the training. Because there may be some variation in the details of state APAs, it's always important to consult an attorney licensed in your jurisdiction.

It's also important to note that there is significant variation at the local level in rulemaking authority and procedures. Because the structure and responsibilities of local health departments can vary widely, it's important for local health officials to consult with their legal team to confirm their rulemaking authority, best practices, and procedures to use *before* beginning the rulemaking process.

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Based on the guidance Wendy received on her state's administrative procedure act, she knows that there are five basic steps in the rulemaking process:

1. Conduct extensive research
2. Draft the text of the proposed regulation
3. Provide notice to the public
4. Provide an opportunity for public comment
5. Revise and finalize the regulation

Although all of the steps are important, steps 3 and 4 are bedrock administrative law requirements. These steps are so fundamental that people often use the term *notice-and-comment rulemaking* to describe the process of issuing regulations. In the following slides, we'll address each of these five steps in turn. We'll also discuss how Wendy can go beyond these minimum requirements to engage community members and promote health equity.

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The first task for Wendy and her team is to conduct extensive research on food safety issues and possible regulatory solutions. Doing research can establish a strong basis and purpose for the regulation, which can be helpful later if the regulation is challenged in court.

Here are some possible research topics for Wendy:

- The scope of the problem being addressed – for example, rates of food safety-related illnesses for mobile food establishments
- Efficacy of different types of solutions – for example, whether construction and design standards would improve food safety
- Public support for various approaches
- Potential effects of the regulation on populations that are disproportionately affected by structural drivers of inequity, like poverty and structural racism
- Costs to the government of different regulatory strategies

One tool that public health agencies can use to support their research is *legal epidemiology*, which is the scientific study and deployment of law as a factor in the cause, distribution, and prevention of disease and injury in a population. Legal epidemiology can help health departments learn how other jurisdictions are regulating a particular subject and can help measure how well those laws are working so they can choose the most effective approach. For more information on this topic, we encourage you to watch the Public Health Law Academy's three-part series on legal epidemiology.

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Wendy's research can also help her tailor her regulatory proposal to avoid unintended negative consequences for populations that have been marginalized or people who are experiencing health inequities. For example, Wendy can consider the questions mentioned in this slide:

- Who has been harmed? Have certain populations experienced disproportionate rates of food safety–related illnesses due to the lack of uniform standards for mobile food vendors? Have mobile food vending regulations adopted in other jurisdictions negatively affected entrepreneurs who have low income or other business owners? Recall, for example, our discussion of New York City's green cart program and the potential negative consequences of the penalties mandated by local ordinance.
- Who stands to benefit, and how? Will the regulations enhance entrepreneurial opportunities for mobile food vendors and their employees by increasing public trust in such establishments? Will consumers benefit from improved health and safety standards? Can specialized regulations be adopted to increase access to healthy, culturally appropriate, and affordable foods in areas where residents have requested such resources? Can Wendy tailor her regulations to ensure that agency resources – including technical assistance and marketing support – are equitably directed to the food vendors who most need them?
- How can future harm be prevented? Can the regulations be tailored to minimize potential negative consequences and maximize benefits for people experiencing health inequities?

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To guide this type of analysis, agencies can consider using an equity assessment tool. For example, at the federal level, the US Department of Agriculture has issued guidance that requires all of its subagencies – such as the Food and Nutrition Service and the Food Safety and Inspection Service – to conduct a Civil Rights Impact Analysis before issuing a regulation that will affect the agency's programs and activities. Among other steps, the agency must "consult with stakeholders, minority groups, disability organizations, educational institutions, and customers, as appropriate, to obtain input prior to decision-making."

Similarly, at the local level, King County, Washington, has developed their Equity Impact Review process to "ensure that equity impacts are rigorously and holistically considered and advanced in the design and implementation" of plans, policies, and projects. The Environmental Health Services Division of the county's public health department used this tool to analyze the effects of a proposed policy change that would have eliminated rodent control outside of the City of Seattle due to lack of funding. The review team mapped complaints related to rodent control and illegal dumping and found that there were hot spots in unincorporated areas and communities with diverse populations. Because of the potential negative impacts of the proposed policy change, the division decided to seek a new funding source and restore rodent control service in the affected communities.

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Conducting extensive research can also help Wendy and her team draft the text of the proposed regulation, which is the second step of the rulemaking process. Typically, state health departments work with their legal team to draft a regulation. Likewise, local health departments may consult with their city attorney's office or county counsel.

It's worth noting that some jurisdictions may require agencies to notify the public of proposed drafting before the drafting itself even starts. Again, health departments should work with their legal team or local counsel to ensure they're following proper procedures.

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Some state APAs authorize state agencies to engage in *negotiated rulemaking*, which allows an agency to convene a committee to provide recommendations about the terms or substance of a proposed rule before it's presented to the general public. In this way, affected stakeholders can participate directly in drafting the text of the proposed regulation. Note that there may be special rules in your state about how negotiated rulemaking is conducted. Such rules might ensure, for example, advance notice of the process, balanced representation among committee members, or public access to committee meetings. In addition, an agency typically needs only to *consider* the recommendations of the committee and is not required to accept or implement the recommendations.

Montana and some other states also allow an agency to engage in more informal consultations to get the advice and viewpoints of interested persons on proposed rulemaking. This approach allows for some flexibility through modes of public engagement such as focus groups and listening sessions. Because there are no legal requirements for how the informal consultations are conducted, agencies can generally tailor them to intentionally include groups that are underrepresented and to avoid the risk of powerful special interests having an outsize influence on the process.

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After Wendy and her team complete their research and draft the text of the proposed regulation, they must provide notice to the public. The purpose of public notice is to make sure that any interested parties are aware of the proposed regulation before it takes effect and have an opportunity to express their views or provide data or evidence. Because regulations may restrict people's individual rights or impose new obligations on people and businesses, it's only fair that those regulated parties should receive notice and have a chance to share their views with the agency. In addition, being transparent about a regulatory proposal can help increase agency accountability and build public support for the final version of the regulation. As we'll discuss later, members of the public can challenge a regulation if they feel that a health department's notice was insufficient – either because timing requirements were not met or because the notice did not adequately inform the public about the agency's proposal.

In most states, a public notice must contain, at a minimum,

- A copy of the proposed regulation;
- A citation or reference to the legislation authorizing the regulation; and
- The procedure for submitting comments.

In Wendy's state, the APA specifies that she must provide public notice by publishing the required information in her state's administrative register at least 30 days before she and her team issue a final regulation.

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Next, Wendy and her team must allow members of the public to submit written comments on the proposed regulation within a certain time period. Some states also require agencies to hold public hearings to allow people to voice their concerns about proposed regulations. Gathering public comments allows for a full and fair analysis of the impact of the proposed rule. In addition, the public comments become part of the administrative record that courts will consider if the regulation is legally challenged.

As mentioned earlier, step 3 – notice – and step 4 – comment – are so central to the rulemaking process that many people use the term *notice-and-comment rulemaking*.

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Agencies often can go beyond standard notice-and-comment procedures, using innovative tools to include a broader range of voices and perspectives. For example, an agency may be allowed to supplement the written comment process with public hearings, meetings, listening sessions, smaller focus groups, or other methods of engagement. Providing different opportunities for members of the public to submit feedback can ensure that everyone is included in the process. It can be intimidating and time-consuming to find and read proposed regulations and draft written comments, and this process may be inaccessible to people who don't speak English well or to people with low literacy levels. Using an alternative process to collect feedback, such as a focus group, can help people overcome some of these barriers.

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These alternative methods of public engagement are consistent with the first three items on the list of equity-promoting strategies we considered at the beginning of this training. They're highlighted on this slide.

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Once the time period for public comments has ended, Wendy and her team are ready to revise and finalize the regulation. They received hundreds of comments, which they must now review. In Wendy's state, like many others, it's mandatory for health department officials to consider the comments they receive and either change the regulation to account for the feedback or explain why they have rejected the feedback. When Wendy and her team publish a final rule, they must also issue a concise statement explaining their reasons for adopting the rule, including their reasons for rejecting any substantial arguments made in the public comments. This requirement doesn't mean that Wendy's team must respond to every comment individually; rather, they can explain their reasoning generally and respond to comments in a summary form.

The process for finalizing a regulation varies by jurisdiction and may require approval by an independent commission or legislative body. For state-level regulations, final rules are typically filed with a state entity, such as the secretary of state, and are eventually published in a register and added to the state's administrative code.

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To summarize, there are five basic steps for rulemaking:

1. Conduct extensive research
2. Draft the text of the proposed regulation
3. Provide notice to the public
4. Provide an opportunity for public comment
5. Revise and finalize the regulation

In addition, an agency can generally go beyond these minimum steps to ensure that everyone who will be affected by a regulation has an opportunity to provide feedback and help decide on the best regulatory solutions.

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State administrative procedure acts, along with public engagement, make health departments responsive, transparent, and accountable to the communities they serve while also preserving a role for agency expertise. These key elements of good governance help to address the two drivers of health inequity emphasized on this slide:

- Disparities in political power
- Governance that limits meaningful participation

By creating opportunities for meaningful input from the people who will be affected by a regulation, health departments can better fulfill their mission of ensuring better health for all and advancing health equity.

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We've just covered a lot of information. Let's take a moment to review what we've learned.

The purpose of providing notice and an opportunity for the public to comment on proposed regulations is to . . .

A. Ensure fairness to regulated people and businesses

B. Increase an agency's transparency and accountability

C. Gather additional data and evidence

D. All of the above: Answers A, B and C

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If you selected D, you're correct! The notice-and-comment requirements for rulemaking serve many purposes – such as ensuring fairness to regulated people and businesses, increasing an agency's transparency and accountability, and gathering additional data and evidence from members of the public. Thus, these procedures help to advance health equity and good governance in health departments.

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Here's another review question:

True or false? Agencies are required to review and respond to public comments on proposed regulations.

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The answer is "True." Most state APAs require agencies to issue a concise statement with their final regulation, explaining their reasons for adopting the rule, including their reasons for rejecting any substantial arguments made in public comments. Note that if members of the public ultimately feel that the agency has ignored pertinent evidence in public comments, they can challenge the final regulation in court . . . which brings us to our next topic:

Part 2: What are common legal challenges to public health regulations?

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What are some common legal challenges to public health regulations? Once a regulation becomes final, an affected party can challenge it in court to prevent it from taking effect. In this section, we'll briefly address common legal challenges to public health regulations. Legal opposition to regulations can be a concern for public health professionals at federal, state, and local levels of government. These challenges can take time and resources or, in the worst cases, diminish public support for regulations or for health departments themselves. Having a greater understanding of potential legal challenges – and best practices for avoiding them – can help health departments reduce their legal liability and better ensure that the rights of the public are being served and protected. As the following examples show, courts typically defer to agencies' expert determinations on how to regulate matters within their authority, allowing public health agencies flexibility to adopt regulations to protect and improve health for all.

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We will examine four common legal challenges to public health regulations.

First, a person or business may challenge a regulation on the grounds that the agency failed to follow proper procedures – for example, a person could argue that an agency failed to provide the public with adequate notice of a proposed regulation before it was adopted. For this reason, public health agencies should be careful to follow the procedures established in the applicable APA – for example, rules on how much time members of the public have to submit comments after receiving notice, what exactly a public notice must include, and how agencies are required to respond to comments and incorporate feedback from comments in the final rule.

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Let's look at an actual case. In 1973, the Massachusetts Department of Public Health began a process to develop food labeling regulations requiring businesses that sell packaged food to disclose either the last use date or the pull date on food packages. In line with the state's rulemaking procedures, the department held several public hearings on food labeling in which they received numerous comments and criticisms. Three years later, the department issued a proposed rule and held another public hearing. The department also solicited feedback from several trade groups, including the Grocery Manufacturers of America, or GMA. Based on the submitted comments, the department modified the proposed regulation and issued a final rule in 1978.

That same year, GMA sued, arguing that the department had failed to comply with various procedural requirements. Among other things, GMA claimed that the modifications the department had made to the regulation in response to public comments had changed the regulation so dramatically that the public had not received adequate notice of what the agency intended to do and that the public was therefore entitled to a new public hearing and opportunity to comment. The Massachusetts Supreme Court rejected GMA's argument. The court concluded that agencies "may and should draw on the comments tendered" during a notice-and-comment process and that changes made in response to public comments do not "automatically generate a new opportunity for comment." Because the court determined that the regulation was "a logical outgrowth of the hearings and related procedures," it concluded that no further hearing was required and upheld the final rule.

As this example demonstrates, courts will generally conclude that notice of a proposed rulemaking fairly informs interested parties about the agency's proposed regulation as long as the final rule is a logical outgrowth of the rulemaking proceedings.

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A second type of challenge claims that the agency exceeded the scope of its delegated authority, thereby violating the *separation of powers* of the legislative and executive branches.

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An example of this type of challenge involves the Cabell-Huntington and Kanawha-Charleston boards of health in West Virginia. Between 2001 and 2003, both of these local boards of health issued regulations that prohibited smoking in all enclosed public areas. In response, various businesses sued, arguing that the state legislature had not delegated authority to local boards of health to issue regulations on clean indoor air.

In considering the challenge, the West Virginia Supreme Court looked to a state statute establishing the general powers and duties of local boards of health. The court wrote that the statute grants local boards of health "express responsibility for 'promoting and maintaining . . . clean and safe air' which may include adoption and promulgation of 'rules consistent with state public health laws and the rules of the West Virginia state department of health and human resources.'" The court stated that although this broad delegation of authority did not expressly grant responsibility for regulating smoking in public places, the clean indoor air regulations were consistent with other statutes demonstrating the state legislature's concern with reducing smoking-related health risks. The court therefore rejected the businesses' challenge and upheld the local regulations.

Historically, courts have often deferred to public health agencies' interpretation of authorizing legislation and the scope of their delegated authority, as the West Virginia Supreme Court did in this case concerning clean indoor air. The level of deference a court will afford to an agency when reviewing the agency's actions can depend on different factors. If the statutory grant of authority the agency has relied on is ambiguous, courts may be more likely to defer to an agency's reasonable interpretation of the statute. However, if the agency's decision implicates major questions of great economic and political significance, courts may require an agency to point to very specific statutory language to support its course of action. The framework for analyzing legal challenges to the scope of an agency's statutory authority can differ across states and between federal and state courts. Because of these nuances, it's always prudent to confirm with your agency's legal team that a regulation aligns with your agency's delegated authority before adopting it as a final rule.

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Another type of legal challenge claims that factual determinations an agency made during a rulemaking process are arbitrary and capricious, which is just another way of saying "unreasonable." When deciding this type of case, a court will look at the evidence the public health agency considered when making the regulation, including any public comments it received, to determine whether the agency made a rational decision – that is, a decision that is supported by evidence. For this reason, it's important for a public health agency to conduct thorough research and keep a clear record that supports its regulatory approach. In addition, a public health agency can provide a short statement summarizing the evidence it relied on in a document accompanying a final regulation.

Although agencies should always follow these best practices, courts have historically been willing to defer to an agency's factual determinations so long as there is some evidence to support them. As we mentioned earlier, legislative bodies often delegate regulatory authority to agencies because agencies have the technical skills and expertise needed to achieve broad legislative goals – such as determining a safe level of contaminants in drinking water or setting appropriate sanitation standards for food establishments. Courts typically recognize this reality and generally won't undermine an agency's expert determination about which regulatory approach is best supported by the evidence.

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To see how "arbitrary and capricious" challenges come up in practice, let's consider a case from New York City. In 2015, the New York City Board of Health adopted a regulation requiring large chain restaurants to post warnings to make customers aware of menu items containing high amounts of sodium. A statement accompanying the final rule included findings to justify the board's decision. The findings addressed the health effects of sodium and stated, "The vast majority of average dietary sodium intake is from processed and restaurant food; chain restaurants account for more than one-third of all restaurant traffic in New York City; a considerable number of individual or combination items on chain restaurant menus have more than 2300 mg of sodium; and consumers typically underestimate the sodium content of restaurant foods."

After the rule was adopted, the National Restaurant Association sued the city, arguing that the sodium rule was arbitrary and capricious because it applied only to large fast-food chain restaurants and not to other types of food outlets. The court rejected this argument, concluding that the board "made the Rule applicable to these Chain Restaurants based on health considerations and for the purpose of making the Rule possible to comply with and administer. Accordingly, this aspect of the Rule has a rational basis." In other words, the court deferred to the board's findings that high-sodium menu items at chain restaurants have a significant impact on health.

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Finally, a person or business may challenge a public health regulation on the grounds that it violates the federal or state constitution. For example, a person could argue that a public health regulation infringes on the person's right to free speech or fails to provide equal protection under the law. Unlike "arbitrary and capricious" challenges, in which courts generally defer to an agency's determination, courts are typically less deferential when reviewing constitutional challenges to agency regulations.

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First Amendment challenges to public health regulations often arise when an agency seeks to mandate certain types of labels or disclosures on consumer products or when an agency seeks to regulate the advertising environment.

In 2011, the US Food and Drug Administration – or FDA – issued regulations requiring graphic warnings on tobacco products to implement the Family Smoking Prevention and Tobacco Control Act. Five tobacco companies sued, claiming that the warnings violated the First Amendment. An appeals court ultimately invalidated the graphic warning regulations, concluding that the FDA had violated the First Amendment because the FDA did not show that the graphic warnings would directly advance the agency's interest in reducing the number of Americans who smoke. The FDA did not further appeal the decision, opting instead to re-initiate the rulemaking process to address the court's concerns. The FDA issued its new proposal for graphic warnings in 2019 – eight years after the first set of regulations had been introduced – and tobacco companies again filed a legal challenge. This example shows how legal challenges can delay the regulatory process or force an agency to change its regulatory approach.

Consultation with legal counsel early in the rulemaking process is essential for public health agencies, to reduce the risk of constitutional challenges and related delays, although, as this example shows, challenges sometimes occur despite an agency's best efforts to avoid them.

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Let's pause again to review what we've learned.

A court will likely find that an agency's regulation is arbitrary and capricious if it . . .

A. Violates the Constitution

B. Is not rational or based on evidence

C. Was adopted before the public had an opportunity to comment

D. Exceeds the agency's delegated scope of authority

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If you selected B, you're right! The phrase *arbitrary and capricious* is just a fancy way of saying "unreasonable," "irrational," or "not supported by the evidence."

In summary, it's important for public health agencies to make reasonable interpretations about the scope of their delegated authority – and procedural and constitutional limits on that authority – in order to avoid legal challenges to regulations they adopt and to ensure that both individual rights and public interests are protected. However, so long as health departments act reasonably within their delegated authority and ground their decisions in evidence, they generally have leeway to adopt regulations that advance the social determinants of health and health equity.

Part 3: What are policies and guidance documents?

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Now that we've learned about the procedures for creating new regulations, let's look at another common activity of public health agencies: writing policies and guidance documents. In this section of the training, we'll explore what policies and guidance documents are and how they differ from regulations.

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Writing policies and guidance documents falls in the middle of the continuum of agency activities because it relates to agencies' power to implement public health laws – such as legislation and regulations. Policies and guidance documents can facilitate smooth implementation of public health laws by increasing public understanding of what the laws mean or by providing guidelines for agency employees on how to administer public health programs. Therefore, policies and guidance documents are key tools for promoting equity in agency actions.

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One way that public health agencies use policies and guidance documents is to inform employees or members of the public about the agency's interpretation of existing laws and how they will be implemented or enforced. Although we use the terms *policies* and *guidance documents* in these slides, your jurisdiction may use different terminology to refer to documents that serve this function. For example, you may see terms like *interpretive rule* or *policy statement*.

To see how guidance documents look in practice, let's consider some examples. The Florida Department of Health has issued guidance for schools, child care facilities, and family day care homes, describing state statutory requirements for compulsory immunizations, exemptions, and reporting requirements.

The Colorado Department of Public Health and Environment has issued guidance for owners and operators of natural swimming areas – such as lakes and reservoirs – that explains state regulations concerning collection of water quality samples and reporting of data.

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Documents that describe how laws will be implemented and enforced are an education and outreach tool that can encourage compliance with legal requirements. In some cases, violations occur – and penalties are imposed – not because of intentional misconduct but because of a lack of understanding on the part of an individual, property owner, or business. A public health statute or regulation may be complicated or may not be well publicized. A simple document that breaks down legal obligations in plain language can help ensure that the requirements are understood by those who must comply – especially when agencies make an effort to distribute the materials and explain them to affected stakeholders in person. Creating and distributing documents like these can promote health equity by minimizing the likelihood of punitive enforcement actions and can improve community relations, promote transparency, and create buy-in for public health laws.

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Agencies may also issue documents that serve functions other than informing employees and the public about the agency's interpretation of existing law. These documents can take a variety of forms, including policy statements, internal agency manuals, and interagency memorandums.

For example, the public health department of Madison & Dane County in Wisconsin has issued a policy statement to provide an overview of the effects of lead in drinking water on children, including lead testing recommendations for Dane County schools and child care centers. Note that the testing recommendations are not based on the agency's interpretation of existing law; rather, they are voluntary best practices that the health department recommends to keep children safe.

An agency may also issue guidance documents that concern only the internal management of the agency and requirements for employees. For example, the Wisconsin Department of Health Services' *Immunization Policy and Procedure Manual* sets internal standards for how local health departments should manage immunization programs.

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Documents that set internal standards and practices for employees can also be used to promote health equity. Earlier in this training, we discussed the Equity Impact Review Process used by King County in Washington State. The county explains that the process is designed to "ensure that equity impacts are rigorously and holistically considered and advanced in the design and implementation" of plans, policies, and projects. This tool is actually an example of a guidance document. Other localities – including Portland, Oregon, and Madison, Wisconsin – have adopted guidance to help their agencies incorporate equity considerations into their day-to-day decision making. Madison has developed a tool to comprehensively analyze the equity impacts of city policies, plans, programs, and budgets. Madison has also created a process guide and an equitable hiring tool.

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Agencies can also issue documents that guide employees when public health laws are violated. Agency officials often have significant discretion to decide when and how to enforce a law. Guidelines can help enforcement officers understand the impact of their discretionary decisions and can provide options to help reduce inequitable outcomes while still incentivizing compliance. For example, the Wisconsin Department of Health Services has issued a manual that sets out guidelines for environmental health inspectors to use when enforcing regulations related to lead and asbestos. The guidelines include a compliance assistance policy that describes education and outreach strategies that inspectors can use to incentivize compliance before violations occur – such as distributing flyers, providing trainings, and responding promptly to phone calls and written inquiries. The guidelines also describe a stepped enforcement process that allows graduated enforcement options – from warnings to compliance plans and a range of monetary penalties – depending on the violator's compliance history, the severity of the violation, and other factors.

In sum, agencies may issue a host of documents to explain their interpretation of the law, set internal standards, or recommend best practices to protect the public and promote health equity. The terminology used to describe these documents can vary widely across and even within jurisdictions.

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Because of these wide variations in terminology, it can be helpful to describe policies and guidance documents not by what they're called but by how they differ from regulations.

To review, regulations are laws drafted by administrative agencies. They have the force and effect of law and set requirements that are binding on private individuals and businesses. In contrast, policies and guidance documents lack the force and effect of law. Although an agency's employees may face disciplinary action or other employment consequences based on their failure to follow the agency's internal policies, such policies are not legally binding on private individuals or businesses outside of government. Under the federal APA and many state APAs, documents that lack the force and effect of law are exempt from the notice-and-comment requirements that apply to regulations. Accordingly, as long as guidance documents and policy statements are truly advisory and not legally binding, a public health agency generally does not need to follow notice-and-comment rulemaking procedures before issuing them.

Note that there can be legal repercussions when an agency treats a guidance document or policy statement as if it were a binding regulation. In such circumstances, members of the public can challenge the agency in court. They could argue that because the agency treated a guidance document as if it were binding, they were entitled to notice and an opportunity to comment before the document was issued. For example, imagine that Wendy issues regulations that fail to address temperature controls for storing or reheating food, but later, she issues a guidance document that delineates temperature control standards. If Wendy's team treats those standards as binding and cites food vendors for failing to comply with them, the food vendors could challenge the agency actions in court, arguing that they were entitled to notice and an opportunity to comment on the standards.

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Some of you might be wondering whether administrative rulemaking procedures – including notice and comment – apply during public health emergencies, such as infectious disease outbreaks. For example, during the COVID-19 pandemic, state and local health officials issued orders requiring social distancing, isolation, and quarantine, to inhibit the spread of the disease.

Although there may be jurisdictional variations, the answer is generally "no." Administrative rulemaking procedures, which are spelled out in state APAs, typically do not apply when public health officials issue these types of emergency orders. However, state and local health officials must still abide by certain legal requirements when issuing such orders, to balance individual rights and liberty interests against the common good. These requirements are generally mandated by federal and state constitutions and state emergency powers acts. To learn about the major sources and limits of public health authority to issue various types of emergency orders, refer to the Public Health Law Academy training called **Public Health Threats & the US Constitution: What Responders Need to Know About Equity, Law, and Public Health Authority**.

Part 4: What are best practices for issuing policies and guidance documents?

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Although a health department generally doesn't need to use notice-and-comment procedures when developing guidance documents, it can use some best practices to advance the public's interest in administrative transparency and accountability and to promote health equity.

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To see how this works, let's revisit Wendy. When we left off, Wendy had just finalized new food safety regulations for food trucks and other mobile vendors. The regulations set out detailed standards for how mobile food establishments must be designed, what types of equipment they must use, and sanitation and safety practices. To help mobile food vendors comply, Wendy can issue a guidance document that describes the standards in clear, easy-to-read language and provides pictures to help with implementation. Based on her research and consultation with her legal department, Wendy has learned that although there are no procedural requirements she must follow before issuing the guidance, there are four best practices she can use to ensure that the process is fair, equitable, and accessible to everyone.

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First, Wendy can publish the guidance document on her agency's website so that members of the public have notice of and easy access to the agency's view on how the mobile food regulations will be implemented and enforced. Some states, like Arizona, have APAs that mandate the publication of guidance documents online.

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Second, Wendy can issue the guidance document in multiple languages so that the information is accessible to speakers with limited English. Some states, such as California, have laws that require or encourage local agencies to provide language access services to speakers with limited English.

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Third, Wendy can follow accessibility standards for persons with disabilities. The federal government and many states have adopted legislation that sets accessibility standards for digital information.

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Finally, Wendy can provide a reasonable explanation if her agency decides to act differently from what the agency has stated in a guidance document. Regulated parties often rely on guidance documents to understand what is required of them and may even invest money to implement what guidance documents say. For example, imagine that legislation requires food vendors to use ventilation equipment but does not specify what type of equipment to use. To clarify the requirement, Wendy issues a guidance document stating that ventilation equipment will be satisfactory so long as a vendor can provide any authoritative evidence that it is safe and effective. In practice, however, she issues citations to vendors who fail to use equipment that has received one particular type of safety certification. In this scenario, a food vendor could legally challenge such a citation, arguing that Wendy treated the vendor unfairly – or, as the courts would say, acted in an arbitrary and capricious manner. For this reason, a public health agency should proceed with caution when enforcing regulations in a manner inconsistent with the agency's own published guidance.

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Let's pause to review what we've just discussed.

True or false? State and local health departments may issue policies and guidance documents without providing public notice and an opportunity to comment.

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The answer is "True." A health department is not required to provide notice to the public or an opportunity for comment before issuing policies and guidance documents if the documents are advisory only and are not legally binding on private individuals and businesses. However, a health department can follow best practices – like publishing the guidance on its website – to ensure that the process of issuing guidance is fair, equitable, and accessible to everyone.

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Finally, guidance documents can promote health equity by . . .

A. Educating the public about regulatory requirements in plain language

B. Establishing internal agency practices to assess equity impacts

C. Setting guidelines for the use of discretion in enforcement

D. All of the above: Answers A, B, and C

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Answer D is the correct choice. Guidance documents promote health equity in several ways:

- Providing information in plain language to educate the public about what public health laws require. This practice can help agencies avoid punitive enforcement actions, especially when the documents are published in multiple languages and in formats that are accessible to persons with disabilities.
- Establishing internal agency practices or adopting tools to assess the equity impacts of various regulatory actions
- Setting guidelines for when and how officials exercise their discretion to enforce public health laws

In sum, policies and guidance documents can help facilitate smooth implementation of public health laws – including legislation and regulations – by promoting transparency, accessibility, and good governance, all of which can help health departments advance health equity.

Final Takeaways & Acknowledgments

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In closing, here's a recap of what we've discussed in this training:

We began by reviewing foundational concepts introduced in Part 1 of this training series, such as the definition of *administrative law* and strategies that agencies can use to maximize the advancement of equity through their regulatory actions – a theme throughout this series.

Then we discussed the process that agencies should generally use when creating regulations, including confirming the agency's rulemaking authority and following key steps, such as conducting foundational research and providing public notice and an opportunity to comment. We also discussed common legal challenges to public health regulations.

Finally, we looked at examples of different types of policies and guidance documents issued by public health agencies, described how they differ from regulations, and learned about best practices that agencies can use when developing policies and guidance documents, to help protect individual rights and promote health equity.

We encourage you to watch the third and final part of this training series, which addresses the question **How Do Health Departments Implement and Enforce the Law?**

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Individuals who work as public health practitioners, lawyers, and policy experts in state, tribal, local, and territorial health departments need measurable skills to move their careers forward. CDC's Public Health Law Program developed the Public Health Law Competency Model to help guide practitioners in their career trajectories. This module of the Public Health Law Academy covers the four competencies listed on this slide, to build skills in public health law for public health practitioners. We want to note that these are not the objectives for this course but are general public health law competencies suitable for public health professionals at all career levels, from students to entry-level staff to supervisors and executive-level managers.

The four competencies are

- Defining basic constitutional concepts that frame the everyday practice of public health;
- Describing public health agency authority and limits on that authority;
- Identifying legal tools and enforcement procedures available to address day-to-day (non-emergency) public health issues; and
- Distinguishing public health agency powers from those of other agencies, legislatures, and the courts.

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