

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

Facilitator's Guide



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Who Should Use Our Facilitator’s Guides?

Our facilitator’s guides are intended for anyone who needs to provide public health practitioners with training about our legal system and its role in improving population outcomes. Public health practitioners may include health department staff, public health lawyers, public health nurses, public health educators, public health advocates, and public health faculty and students in graduate and undergraduate programs. To access facilitator’s guides for our other trainings, visit publichealthlawacademy.org.

Training Overview

About This Training

Building on [Part 1](#), this training focuses on the laws governing how public health practitioners carry out common regulatory activities and highlights 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. This training . . .

- Explores regulations, including what they are and when and how public health agencies can create them in line with administrative law principles;
- Identifies strategies to promote health equity while developing regulations;
- Discusses common legal challenges to public health regulations and explains why it's important for public health practitioners to be aware of these types of legal issues;
- Explores what policies and guidance documents are and how they differ from regulations; and
- Shares best practices that public health agencies can use to ensure that the process of developing and implementing policies and guidance documents is fair, equitable, and accessible to everyone.

Target Audience

This training was developed for public health practitioners, including policy analysts, public health lawyers, educators, nurses, and students. No legal background is necessary.

Learning Objectives

- Explain what regulations are, when and how health departments create them, and how the process can promote health equity
- Describe common legal challenges to public health regulations
- Explain what policies and guidance documents are and how they differ from regulations
- Identify and implement best practices for issuing policies and guidance documents to ensure that the process is fair, equitable, and accessible to everyone

Materials

- Facilitator's Guide: This document can be adapted to provide a training that is customized for your audience.
- Slide Presentation & Script: The slides and script are separate files that can be modified to reflect your audience, training content, and speakers.
- Facilitator's Checklist: The checklist is a separate file that will help you prepare to deliver any training offered by the [Public Health Law Academy](#).

Equipment

- Computer
- Projector

Instructions for Facilitators

Before you start, we recommend that you download the [Facilitator's Checklist](#), which is intended to help you prepare to deliver any training offered by the [Public Health Law Academy](#). In this section, we have identified options for tailoring this training, [How Do Health Departments Create Regulations, Policies, and Guidance Documents? Overview of Administrative Law: Part 2](#), for your audience and venue.

Prepare for the Presentation

As the facilitator, you should first go through the materials to familiarize yourself with the content. We recommend that you watch the entire training: [How Do Health Departments Create Regulations, Policies, and Guidance Documents? Overview of Administrative Law: Part 2](#). You may also need to familiarize yourself with the content in [Part 1](#). Once you are familiar with the material, you can modify the content and length of Part 2 to suit your audience, available time, and venue.

Before Starting the Presentation

We suggest that you have participants complete the following:

- *The Q&A handout found on pp. 16–17 of this guide.* The Q&A handout will help participants assess their knowledge before and after the training. An answer key is provided on pp. 18–20.
- *The pre-training survey included in this guide on page 22.* The pre-training survey will provide information to help you evaluate the overall quality of the session.

If you are not giving the presentation in person, you can distribute these handouts electronically prior to the training (and distribute the answer sheet electronically after the training).

During the Presentation

You'll want to decide how to use the Q&A handout to engage participants in the training, depending on the length of your presentation. Two options are outlined here. These approaches not only re-emphasize key points but also create a more interactive experience for participants.

- *Option 1: Poll the Room*
One approach is to weave the questions throughout the presentation. You can stop after each question and ask the audience to answer it before moving to the next slide. The slide deck is set up to support this option.
- *Option 2: Discussion Activity*
You can move all the question-and-answer slides to the end of the presentation and create an opportunity for a longer discussion after you've covered all of the content. Depending on the number of people attending your training, this discussion activity can be done as a full group or in small groups. The Training Agenda item "Q&A Discussion" provides additional details on when to include this activity if you select this option.

Lastly, our sample agenda suggests allowing 10 minutes at the end of the presentation for final remarks, acknowledgments, and general questions. Of course, this time can be adjusted to suit the needs of the presentation setting and your audience.

After the Presentation

When the presentation is complete, participants should fill out the post-training survey on pp. 23–24.

Finally, we are interested in your experience with using this curriculum. Please let us know at PHLAcademy@changelabsolutions.org if you have any questions or feedback on how to improve these materials.

Training Agenda

Pre-Training Survey & Q&A Handout

10 minutes*

Objectives

- Have participants complete the pre-training survey and answer the questions in the Q&A handout

Resources

- Pre-training survey (p. 22 of this guide)
- Q&A handout (pp. 16–17 of this guide)

Public Health Law Competency Addressed

- [Public Health Law Competency Model](#), Domain 2
-

Introduction & Presentation Overview

10 minutes*

Objectives

- Introduce presentation topic and presenter(s)
- Provide any necessary disclaimers and introductory comments
- Provide a roadmap for the rest of the presentation
- Review key concepts from Part 1 of this series, **What Legal Powers Do Health Departments Have?**

Resource

- Slide presentation (slides 1–16)
-

What are the steps for creating regulations?

20 minutes*

Objectives

- Define the term *regulation* and review how regulations differ from legislation
- Understand when health departments can create regulations
- Discuss how health departments create regulations and how the process can promote health equity
- Explore how rulemaking works in practice, using the example of Wendy

Resource

- Slide presentation (slides 17–57)

Public Health Law Competency Addressed

- [Public Health Law Competency Model](#), Domain 2

What are common legal challenges to public health regulations?

15 minutes*

Objectives

- Summarize the four common challenges to public health regulations
- Introduce the *Grocery Manufacturers of America, Inc. v. Department of Public Health* case and discuss the importance of following rulemaking procedures to avoid legal challenges
- Examine the case of *Foundation for Independent Living, Inc. v. Cabell-Huntington Board of Health* and discuss how to avoid legal challenges by ensuring that agencies work within the scope of their delegated authority
- Review the *National Restaurant Association v. New York City Department of Health & Mental Hygiene* case and how arbitrary and capricious challenges come up in practice
- Explore one type of constitutional challenge to a public health regulation through the case of *R.J. Reynolds Tobacco Co. v. Food & Drug Administration*, which involves the First Amendment

Resource

- Slide presentation (slides 58–68)

Public Health Law Competency Addressed

- [Public Health Law Competency Model](#), Domain 2

What are policies and guidance documents?

10 minutes*

Objectives

- Define what policies and guidance documents are and how they differ from regulations
- Consider how policies and guidance can facilitate implementation of public health laws
- Discuss the ways that public health agencies can use guidance documents to promote health equity

Resource

- Slide presentation (slides 69–77)

Public Health Law Competency Addressed

- [Public Health Law Competency Model](#), Domain 2

What are best practices for issuing policies and guidance documents?

10 minutes*

Objectives

- Explore best practices to advance the public's interest in administrative transparency and accountability and to promote health equity
- Reintroduce the example of Wendy and the use of policies and guidance documents in practice

Resource

- Slide presentation (slides 78–87)

Public Health Law Competency Addressed

- [Public Health Law Competency Model](#), Domain 2

Q&A Discussion (optional)

20 minutes*

Objectives

- If you chose not to weave the questions from the Q&A handout throughout the presentation, have participants discuss the answers to the questions as a full group or in small groups
- Provide the answers to the Q&A handout

Resource

- Q&A handout answer key (pp. 18–20 in this guide)

Public Health Law Competency Addressed

- [Public Health Law Competency Model](#), Domain 2

Final Takeaways & Acknowledgments

10 minutes*

Objectives

- Summarize the topics discussed and provide concluding remarks
- Direct participants to more resources, should they wish to delve more deeply into the legal issues covered in the training
- Allow participants to ask general questions
- Have participants complete the post-training survey

Resources

- Slide presentation (slides 88–91)
- Post-training survey (pp. 23–24 in this guide)

**All times are approximate; total training time is about 1 hour, 45 minutes.*

Additional Resources

As you prepare to tailor content from [How Do Health Departments Create Regulations, Policies, and Guidance Documents? Overview of Administrative Law: Part 2](#), we recommend familiarizing yourself with the resources listed in this section. These resources informed the development of the content of this training and can provide background information as you prepare to tailor the content of your presentation. Finally, as questions from audience members arise during and after the training, you can refer them to these resources for additional information.

Organizations

CDC, Public Health Law Program

cdc.gov/phlp

The Public Health Law Program – part of the CDC’s Center for State, Tribal, Local, and Territorial Support – works to improve the health of the public by developing law-related tools and providing legal technical assistance to public health practitioners and policymakers.

ChangeLab Solutions

changelabsolutions.org

ChangeLab Solutions is a national organization whose mission is to create healthier communities for all through equitable laws and policies. Their interdisciplinary team of public health lawyers, policy analysts, planners, and other professionals works with state, tribal, local, and territorial health departments; other government agencies; public health organizations; and anchor institutions to create thriving communities.

Background Reading

For additional information on the concepts discussed in this training, see the following resources:

- Adams C. Home rules: the case for local administrative procedure. *Fordham Law Rev.* 2018;87(2):629–669. ir.lawnet.fordham.edu/flr/vol87/iss2/5.
- *A Blueprint for Changemakers: Achieving Health Equity Through Law & Policy*. Oakland, CA: ChangeLab Solutions; 2019. changelabsolutions.org/product/blueprint-changemakers.
- Braveman P, Arkin E, Orleans T, Proctor D, Plough A. *What Is Health Equity? And What Difference Does a Definition Make?* Princeton, NJ: Robert Wood Johnson Foundation; 2017. rwjf.org/en/library/research/2017/05/what-is-health-equity-.html.
- Brennan Ramirez LK, Baker EA, Metzler M. *Promoting Health Equity: A Resource to Help Communities Address Social Determinants of Health*. Atlanta, GA: Centers for Disease Control and Prevention, US Department of Health and Human Services; 2008. cdc.gov/nccdphp/dch/programs/healthycommunitiesprogram/tools/pdf/SDOH-workbook.pdf.
- Burris S, Berman ML, Penn M, Holiday TR. Administrative challenges. In: Burris S, Berman ML, Penn M, Holiday TR. *The New Public Health Law: A Transdisciplinary Approach to Practice and Advocacy*. New York, NY: Oxford University Press; 2018:173–179.

- CDC regulations. Centers for Disease Control and Prevention website: [cdc.gov/regulations](https://www.cdc.gov/regulations). 2016.
- *Common Language Access Questions, Technical Assistance, and Guidance for Federally Conducted and Federally Assisted Programs*. Washington, DC: Federal Coordination and Compliance Section, Civil Rights Division, US Department of Justice; August 2011. [lep.gov/sites/lep/files/resources/081511_Language_Access_CAQ_TA_Guidance.pdf](https://www.lep.gov/sites/lep/files/resources/081511_Language_Access_CAQ_TA_Guidance.pdf). Accessed July 29, 2020.
- Davidson NM. Localist administrative law. *Yale Law J.* 2017;126(3):43–44. [yalelawjournal.org/article/localist-administrative-law](https://www.yalelawjournal.org/article/localist-administrative-law).
- Davis J, Morales A. *Fining the Hand That Feeds You: Street Vendor Fines and Increasing Revenues to New York City*. Madison, WI: Department of Urban and Regional Planning, University of Wisconsin–Madison/Extension. Working Paper 12-01. April 2012. [scribd.com/document/90899143/Fining-the-Hand-That-Feeds-You](https://www.scribd.com/document/90899143/Fining-the-Hand-That-Feeds-You). Accessed July 27, 2020.
- Diller PA. Local health agencies, the Bloomberg soda rule, and the ghost of Woodrow Wilson. *Fordham Urban Law J.* 2013;40(5):1859–1901. [ir.lawnet.fordham.edu/ulj/vol40/iss5/4](https://www.ir.lawnet.fordham.edu/ulj/vol40/iss5/4).
- *Equitable Enforcement to Achieve Health Equity: An Introductory Guide for Policymakers and Practitioners*. Oakland, CA: ChangeLab Solutions; 2020:28, 31–32. [changelabsolutions.org/product/equitable-enforcement-achieve-health-equity](https://www.changelabsolutions.org/product/equitable-enforcement-achieve-health-equity).
- Equity & social justice: tools and resources. King County, Washington, website: [kingcounty.gov/elected/executive/equity-social-justice/tools-resources.aspx](https://www.kingcounty.gov/elected/executive/equity-social-justice/tools-resources.aspx).
- *Foundation for Independent Living, Inc. v. Cabell-Huntington Board of Health*, 591 S.E.2d 744, 751-54 (W. Va. 2003). [courtlistener.com/opinion/1418546/found-for-ind-liv-v-cabell-huntington/?show_alert_modal=yes&q=cites%3A\(1328666\)](https://www.courtlistener.com/opinion/1418546/found-for-ind-liv-v-cabell-huntington/?show_alert_modal=yes&q=cites%3A(1328666)).
- Fuchs ER, Holloway SM, Bayer K, Feathers A. *Innovative Partnership for Public Health: An Evaluation of the New York City Green Cart Initiative to Expand Access to Healthy Produce in Low-Income Neighborhoods*. New York, NY: Columbia University School of International and Public Affairs; June 2014. Columbia University School of International and Public Affairs Case Study Series in Global Public Policy: Volume 2, Case 2. [foodpolitics.com/wp-content/uploads/Green-Carts-Report-Final-June-11.pdf](https://www.foodpolitics.com/wp-content/uploads/Green-Carts-Report-Final-June-11.pdf). Accessed July 27, 2020.
- Funk W. Public participation and transparency in administrative law: three examples as an object lesson. *Adm Law Rev.* 2009;61:171–198.
- Funk WF, Shapiro SA, Weaver RL. Administrative law practice: what is administrative law and why should we study it? In: Funk WF, Shapiro SA, Weaver RL. *Administrative Procedure and Practice*. 5th ed. St. Paul, MN: West Academic; 2014:6–37.
- Gostin LO, Wiley LF. Public health governance: democracy and delegation. In: Gostin LO, Wiley LF. *Public Health Law: Power, Duty, Restraint*. 3rd ed. Oakland, CA: University of California Press; 2016:153–190.
- *Grocery Mfrs. of Am., Inc. v. Dep’t of Pub. Health*, 379 Mass. 70, 78, 393 N.E.2d 881, 888 (1979). [masscases.com/cases/sjc/379/379mass70.html](https://www.masscases.com/cases/sjc/379/379mass70.html).
- *Know the Rules: An Overview of State Agency Rulemaking*. Oakland, CA: ChangeLab Solutions; 2015. [changelabsolutions.org/product/know-rules](https://www.changelabsolutions.org/product/know-rules).
- *Language Access Laws and Legal Issues: A Local Official’s Guide*. Sacramento, CA: Institute for Local Government; 2011. [ca-ilg.org/sites/main/files/file-attachments/language_access_guide_formatted_9-27-11_2.pdf](https://www.ca-ilg.org/sites/main/files/file-attachments/language_access_guide_formatted_9-27-11_2.pdf). Accessed July 29, 2020.

- *Laws, Policies and Regulations: Key Terms & Concepts*. St. Paul, MN: Tobacco Control Legal Consortium, Public Health Law Center. publichealthlawcenter.org/sites/default/files/resources/tclc-fs-laws-policies-regs-commonterms-2015.pdf. Updated March 2015. Accessed July 24, 2020.
- Michel KH, Glass P. Public health regulations: 4 common legal challenges. ChangeLab Solutions website: changelabsolutions.org/blog/public-health-regulations. March 9, 2020.
- National Conference of Commissioners on Uniform State Laws. *Revised Model State Administrative Procedure Act*. Chicago, IL: Uniform Law Commission; October 15, 2010. uniformlaws.org/HigherLogic/System/DownloadDocumentFile.ashx?DocumentFileKey=3ab796d4-9636-d856-48e5-b638021eb54d&forceDialog=0. Accessed July 27, 2020.
- *National Restaurant Association v. New York City Department of Health & Mental Hygiene*, 148 A.D.3d 169 (N.Y. App. Div. 2017). cite.case.law/ad3d/148/169/.
- Office of Disease Prevention and Health Promotion, US Department of Health and Human Services. Pushing produce in New York City's neighborhoods: the Green Carts Initiative. HealthyPeople.gov website: healthypeople.gov/2020/law-and-health-policy/bright-spot/pushing-produce-in-new-york-city. Accessed July 27, 2020.
- Philip Morris USA Inc. and Sherman Group Holdings, LLC v. U.S. Food and Drug Administration et al. (2020). Public Health Law Center website: publichealthlawcenter.org/litigation-tracker/philip-morris-usa-inc-and-sherman-group-holdings-llc-v-us-food-and-drug. Updated June 9, 2020. Accessed July 27, 2020.
- Pomeranz JL. The unique authority of state and local health departments to address obesity. *Am J Public Health*. 2011;101(7):1192–1197. ncbi.nlm.nih.gov/pmc/articles/PMC3110220.
- Public availability of agency guidance documents. Recommendation 2019-3. Administrative Conference of the United States website: acus.gov/recommendation/public-availability-agency-guidance-documents. August 8, 2019. Accessed July 29, 2020.
- Public engagement in rulemaking. Recommendation 2018-7. Administrative Conference of the United States website: acus.gov/recommendation/public-engagement-rulemaking. December 20, 2018. Accessed July 28, 2020.
- Public Health Law Academy. Public health threats & the US Constitution: what responders need to know about equity, law, and public health authority. [training video]. Oakland, CA: ChangeLab Solutions; Centers for Disease Control and Prevention; 2021. changelabsolutions.org/product/public-health-threats-us-constitution.
- Public Health Law Academy. Structure of government: exploring the fabric and framework of public health powers. [training video]. Oakland, CA: ChangeLab Solutions; Centers for Disease Control and Prevention; 2019. changelabsolutions.org/product/structure-government.
- *R.J. Reynolds Tobacco Co. v. Food & Drug Administration*, 696 F.3d 1205 (D.C. Cir. 2012). casetext.com/case/rj-reynolds-tobacco-co-v-food-drug-admin.
- Separation of powers: an overview. National Conference of State Legislatures website: ncsl.org/research/about-state-legislatures/separation-of-powers-an-overview.aspx. 2019.
- *Spoiled! How Relentless Enforcement and \$1,000 Tickets Are Ruining Chinatown's Largest Fruit & Vegetable Market*. New York, NY: Street Vendor Project, Urban Justice Center; July 2011. scribd.com/doc/306156512/Spoiled.

- State administrative procedure acts. Ballotpedia website: ballotpedia.org/State_administrative_procedure_acts. Accessed July 21, 2020.
- Tobacco Products; Required Warnings for Cigarette Packages and Advertisements, 84 Fed. Reg. 42754 (Aug. 16, 2019). [federalregister.gov/documents/2019/08/16/2019-17481/tobacco-products-required-warnings-for-cigarette-packages-and-advertisements](https://www.federalregister.gov/documents/2019/08/16/2019-17481/tobacco-products-required-warnings-for-cigarette-packages-and-advertisements).
- US Department of Agriculture. Departmental Regulation 4300-04: Civil Rights Impact Analysis. October 17, 2016. [usda.gov/directives/dr-4300-004](https://www.usda.gov/directives/dr-4300-004).
- US General Services Administration. Create accessible digital products. Section 508.gov website: [section508.gov/create](https://www.section508.gov/create). Accessed July 29, 2020.
- US General Services Administration. State policy. Section 508.gov website: [section508.gov/manage/laws-and-policies/state](https://www.section508.gov/manage/laws-and-policies/state). Accessed July 29, 2020.
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Relevant Cases

PROPER PROCEDURES

Grocery Manufacturers of America, Inc. v. Department of Health, 393 N.E.2d 881 (Mass. 1979)

SUMMARY: An aggrieved party can challenge a regulation on the grounds that the agency that issued the regulation failed to follow the procedural requirements established in the relevant federal or state Administrative Procedures Act, such as requirements related to providing public notice and an opportunity to comment. For example, in 1973, the Massachusetts Department of Public Health began a process to develop food labeling regulations that would require people who 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 at 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 hearing[s] and related procedures,” it concluded that no further hearing was required and upheld the final rule.

TAKEAWAY: 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.

SCOPE OF AUTHORITY

[Foundation for Independent Living, Inc. v. Cabell-Huntington Board of Health, 591 S.E.2d 744 \(W. Va. 2003\)](#)

SUMMARY: An aggrieved party can challenge a regulation by claiming that the agency that issued the regulation exceeded the scope of authority delegated to the agency by the legislature. For example, between 2001 and 2003, the Cabell-Huntington and Kanawha-Charleston boards of health in West Virginia 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 acknowledged 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.

TAKEAWAY: Courts are typically very deferential to public health agencies’ interpretation of authorizing legislation and the scope of their delegated authority. Nevertheless, 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.

ARBITRARY & CAPRICIOUS

[National Restaurant Association v. New York City Department of Health & Mental Hygiene, 148 A.D. 3d 169 \(N.Y. App. Div. 2017\)](#)

SUMMARY: An aggrieved party can challenge a regulation on the grounds that it is arbitrary and capricious, which is just another way of saying “unreasonable” or “inconsistent with evidence.” For example, 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.

TAKEAWAY: To avoid “arbitrary and capricious” challenges to public health regulations, 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, a court will typically defer to an agency and will uphold a regulation as reasonable if there is any evidence at all to support it. Legislative bodies often delegate regulatory authority to agencies because agencies have the technical skills and expertise needed to achieve broad legislative goals. Courts recognize this reality and generally won’t undermine an agency’s expert determination about which regulatory approach is best supported by the evidence.

CONSTITUTIONAL CHALLENGES

R.J. Reynolds Tobacco Co. v. Food & Drug Administration, 696 F.3d 1205 (D.C. Cir. 2012)

SUMMARY: An aggrieved party can challenge a regulation on the grounds that it violates constitutional protections – for example, that it infringes on the challenger’s right to free speech or fails to provide equal protection under the law. For example, in 2011, the US Food and Drug Administration (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’s protections against compelled speech – in other words, the companies claimed that the government could not *require* them to share the information in the graphic warnings without violating their First Amendment rights. 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.

TAKEAWAY: 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. First Amendment issues are just one of many possible types of constitutional challenges to public health regulations. 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, sometimes challenges occur despite an agency’s best efforts to avoid them.

Welcome Activity: Q&A Handout

Expected time: 30 minutes total (approximately 10 minutes before the presentation and 20 minutes during or after the presentation)

Instructions for Facilitators

- Welcome the participants and introduce yourself
- Explain housekeeping items, such as estimated length of the training, break times, and restroom locations
- Ask participants to complete the Q&A handout
- Remind participants that they are not expected to know all of the answers
- Encourage participants to do their best, and explain that the answers to some of the questions will be addressed throughout the presentation
- Where applicable, the answer key (found on pp. 18–20) references the slides in the presentation where relevant concepts are expressly addressed or implied
- Review answers to the questions in the Q&A handout by either
 - Weaving the questions throughout the presentation (this is how the slide deck is currently structured) and stopping after each question to ask the audience for the answer before moving to the next slide; or
 - Moving all the questions in the slide deck to the end of the presentation and holding time then to have participants discuss the questions as a full group or in small groups

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Q&A Handout

Instructions: As an individual, answer the following questions.

1. 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 in the same way to everyone, irrespective of need
2. 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 when engaging in regulatory activities
 - C. The law that applies to the legislative branch of government
 - D. Answers A (legal principles that govern agencies' activities) and B (guardrails for the regulatory activities of agencies)
3. 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. Answers A, B, and C
4. **TRUE or FALSE?** State and local health departments have inherent authority to adopt regulations.
5. 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 agency transparency and accountability
 - C. Gather additional data and evidence
 - D. Answers A, B, and C
6. **TRUE or FALSE?** Agencies are required to review and respond to public comments on proposed regulations.
7. 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 in evidence
 - C. Was adopted before the public had an opportunity to comment
 - D. Exceeds the agency's delegated scope of authority

8. **TRUE or FALSE?** State and local health departments may issue policies and guidance documents without public notice and comment.
9. 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 enforcement discretion
 - D. Answers A, B, and C

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

Q&A Handout

ANSWER KEY

1. What is health equity?

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

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

Answer: 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."

➤ This material is discussed in slides 10–11.

2. 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 (legal principles that govern agencies' activities) and B (guardrails for the regulatory activities of agencies) – CORRECT ANSWER

Answer: If you chose D, you're right! As we learned in Part 1 of this series, 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 as 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.

➤ This material is discussed in slides 13–14.

3. 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. Answers A, B, and C – CORRECT ANSWER

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

➤ This material is discussed in slides 15–16.

4. **TRUE or FALSE?** State and local health departments have inherent authority to adopt regulations.

Answer: 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 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.

➤ This material is discussed in slides 34–35.

5. 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. Answers A, B, and C – CORRECT ANSWER

Answer: If you selected D, you're correct! The notice-and-comment requirements for rulemaking serve many purposes, including 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.

➤ This material is discussed in slides 54–55.

6. **TRUE or FALSE?** Agencies are required to review and respond to public comments on proposed regulations.

Answer: True. Administrative procedure acts in most states 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.

➤ This material is discussed in slides 56–57.

7. 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 – CORRECT ANSWER**
- C. Was adopted before the public had an opportunity to comment
- D. Exceeds the agency's delegated scope of authority

Answer: 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."

It's important for public health agencies to understand the specific 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, as we have seen, courts are generally very deferential to agency rulemaking and will invalidate public health regulations only if there is a clear violation of procedural rules or constitutional requirements. Therefore, health departments generally have significant leeway to adopt regulations that address the social determinants of health and advance health equity.

➤ This material is discussed in slides 67–68.

8. **TRUE or FALSE?** State and local health departments may issue policies and guidance documents without public notice and an opportunity to comment.

Answer: 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.

➤ This material is discussed in slides 84–85.

9. 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. Answers A, B, and C – CORRECT ANSWER

Answer: 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.

➤ This material is discussed in slides 86–87.

Pre- and Post-Training Surveys

Instructions for Facilitators

- Pages 22–24 contain two sample surveys (pre- and post-training evaluation tools) that you can use to gather feedback on the content and quality of your presentation.*
- Depending on the format of your presentation (in person or online), you can provide hard copies of the survey at the presentation or make the survey available electronically.

* Before asking participants to complete the pre- and post-training surveys, please note that the Paperwork Reduction Act has specific requirements for federal agencies in regard to collection and housing of data. You may need permission from the Office of Management and Budget if you are collecting information from 10 or more members of the public.

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

PRE-TRAINING SURVEY

Thank you for completing the following survey!

Learning Objectives

Please indicate your current confidence level for each of the following learning objectives:

1. I can explain what regulations are, when and how health departments create them, and how the process can promote health equity.
 - a. Not confident
 - b. Somewhat confident
 - c. Confident
 - d. Very confident
2. I can describe common legal challenges to public health regulations.
 - a. Not confident
 - b. Somewhat confident
 - c. Confident
 - d. Very confident
3. I can explain what policies and guidance documents are and how they differ from regulations.
 - a. Not confident
 - b. Somewhat confident
 - c. Confident
 - d. Very confident
4. I can identify and implement best practices for issuing policies and guidance documents to ensure that the process is fair, equitable, and accessible to everyone.
 - a. Not confident
 - b. Somewhat confident
 - c. Confident
 - d. Very confident

Additional Feedback

5. What questions do you have about how health departments create regulations, policies, and guidance documents?

Thank you for your feedback!

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

POST-TRAINING SURVEY

Thank you for completing the following survey!

Learning Objectives

As a result of attending the session **How Do Health Departments Create Regulations, Policies, and Guidance Documents? Overview of Administrative Law: Part 2**, please indicate your current confidence level for each of the following learning objectives of the course:

1. I can explain what regulations are, when and how health departments create them, and how the process can promote health equity.
 - a. Not confident
 - b. Somewhat confident
 - c. Confident
 - d. Very confident
2. I can describe common legal challenges to public health regulations.
 - a. Not confident
 - b. Somewhat confident
 - c. Confident
 - d. Very confident
3. I can explain what policies and guidance documents are and how they differ from regulations.
 - a. Not confident
 - b. Somewhat confident
 - c. Confident
 - d. Very confident
4. I can identify and implement best practices for issuing policies and guidance documents to ensure that the process is fair, equitable, and accessible to everyone.
 - a. Not confident
 - b. Somewhat confident
 - c. Confident
 - d. Very confident

Overall Impression

5. How would you rate the overall session?
 - a. Poor
 - b. Fair
 - c. Good
 - d. Very good
 - e. Excellent

6. I would recommend this session to others.
 - a. Disagree
 - b. Somewhat disagree
 - c. Neither agree nor disagree
 - d. Somewhat agree
 - e. Agree

Additional Feedback

7. What was the most valuable part of the session?

8. How could this session have been improved?

9. What topics would you like to see addressed in future sessions on public health law?

Thank you for your feedback!