

Getting Your Voice Heard: Commenting on Federal Regulations

Most people know that Congress creates new federal laws by passing bills that are signed by the President, but that's not the only way federal rules are established. Federal agencies also issue new regulations that have the same force and effect as the laws passed by Congress. This fact sheet explains the legal process for creating those regulations, including how and when the public can provide input.

Why Do Federal Agencies Issue Regulations?

When Congress writes laws, it does not always specify how they should be implemented. Instead, Congress can give an executive branch or independent federal agency the authority to implement certain provisions. For example, the Patient Protection and Affordable Care Act of 2010 requires the Food and Drug Administration (FDA) to implement a provision requiring chain restaurants to post calorie-counts of their menu items.¹ Congress often defers to agencies due to their expertise in certain fields; in this example, Congress acted on the idea that the FDA can create menu-labeling regulations more efficiently and maintain closer contact with the restaurant industry, nutrition advocates, and other stakeholders.

Unlike members of Congress, however, agency employees are not democratically elected. In order to provide greater accountability and transparency, Congress requires that agencies work with and solicit feedback from the public during each step of the rulemaking process. This gives the public an opportunity to influence the regulations.

Glossary

Rulemaking

The process of creating new rules or regulations. All federal agency action is considered either *rulemaking* or *adjudication* – that is, either creating obligations or overseeing and enforcing them.

Rule or Regulation

A new legal right or obligation created by an agency, which must be followed just as any other law.

Comment Period

The time period established by an agency for accepting input from the public about potential new rules.

The Federal Register

A daily journal published by the federal government containing proposed rules, final rules, and notices from all federal agencies.

When Does Rulemaking Happen?

The public cannot force an agency to make regulations. Rulemaking happens either (1) when Congress requires it, or (2) when an agency identifies a need for regulation.

Congress may require an agency to fill in the details of a broadly-written law. For example, Congress passed

Guidance vs. Regulations

In addition to regulations, federal agencies may issue guidance through informal documents such as memoranda, circulars, bulletins, manuals, or policy statements. These are different from regulations because they do not go through the public comment period⁴ and are not legally binding. The information in guidance documents is meant to help the public understand laws and regulations, but courts have ruled that compliance with guidance is not mandatory if it goes beyond what a law or regulation mandates.⁵

the Americans with Disabilities Act to ensure that people with disabilities can participate more fully in society, and the law required that buildings be made accessible for those who use wheelchairs. Instead of specifying all of the particulars in the law, Congress directed the Department of Justice to draft and issue regulations with respect to such details as the physical requirements of wheelchair ramps.²

Alternatively, an agency may find an area of the law that needs clarifying or updating and decide

to issue new regulations on its own initiative. For example, the Bureau of Alcohol, Tobacco, and Firearms (BATF) has the authority to regulate advertising and labeling of alcohol products. When the BATF observed a growing trend of advertisements depicting alcoholic beverages as promoting good health, it initiated rulemaking to ensure alcohol producers do not make misleading statements on their labels.³

You can search www.regulations.gov to find proposed regulations with open comment periods. You can also sign up to request alerts (including notification of comment periods) from particular government agencies. For example:

Center for Food Safety and Applied Nutrition

Centers for Disease Control and Prevention

Department of Agriculture

FDA

Federal Communications Commission

A list of other federal Health and Human Services agencies offering email alerts is [here](#).

How are Rules Created?

Federal agency rulemaking will generally follow this four-step process:⁶

Step 1: Notice Issued.

Once an agency decides to craft a new regulation, it will create a draft version and then seek feedback from the public through a published notice in the Federal Register. This notice serves two important functions. First, it gives people an opportunity to review the draft and provide feedback on how it will affect their interests. Second, the notice defines the parameters of and provides deadlines for the public comment period.

Step 2: Comment Period.

During this stage, the public can submit comments about the proposed regulation directly to the agency (either through the mail or online at www.regulations.gov). This period usually lasts 30 or 60 days, but can vary anywhere from ten days to nine months.⁷

Step 3: Agency Consideration.

Once the initial public comment period closes, the agency will move to reading and considering the feedback it has received.⁸ The agency is required to read *all* comments submitted, and to respond to significant comments and alternative regulatory proposals.⁹

Step 4: Final Rule Issued.

After considering the comments, the agency will publish the new regulation in the Federal Register. Once it formally takes effect, the regulation will have the force of law. Along with the publication of the new regulation, the agency must also include responses to the public's major comments and explain why proposed changes to the draft comments were either included or rejected.

This cycle can begin and end at any time, so being prepared in advance for each stage of the process is crucial.

How Can the Public Get Involved?

During the comment period on a proposed regulation, anyone – including local government officials, advocacy groups, and individual citizens – can submit *any* relevant material to help educate the agency about a regulation's potential impact or convey an opinion on the issue. If you know of an agency that is gearing up to take action on a topic of interest, preparing materials in advance (including facts, statistics, and comments) will be very useful.

State and local governments can also pass resolutions in support of or opposition to a particular issue. Resolutions are non-binding documents passed by a state legislature, city council, board of supervisors, or other government body expressing opinions related to a policy goal or intention. For example, communities may consider resolutions related to potential FDA action on menthol-

flavored cigarettes. If and when the FDA began a rulemaking process on such an initiative, the resolutions can be submitted during the public comment period to illustrate a desire for further regulation of tobacco in order to protect public health. Unlike asking a member of Congress to vote for or against a specific bill, submitting public comments to an agency *is not considered lobbying under federal law*.¹⁰

The federal rulemaking process gives the American people an important opportunity to influence federal regulations. To make sure your community's voice and opinions are heard, participation and preparation are key.

¹ 21 U.S.C. § 343(q)(5)(H).

² 42 U.S.C. § 12134.

³ 64 F.R. 57413.

⁴ 5 U.S.C. § 553(b)(3)(A).

⁵ See e.g., *American Trucking Ass'ns v. ICC*, 659 F.2d 452, 462 (5th Cir. 1981), cert. denied, 460 U.S. 1022 (1983).

⁶ 5 U.S.C. § 553.

⁷ 5 U.S.C. § 553(c).

⁸ 5 U.S.C. § 553.

⁹ *Indep. U.S. Tankers Owners v. Dole*, 809 F.2d 847 (1987).

¹⁰ Lobbying Disclosure Act of 1995, 2 U.S.C. § 1602(8)(B)(x). While federal law does not consider commenting on proposed regulations or publicly encouraging agency action to be lobbying, individual states may have different lobbying laws. Additionally, organizations or their funders may have their own rules about what constitutes lobbying. Readers should consult their own attorney for advice about potential lobbying.

The National Policy & Legal Analysis Network to Prevent Childhood Obesity (NPLAN) is a project of Public Health Law & Policy (PHLP). PHLP is a nonprofit organization that provides legal information on matters relating to public health. The legal information in this document does not constitute legal advice or legal representation. For legal advice, readers should consult a lawyer in their state.

Support for this document was provided by a grant from the Robert Wood Johnson Foundation, and the California Department of Public Health under contract #09-11182.