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Law & policy innovation for the common good.

# Getting Your Voice Heard: Commenting on Federal Regulations

Most people know that Congress creates new federal laws by passing bills that are signed into effect. But that's not the only way that federal requirements and restrictions are created. Federal agencies also can issue new regulations that have the same force and effect as the laws passed by Congress – regulations that affect many aspects of our everyday lives. This fact sheet explains the legal process for creating those regulations, including how and when the public can provide input on proposed new rules.

## Why Do Federal Agencies Issue Regulations?

When Congress creates laws, it does not always specify how they should be implemented. Instead, Congress can give an agency the right to regulate a particular field or industry. For example, the Family Smoking Prevention and Control Act of 2009 (the "2009 FDA Law") gave the U.S. Food and Drug Administration (FDA) the authority to create and oversee regulations relating to tobacco products.[1] Because agencies are experts in a certain field, they can create regulations more efficiently and maintain closer contact with individuals affected by the law.

Unlike members of Congress, agency employees are not democratically elected. So to provide greater accountability, Congress has placed various restrictions on agencies' rulemaking abilities, such as requiring that agencies work with the public during the rulemaking process. This gives the public an opportunity to influence the regulations.

## When Does Rulemaking Happen?

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

Congress may require an agency to fill in the details in a broad law. For example, Congress passed 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 details in the law, Congress asked the Department of Justice to make particular regulations such as precisely how steep wheelchair ramps must be.[2]

Alternatively, an agency may find an area of the law that needs clarifying or updating and decide to regulate on its own volition. For example, the Bureau of Alcohol, Tobacco, and Firearms has the authority to regulate advertising and labels for alcohol products. Realizing a trend in the industry, where certain products contained statements about alcoholic beverages promoting good health, the agency began rulemaking to clarify labeling requirements to ensure alcohol producers did not make misleading statements.[3]

The 2009 FDA Law gives the FDA the authority to create a variety of regulations affecting the production, sale, and marketing of tobacco products. In November 2010, the FDA proposed regulations regarding graphic warnings on tobacco packages. Over the next few years the FDA will likely issue proposed regulations on issues such as menthol-flavored cigarettes and dissolvable tobacco products.

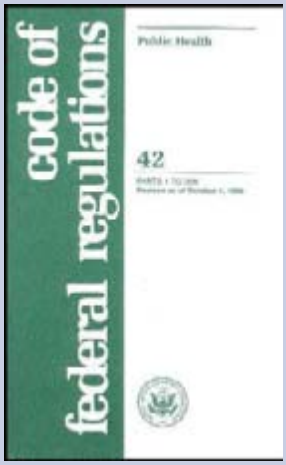
## A Few Terms

***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 (at **www.gpoaccess.gov/fr**) containing rules, proposed rules, and notices from all federal agencies.




*Final rules passed by all federal agencies are entered into the Code of Federal Regulations.*

This document is one in a series of FDA Law Notes addressing issues around the 2009 law. All of the FDA Law Notes are available at **www.changelabsolutions.org/tobacco-control.**

## How are Rules Created?

All federal agency rulemaking will generally follow this four-step process:[4]

***Step 1: Notice Issued***

Once an agency decides to make a new regulation, it will create a draft version and then seek feedback from the public by publishing a notice in the Federal Register. This notice serves two important functions. First, it alerts the public that the agency is considering creating a new regulation, giving people an opportunity to review the draft and evaluate how it will affect their community. Second, the notice says how and for what period of time to comment. You can sign up on agency websites to be alerted when the agency issues a notice (the notification sign-up for the FDA is at **https://service.govdelivery.com/service/subscribe.html?code=USFDA_131**).

***Step 2: Comment Period***

During this stage, the public can submit documents about the proposed regulation directly to the agency (through the mail or online at **www.regulations.gov**). This period usually lasts 60 days, but can vary from ten days to nine months depending on the time allotted in the notice.[5]

***Step 3: Agency Consideration***

During this stage, the agency will read and consider the comments.[6] The agency is required to read *all* comments submitted, and to respond to significant comments and alternative regulatory proposals.[7]

***Step 4: Final Rule Issued***

After considering the comments, the agency will publish the new regulation in the Federal Register. With the publication of the new regulation, the agency must respond to the public's major comments and explain why other regulatory alternatives were not pursued. The regulation will later be compiled with all of the other regulations passed by federal agencies in the Code of Federal Regulations, where it will have the force of law.

This four-step cycle can begin at any time, so being prepared is crucial.

## How Can the Public Get Involved?

During the comment period on a proposed regulation, anyone – including local government officials, advocacy groups, and individuals – can submit *any* relevant material to help educate the agency about a regulation's potential impact or convey the public's opinion on the issue. If you know an agency may be taking action, preparing materials in advance (including facts, statistics, and comments) will be useful.

Local governments can also pass resolutions in support of (or opposition to) a particular issue. Resolutions are non-binding documents passed by a city council or board of supervisors, expressing a policy goal or intention. For example, communities may consider passing resolutions asking the FDA to ban menthol-flavored cigarettes. When the FDA begins the rulemaking process on the subject, the resolutions can be submitted during the public comment period to illustrate the public's desire for further regulation of tobacco. Submitting public comments to an agency is not considered lobbying under federal law.[8]

The federal rulemaking process gives the American public an opportunity to influence federal regulations, but the chance to do so is brief. To make sure your community's voice and opinions are heard, participation and preparation are key.

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[1] Pub. L. No. 111-31, § 102, 123 Stat. 1776 (codified as amended in scattered sections of 5 U.S.C., 15 U.S.C., and 21 U.S.C.); 21 U.S.C. § 387a-1 (2009). For more information, *see* TALC's publication "Tobacco Laws Affecting California, 2010 Supplement." Available at: www.phlpnet.org/tobacco-control/products/tobaccolawsca.

[2] 42 U.S.C. § 12134 (2010).

[3] 64 F.R. 57413 (1999).

[4] 5 U.S.C. § 553 (2010).

[5] 5 U.S.C. § 553(c) (2010).

[6] 5 U.S.C. § 553 (2010).

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

[8] Lobbying Disclosure Act of 1995, 2 U.S.C. § 1602(8)(B)(x) (2010). 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.

*ChangeLab Solutions formerly existed under the name Public Health Law & Policy (PHLP), which included the Technical Assistance legal Center (TALC). Any references to PHLP or TALC in this publication should now be understood to refer to ChangeLab Solutions.*

*ChangeLab Solutions is a nonprofit organization that provides legal information on matters relating to public health. The legal information provided in this document does not constitute legal advice or legal representation. For legal advice, readers should consult a lawyer in their state. This material was made possible with funds received from the California Department of Public Health under contract #09-11182.*