Participatory Rulemaking: A Guide to Locating and Commenting on Proposed Federal Regulations
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Public Health and Tobacco Policy Center

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The Public Health and Tobacco Policy Center is a resource for the New York Department of Health. It is funded by the New York State Department of Health and works with the New York State Tobacco Control Program, the New York Cancer Prevention Program, as well as the programs’ contractors and partners to develop and support policy initiatives that will reduce the incidence of cancer and tobacco-related morbidity and mortality.

This work provides educational materials and research support for policy initiatives. The legal information provided does not constitute and cannot be relied upon as legal advice.
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Notice and Comment Rulemaking

Introduction
Did you know you have the ability to influence federal regulations? You do!

In fact, the “notice and comment” rulemaking process that federal agencies use relies on public input. As the name implies, an agency must give public notice of its proposed rule and then solicit public comment on that proposal. Anyone with relevant experience, knowledge or opinions on the proposed agency action, including how it may be improved and why it should remain in its current form, may contribute comments. The agency is obliged to consider each sound contribution and explain the outcome. Public submissions and agency analyses are recorded in and available for public and judicial review. Widespread input on the draft rule is important: it helps ensure an agency has weighed diverse perspectives and research and should thus result in a more effective final regulation. Because federal agencies are not comprised of elected individuals, the public’s opportunity to influence legislation and hold government accountable stems from the notice and comment rulemaking process and is therefore integral to our democratic process.

Purpose of this Guide
As an educator of tobacco control measures, you have firsthand experience with these issues and serve as the agency’s eyes and ears on policy efficacy, practicality, feasibility and more. Your input on relevant regulations is not only valuable, it’s vital. Through notice and comment rulemaking, you can review proposed rules and share your insights with regulators by submitting a comment.

This guide outlines the purpose and process of notice and comment rulemaking. It intends to familiarize the reader with relevant federal government publications and requirements, as well as how the public may submit comments on a proposed federal rule. The guide includes steps detailing how to:

- find a proposed rule of interest in print and online;
- submit a comment on a proposed rule by U.S. Mail and the internet;
- craft a relevant comment easily linked to the proposed rule;
- track a submission and verify the agency has reviewed it.

How does an agency provide “notice” of a proposed rule?
- Federal agencies publish proposed rules in the government’s daily newspaper, called the Federal Register.¹ The Federal Register is published in print and on the internet.
- Through publishing the proposed rule in the Federal Register, an agency has satisfied its requirement to give “notice” to the public of upcoming regulations. Most agencies will also announce the existence of their proposed rule on its website and through email to recipients registered for such updates.
- These proposed rules are published for public input and are not final rules; accordingly, they are not in effect and are not enforceable. An agency must complete the required rulemaking process, including seeking and evaluating public comments, before a rule becomes binding.

¹ Federal Register
What is Federal “comment”? 

- A proposed agency rule is published to allow the public opportunity for input on the rule. When this written input is submitted to the agency, it is considered a “comment” and becomes part of the agency’s official record.
- A comment may be formal or informal; based on research, experience and/or observations; on behalf of a group or individual or anonymous. The purpose is to explain which aspects of a proposed rule you agree or disagree and the support for your position. Including your relevant education, training or experience may increase the value of your comment. Comments may include policy alternatives or language changes and their rationale, such as explaining how your suggestions would strengthen the final rule and/or the agency objective.
- Comments on proposed rules are accepted during a defined time period, beginning with the rule’s publication in the Federal Register. (Note, comments on requests for guidance documents may be submitted even after the guidance is finalized.)
- This announcement and posting includes details on how comments may be submitted and when the comment period ends. In some instances the agency might hold a hearing wherein oral comments from interested and affected parties are presented.
- Agencies are not required by law to maintain the comment period for a specific amount of time, but rather are required to provide a public comment period of “not less than 30 days before [the rules] effective date.” Since comment periods vary, interested parties should check the announcement reporting the comment period for the regulation of interest.
- All written and oral comments become part of the rulemaking record.
- Neither federal law nor New York law considers commenting a form of lobbying.

What happens after “notice and comment” is complete? 

- After the comment period closes, the agency must consider all submitted comments and hearing testimony. The agency may choose to revise the rule in light of the feedback.
- If the agency significantly changes the initial rule, there must be an additional public comment period and the above process is repeated.
- Once the agency has finalized the rule, it publishes this “final rule” in the Federal Register and sets a date for the rule to go into effect.
- The final rule is then added to the Code of Federal Regulations.
- A record of the entire process, including summaries of all submitted comments and the agency’s decision regarding these comments, is created and is publically available in the Federal Register.
- A rule could be challenged based on several things, including claims that it was passed “without observance of [agency] procedure required by law; unsupported by substantial evidence... or unwarranted by the facts...” The official record serves to document that there is strong basis in facts and evidence for the final rule. It also documents the process undertaken by an agency and may be reviewed by a judge if the legitimacy of that process is challenged.
Step One – Finding Proposed Rules

There are several ways to learn of proposed rules calling for public comment:

a. The Federal Register
b. Regulating Agency Website
c. Regulations.gov

The Federal Register

The Federal Register is published daily online and in print and lists all Federal agencies’ proposed rules, alongside newly implemented rules. Included in the announcement is the duration of the public comment period. Comments on proposed rules must be submitted before the comment period closes.

Subscribe to Federal Register notifications; choose notifications pertaining to an agency, topic, or personalized search results.

The print edition organizes the regulations by overseeing agency (listed alphabetically). [Note FDA is an agency within Dep’t of Health & Human Services.] The website may be searched several ways, including by agency (e.g., "FDA"), topic (e.g., “tobacco”) and current proposed rules.

Subscribe to Federal Register notifications; choose notifications pertaining to an agency, topic, or personalized search results.
Regulating Agency Website

Many agencies post their proposed rules on their website. For example, the FDA’s website has a “Tobacco Products” section identifying dockets currently open for public comment.

You may also register for FDA email or text general updates regarding tobacco products, including relevant rules.\(^ {14} \)
Regulations.gov lists all open matters or “dockets” for all federal agencies. Search by title, docket number, agency or keywords, such as “secondhand smoke” or “tobacco products” to find related rules open for comment.

Or, browse the site by featured regulations and subject. Tobacco control regulations may fall under “Food Safety, Health, and Pharmaceutical.”

You may narrow your search using the filter, located on the left side of the screen. For example, you may opt to view only open proposed rules.

To view or register for Regulations.gov alerts about a specific proposed rule, locate the rule on the website, then navigate to the “Docket Folder Summary” by clicking the Docket ID hyperlink.
The Docket Folder Summary page posts links to communications about the rule, such as comment period extensions and recent additions or redactions as well as third party comments on the proposal. (Check back - your comment may ultimately be filed and placed in this docket!)

The Docket Folder Summary page also links to the “Email Alert” registration page.
Step Two – Drafting a Comment

Who may comment on proposed rules?

Everyone is invited to submit a comment. Private individuals, subject matter experts, affected persons, communities or businesses, non-profits and health departments are just some examples of parties whose participation in the rulemaking process help strengthen an agency rule. Tobacco companies make it a priority to ensure the industry’s perspective is well represented. They typically submit numerous lengthy comments, citing industry-funded research and data. It is crucial to balance that perspective and ensure the agency receives the opinions and perspectives of the public health community.

What should comments look like?

- Provide a clear statement of whether you support or oppose the proposed rule or guidance. Determine whether the agency is seeking general comments or guidance on a specific question and accordingly tailor your remarks. It is important to make your comment relevant or the agency will not be required to address your issue.15
- Explain why you support or disagree with the existing proposal, and include rationale for your suggested changes.
- Detail the information and/or professional or personal experiences that support your opinion.
  - State your opinion as specifically as possible, provide as much support for your opinion as you can, and explain - preferably with real world examples - your concerns and how your suggestions benefit the public.16
  - When applicable, include a copy of articles or other references.
- Be sure to identify the proposed regulation or guidance on which you are commenting by including the docket number, the subject heading, or the citation to the Federal Register.17
Step Three – Submitting a Comment

How may I comment on proposed rules?

a) Submit a comment through the interweb
b) Submit a comment by facsimile or US Post

Submitting a comment through the interweb

Submit comments via the internet using Regulations.gov. Upon finding a proposed regulation of interest, click its title to review, or click “Comment Now!” to submit your comment.

Selecting “Comment Now!” brings you to the comment submission page. Here, you may type your comments on the screen or upload a file containing your comment.

If you enter your comments directly onto the webpage, you will still have the option to preview and edit it prior to Submission; click “Preview Comment” or “Submit.”
Examples of comments submitted as a file attachment through regulations.gov.

Example of comment typed directly onto regulations.gov webpage.
Submitting by fax or US Post

Comments may be faxed or mailed to the agency using the address and contact person stated in the Federal Register. The Federal Register will also include the deadline for submitting comments on proposed regulations. Be sure any submission includes the rule title and docket number.

Some agencies also provide a U.S. Postal address on regulations.gov. If so, the comment submission page will offer “Alternate Ways to Comment,” which displays the U.S. Postal address to which comments may be sent.
Step Four – After Comment Submission

What to expect after submitting a comment.

- If you submit your comment electronically through regulations.gov, upon submission you will receive a confirmation page with a “Comment Tracking Number.” This unique number is the easiest way to recall your comment in the future. After the agency has processed your comment it will be posted to the regulations.gov website.

- If you submit a comment through U.S. Mail, consider using a delivery service, such as certified mail, signature confirmation or delivery confirmation. Do not expect the agency to confirm receipt of a submission. However, your comment may also be posted on regulations.gov, along with comments submitted directly through the internet.

- Allow time for processing; your comment may not appear in the electronic docket for several weeks, regardless of submission method.

- An agency is not obligated to respond individually to each individual comment; however, the published record must acknowledge all received submissions.

How can I be sure an agency has read my comment?

- The Final Rule must be published in the Federal Register and must include:
  - Summaries of all relevant comments the agency received during the notice and comment period; and
  - An explanation of the agency’s reasoning for making or not making changes consistent with the comments they received.¹

- These comments and the agency response to them are compiled and available to the public; visit regulations.gov or the website identified in the publication of the final rule.

- Review the comment summaries and note the agency response. The concept of your comment should be reflected, even if it is worded differently from your submission. Record must acknowledge all received submissions.

¹To view the proposed rule, supporting documents, and the comments we received, go to http://www.regulations.gov/#docketDetail;D=APHIS-2011-0073.
## Resources

<table>
<thead>
<tr>
<th>Federal Register</th>
<th><a href="https://www.federalregister.gov/">https://www.federalregister.gov/</a></th>
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| Federal Register Purchase by U.S. Mail | Superintendent of Documents  
P.O. Box 371954  
Pittsburgh, PA 15250-7954 |
| Federal Register Subscribe to Table of Contents Listserve | [http://listserv.access.gpo.gov/](http://listserv.access.gpo.gov/) |
| Food & Drug Administration Comment Online | [www.regulations.gov](http://www.regulations.gov)  
(enter “Food and Drug Administration” or notice number in the search box) |
| New York State Department of Health Mailing Address | New York State Department of Health  
Corning Tower  
Empire State Plaza  
Albany, NY 12237 |
Citations

6 5 U.S.C.A. § 557(c)(3).
8 N.Y. LEGIS. LAW § 1-c (c)(E) (McKinney) (2011).
10 Id.
14 To sign up for docket updates through regulations.gov, go to the docket folder, click “sign up for E-mail alerts” link and enter your e-mail address along with the frequency of updates you would like to receive. Frequently Asked Questions, REGULATIONS.GOV, http://www.regulations.gov/#!faqs;qid=6-2 (last visited June 14, 2012).
15 About the Federal Register, supra note 1.
17 Frequently Asked Questions, REGULATIONS.GOV, supra note 14.
18 To find out if an agency accepts comment by mail, click the “Alternate Ways to Comment Link” on the online comment page through regulations.gov (displayed on page 5). Frequently Asked Questions, REGULATIONS.GOV, supra note 14.
Providing legal expertise to support policies benefiting the public health.

The Public Health and Tobacco Policy Center is a legal research Center within the Public Health Advocacy Institute. Our shared goal is to support and enhance a commitment to public health in individuals and institutes who shape public policy through law. We are committed to research in public health law, public health policy development; to legal technical assistance; and to collaborative work at the intersection of law and public health. Our current areas of work include tobacco control and childhood obesity and chronic disease prevention. We are housed in Northeastern University School of Law.

**What we do**

**Research & Information Services**
- provide the latest news on tobacco and public health law and policy through our legal and policy reports, fact sheets, quarterly newsletters, and website

**Policy Development & Technical Assistance**
- respond to specific law and policy questions from the New York State Tobacco Control Program and its community coalitions and contractors, including those arising from their educational outreach to public health officials and policymakers
- work with the New York State Cancer Prevention Program to design policies to prevent cancer
- assist local governments and state legislators in their development of initiatives to reduce tobacco use
- develop model ordinances for local communities and model policies for businesses and school districts

**Education & Outreach**
- participate in conferences for government employees, attorneys, and advocates regarding critical initiatives and legal developments in tobacco and public health policy
- conduct smaller workshops, trainings webinars, and presentations focused on particular policy areas
- impact the development of tobacco law through *amicus curiae* ("friend of the court") briefs in important litigation

**Find us online**

[www.tobaccopolicycenter.org](http://www.tobaccopolicycenter.org)

The Center’s website provides information about recent tobacco news and case law, New York tobacco-related laws, and more. Current project pages include: tobacco-free outdoor areas; tobacco product taxation; smoke-free multiunit housing; and retail environment policies. The website also provides convenient access to reports, model policies, fact sheets, and newsletters released by the Center.

[http://twitter.com/CPHTP](http://twitter.com/CPHTP)  
[https://www.facebook.com/CPHTP](https://www.facebook.com/CPHTP)

Follow us on Twitter and Facebook for informal updates on the Center and current events.

**Requests for Assistance**

The Center is funded to support the New York State Tobacco Control Program, the New York State Cancer Prevention Program and community coalitions and educators. The Center also assists local governments and other entities as part of contractor-submitted requests. If we can help with a tobacco-related legal or policy issue, please contact us.

The Center provides educational information and policy support. The Center does not represent clients or provide legal advice.