

A Guide to the Rulemaking Process

Prepared by the Office of the Federal Register¹

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¹ The material presented in this guide is necessarily general in nature and should not be used to make legal decisions. We use the terms “rule” and “regulation” interchangeably in the text. The guide is adapted from several major sources: the Cornell e-Rulemaking Initiative (CeRI) “Regulation Room,” hosted by the Cornell Legal Information Institute (LII) at <http://regulationroom.org/learn-about-rulemaking/>; the “Reg Map” created by ICF Consulting with the cooperation of the General Services Administration’s Regulatory Information Service Center at <http://www.reginfo.gov/public/reginfo/Regmap/index.jsp>; the Office of the Federal Register’s tutorial: “The Federal Register: What it Is and How to Use It” at <http://www.archives.gov/federal-register/tutorial/online-html.html#top>; and the Department of Transportation’s “The Informal Rulemaking Process,” which has more detailed information and examples on the rulemaking process. In addition, you may wish to consult DOT’s “Rulemaking Requirements” (prepared by Neil Eisner, April 2009), which provides hyperlinks for easy access to the statutes, executive orders, guidance documents, memoranda, etc. that contain the actual legal requirements or provide guidance on the rulemaking process.

What gives agencies the authority to issue regulations?

Agencies get their authority to issue regulations from laws (statutes) enacted by Congress. In some cases, the President may delegate existing Presidential authority to an agency. Typically, when Congress passes a law to create an agency, it grants that agency general authority to regulate certain activities within our society. Congress may also pass a law that more specifically directs an agency to solve a particular problem or accomplish a certain goal.

An agency must not take action that goes beyond its statutory authority or violates the Constitution. Agencies must follow an open public process when they issue regulations, according to the Administrative Procedure Act (APA). This includes publishing a statement of rulemaking authority in the *Federal Register* for all proposed and final rules.

How does an agency decide to begin rulemaking?

Congress may pass a law that directs an agency to take action on a certain subject and set a schedule for the agency to follow in issuing rules. More often, an agency surveys its area of legal responsibility, and then decides which issues or goals have priority for rulemaking.

These are a few of the many factors that an agency may consider:

- New technologies or new data on existing issues;
- Concerns arising from accidents or various problems affecting society;
- Recommendations from Congressional committees or federal advisory committees;
- Petitions from interest groups, corporations, and members of the public;
- Lawsuits filed by interest groups, corporations, States, and members of the public;
- Presidential directives;
- “Prompt letters” from the Office of Management and Budget (OMB);
- Requests from other agencies;
- Studies and recommendations of agency staff.

When can the public learn that an agency plans to start a rulemaking?

Agencies are required to publish a “Regulatory Plan” once a year in the fall and an “Agenda of Regulatory and Deregulatory Actions” in the spring and fall. The Regulatory Plan and the Regulatory Agenda are often referred to as the “Unified Agenda.” The Unified Agenda is how agencies announce future rulemaking activities update the public on pending and completed regulatory actions.

The Unified Agenda is posted on [RegInfo.gov](https://www.reginfo.gov) and [Regulations.gov](https://www.regulations.gov). Agencies also publish most of this material (their regulatory plans) in the *Federal Register*. The *Federal Register* version and a separate Unified Agenda collection are available on the Government Printing Office’s (GPO) Federal Digital system ([FDsys.gov](https://www.fdsys.gov)).

How does an agency involve the public in developing a proposed rule?

An agency may take some preliminary steps before issuing a proposed rule. They gather information through unstructured processes and informal conversations with people and organizations interested in the issues. If an agency receives a “Petition for Rulemaking” from a member of the public, it may decide to announce the petition in the *Federal Register* and accept public comments on the issue.

An agency that is in the preliminary stages of rulemaking may publish an “Advance Notice of Proposed Rulemaking” in the *Federal Register* to get more information. The Advance Notice is a formal invitation to participate in shaping the proposed rule and starts the notice-and-comment process in motion.

Anyone interested (individuals and groups) may respond to the Advance Notice by submitting comments aimed at developing and improving the draft proposal or by recommending against issuing a rule. Some agencies develop proposed rules through a negotiated rulemaking. In this process, an agency invites members of interested groups to meetings where they attempt to reach a consensus on the terms of the proposed rule. If the participants reach agreement, the agency may endorse their ideas and use them as the basis for the proposed rule.

What is the role of the President in developing a proposed rule?

Before a proposed rule is published in the *Federal Register* for public comment, the President, as head of the Executive branch, may take the opportunity to review the rule. The President is assisted by the Office of Information & Regulatory Affairs (OIRA), which analyzes draft proposed rules when they are “significant” due to economic effects or because they raise important policy issues. For significant rules, the agency must estimate the costs and benefits of the rule and consider alternate solutions.

If the proposed rule requires the public to provide information to the government, the agency must estimate the paperwork burden on the public and obtain permission to proceed from OIRA. In addition, the agency may be required to analyze a proposed rule's impact on: small businesses; state, local and tribal governments; families; federalism. It may also need to analyze issues of just compensation and unfunded mandates.

The Proposed Rule

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What is the purpose of the proposed rule?

The proposed rule, or Notice of Proposed Rulemaking (NPRM), is the official document that announces and explains the agency's plan to address a problem or accomplish a goal. All proposed rules must be published in the *Federal Register* to notify the public and to give them an opportunity to submit comments. The proposed rule and the public comments received on it form the basis of the final rule.

How is the proposed rule structured?

Proposed rules have preambles which contain a summary, date and contact information, and supplementary information. A proposed rule begins with a "Summary" of the issues and actions under consideration; it also states why the rule is necessary. Under the "Dates" and "Addresses" captions, the agency invites everyone to comment on the proposed rule, sets a date for comments to be submitted, and specifies various methods for conveying comments. Many agencies give several options for submitting comments, including U.S. mail, private courier, email, and the official federal electronic comment portal: Regulations.gov.

In the "Supplementary Information" portion, the agency discusses the merits of the proposed solution, cites important data and other information used to develop the action, and details its choices and reasoning. The agency must also identify the legal authority for issuing the rule.

Following the preamble, the agency usually publishes the regulatory text of the proposal in full. The regulatory text sets out amendments to the standing body of law in the Code of Federal Regulations. If the amendments are not set out in full text, the agency must describe the proposed action in a narrative form.

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What is the time period for the public to submit comments?

In general, agencies will specify a comment period ranging from 30 to 60 days in the “Dates” section of the *Federal Register* document, but the time period can vary. For complex rulemakings, agencies may provide for longer time periods, such as 180 days or more. Agencies may also use shorter comment periods when that can be justified.

Members of the public may request that the agency allow more time to submit comments, and agencies may consider late-filed comments, if their decision-making schedule permits it. Commentors should be aware that agencies generally are not legally required to consider late-filed comments. Agencies usually provide information in the proposed rule and/or their procedural rules indicating whether they will consider late-filed comments.

Why do agencies re-open comments or issue multiple proposed rules?

An agency may extend or re-open a comment period when it is not satisfied that it has enough high quality comments or when the public comments make a good case for adding more time.

Similarly, an agency may find that people have raised new issues in their comments that were not discussed in the initial proposed rule. As new issues or additional complexity arises, the agency may publish a series of proposed rules in the *Federal Register*.

Do agencies have additional options for gathering public comments?

During the comment period, an agency may also hold public hearings where people can make statements and submit data. Some agencies operate under laws that require rulemaking hearings. Others may hold public meetings to collect more information or to help affected groups get a better understanding of the proposed rule. Many agencies are beginning to use webcasts and interactive Internet sessions to broaden the audience attending public meetings.

After the comment period closes, an agency may establish a second period for reply comments (comments that respond to prior comments). A reply period is not required by law. The reply comment period enables people to respond to comments that agencies received at the end of comment period, creating more of a public dialog.

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Why should you consider submitting electronic comments?

Most agencies now prefer to receive comments electronically so that your input on a proposed rule or other document is more easily available to the public. Having electronic data helps agencies organize the comments by subject or in other ways to help the public and the agency make more effective use of them.

You can submit electronic comments to the agency docket site by following the instructions in the *Federal Register*. Many of the proposed rules and other documents on this site display a special button for submitting comments directly to the official electronic docket. For information on using the federal eRulemaking portal to submit comments, go to the Regulations.gov “Help” pages on submitting a comment.

Before the Final Rule

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How do public comments affect the final rule?

The notice-and-comment process enables anyone to submit a comment on any part of the proposed rule. This process is not like a ballot initiative or an up-or-down vote in a legislature. An agency is not permitted to base its final rule on the number of comments in support of the rule over those in opposition to it. At the end of the process, the agency must base its reasoning and conclusions on the rulemaking record, consisting of the comments, scientific data, expert opinions, and facts accumulated during the pre-rule and proposed rule stages.

To move forward with a final rule, the agency must conclude that its proposed solution will help accomplish the goals or solve the problems identified. It must also consider whether alternate solutions would be more effective or cost less.

If the rulemaking record contains persuasive new data or policy arguments, or poses difficult questions or criticisms, the agency may decide to terminate the rulemaking. Or, the agency may decide to continue the rulemaking but change aspects of the rule to reflect these new issues. If the changes are major, the agency may publish a supplemental proposed rule. If the changes are minor, or a logical outgrowth of the issues and solutions discussed in the proposed rules, the agency may proceed with a final rule.

What is the role of the President in developing a final rule?

In the same way that the President and the Office of Information & Regulatory Affairs (OIRA) review draft proposed rules prior to publication, the President and OIRA analyze draft final rules when they are “significant” due to economic effects or because they raise important policy issues. The Presidential level review takes place before the final rule is published in the *Federal Register*. OIRA’s final analysis of estimated costs and benefits may take into consideration any comments and alternate solutions suggested in public comments.

Agencies may also use this review and analysis phase to consult with other agencies who share responsibility for issues covered by the rule. In some cases, interagency review is mandatory.

The Final Rule

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How is the final rule structured?

Final rules also have preambles, including the summary, effective date, and supplementary information. The final rule published in the *Federal Register* begins with a “Summary” of the societal problems and regulatory goals and explains why the rule is necessary.

Every final rule must have an “Effective Date.” However, any portions that are subject to later approval under the Paperwork Reduction Act or are subject to Congressional approval may be excepted from that effective date. The “Dates” caption in the *Federal Register* may also contain compliance or applicability dates.

The agency must state the “basis and purpose” of the rule in the “Supplementary Information” part of the preamble. This statement sets out the goals or problems the rule addresses, describes the facts and data the agency relies on, responds to major criticisms in the proposed rule comments, and explains why the agency did not choose other alternatives.

The agency must identify its legal authority for issuing the rule and publish the regulatory text in full. The regulatory text sets out amendments to the Code of Federal Regulations (CFR). Each amendment begins with instructions for changing the CFR.

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When do final rules go into effect?

When an agency publishes a final rule, generally the rule is effective no less than thirty days after the date of publication in the *Federal Register*. If the agency wants to make the rule effective sooner, it must cite “good cause” (persuasive reasons) as to why this is in the public interest.

Significant rules (defined by Executive Order 12866) and major rules (defined by the Small Business Regulatory Enforcement Fairness Act) are required to have a 60 day delayed effective date.

Can an agency issue a final rule without publishing a proposed rule?

Yes, the Administrative Procedure Act (APA) permits agencies to finalize some rules without first publishing a proposed rule in the *Federal Register*. This exception is limited to cases where the agency has “good cause” to find that the notice-and-comment process would be “impracticable, unnecessary, or contrary to the public interest.” These situations may include emergencies where problems must be addressed immediately to avert threats to public health and safety, minor technical amendments and corrections where there is no substantive issue, and some instances where an agency has no discretion to propose a rule because Congress has already directed a specific regulatory outcome in a law. The agency must state its reasoning for finding good cause in the preamble of the final rule published in the *Federal Register*.

There are other exceptions to conventional notice-and-comment rulemaking. An agency may go straight to final rulemaking without a proposed rule when they issue internal agency procedures, rules that affect only federal employees, and rules that manage federal property and real estate. Even these types of rules can be subject to proposed rulemaking because of a special statutory requirement or because an internal agency rule also has a substantial effect on the public.

Agencies can also issue and enforce rules by using “actual notice,” which requires direct notification of all affected persons and entities. Because it is difficult to pinpoint every person and entity affected by a rulemaking, this option is used mostly for rules that have a very narrow effect on known or readily definable persons or corporations.

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What are interim final rules & direct final rules?

Interim Final Rule: When an agency finds that it has good cause to issue a final rule without first publishing a proposed rule, it often characterizes the rule as an “interim final rule,” or “interim rule.” This type of rule becomes effective immediately upon publication. In most cases, the agency stipulates that it will alter the interim rule if warranted by public comments. If the agency decides not to make changes to the interim rule, it generally will publish a brief final rule in the *Federal Register* confirming that decision.

Direct Final Rule: When an agency decides that a proposed rule is unnecessary because it would only relate to routine or uncontroversial matters, it may publish a direct final rule in the *Federal Register*. In a direct final rule, the agency states that the rule will go into effect on a certain date, unless it gets substantive adverse comments during the comment period. An agency may finalize this process by publishing in the *Federal Register* a confirmation that it received no adverse comments. If adverse comments are submitted, the agency is required to withdraw the direct final rule before the effective date. The agency may re-start the process by publishing a conventional proposed rule or decide to end the rulemaking process entirely.

After the Final Rule

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How are final rules integrated into the Code of Federal Regulations?

Agencies must publish the changes to the Code of Federal Regulations (CFR) in the final rule, instructing how amendments add, revise, remove, or re-designate regulatory text. The CFR contains all of the generally applicable rules of the Federal government with current or future effect.

On the day a final rule is published in the *Federal Register*, Office of the Federal Register and GPO staff being processing the material for codification into the CFR. Rules that are immediately effective are integrated into the “Electronic Code of Federal Regulations” (e-CFR) database (ecfr.gpoaccess.gov). Rules with delayed effective dates are placed in amendment files and linked from the main e-CFR database. The e-CFR is an unofficial, but authoritative editorial compilation published by the Office of the *Federal Register* and GPO. Users can check the update status of the e-CFR by consulting the home page.

The official annual editions of the CFR are assembled from the material published in the e-CFR. Each of the 50 subject matter titles are republished each year on a staggered, quarterly basis, and appear in print and online (<http://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR>).

How is the Congress involved in reviewing final rules?

Under the Small Business Regulatory Enforcement Fairness Act (also known as the Congressional Review Act), new final rules must be sent to Congress and the Government Accountability Office for review before they can take effect. “Major rules” (ones that are economically significant and require OIRA review) must be made effective at least 60 days after the date of publication in the *Federal Register*, allowing time for Congressional review. In emergency situations, a major rule can be made effective before 60 days.

If the House and Senate pass a resolution of disapproval and the President signs it (or if both houses override a presidential veto), the rule becomes void and cannot be republished by an agency in the same form without Congressional approval. Since 1996, when this process started, Congress has disapproved only one rule.

Congress may also exercise its oversight in other ways, by holding hearings and posing questions to agency heads, by enacting new legislation, or by imposing funding restrictions.

Does the regulatory process continue after rules are published?

The regulatory process enters the compliance, interpretation, and review phase after a final rule is published. Individuals and industries affected by a rule, and the agency compliance officers and inspectors who must enforce a rule, may need guidance to better understand the regulatory requirements. Agencies may write compliance materials and technical assistance manuals to distribute to the public. These guidance materials may be posted on a website or published in the *Federal Register* as interpretive rules. See more about interpretive rules and policy statements below.

Based on its experience in enforcing a rule, an agency may decide to change a rule, remove it from the CFR entirely, or let it stand. A law or a Presidential directive may require a formal review process every few years. An agency may undertake a review based on a petition from the public. Its own experts may also begin a review process when conditions change and rules seem outdated. If an agency decides to amend or revoke a rule, it must use the notice-and-comment process to make the change.

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What are interpretive rules and policy statements?

Interpretive rules, policy statements, and other guidance documents may be issued anytime after a final rule is published to help the public understand to how a regulation applies to them and affects their interests. An agency may explain how it interprets an existing regulation or statute, how a rule may apply in a given instance, and what things a person or corporation must do to comply.

There is a key distinction between an interpretive rule and a final “legislative” or “substantive” rule. The interpretive rule or policy statement must not set new legal standards or impose new requirements. Guidance documents do not contain amendments to the CFR and are not subject to the notice and comment process. But in some cases, agencies choose to request comments on interpretive rules and other guidance documents to improve the quality and clarity of the material. Interpretive rules and policy statements that have broad applicability are often published in the *Federal Register*, but some may only appear on agency websites.

When do the courts get involved in rulemaking?

Individuals and corporate entities may go into the courts to make a claim that they have been, or will be, damaged or adversely affected in some manner by a regulation. The reviewing court can consider whether a rule: is unconstitutional; goes beyond the agency’s legal authority; was made without following the notice-and-comment process required by the Administrative Procedure Act or other law; or was arbitrary, capricious, or an abuse of discretion. An agency head can also be sued for failing to act in a timely manner in certain cases.

If a court sets aside (vacates) all or part of a rule, it usually sends the rule back to the agency to correct the deficiencies. The agency may have to reopen the comment period, publish a new statement of basis and purpose in the *Federal Register* to explain and justify its decisions, or restart the rulemaking process from the beginning by issuing a new proposed rule.

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