

FACT SHEET

REGULATIONS

An Introduction to the Federal Regulatory Process

Federal regulations (or rules) are specific directives or requirements enacted by federal agencies. Regulations are necessary to interpret, implement, and enforce laws passed by Congress. The federal regulatory process is carried out by the executive branch, through its various cabinet agencies (e.g, the US Department of Health and Human Services). Once finalized, regulations have the force of law. All finalized regulations can be found in the Code of Federal Regulations (CFR), and are often referred to by the section of the CFR where the regulation resides (e.g., 42 CFR 59 is the citation for the regulations governing the Title X family planning program).

ELEMENTS OF A REGULATION

- A rule or regulation is an administration's interpretation of how a law should be implemented and once finalized has the force of law. Rulemaking, the process of writing and implementing rules, is governed by the Administrative Procedures Act (APA).¹
- The APA was crafted to achieve the following goals: to require agencies to keep the public informed of their organization, procedures, and rules; provide for public participation in the rulemaking process through public commenting; establish a set of standards for the conduct of formal rulemaking and adjudication; and define the scope of judicial review."²
- Proposed or final new regulations are usually published in the Federal Register, with two main sections: the preamble, and the regulatory text. The preamble language is not technically binding but provides good insight into the administration's rationale and intentions. The Federal Register publication often also contains the agency's Regulatory Impact Statement that can include estimations of the potential burden, impact, and cost of the regulation.

STANDARD REGULATORY PROCESS

NPRM Development

A federal agency will write a notice of proposed rulemaking (NPRM), which will then be reviewed by a variety of administration stakeholders, including general counsel, agency political staff, and the White House Office of Management and Budget (OMB) Office of Information and Regulatory Affairs (OIRA). Generally, OIRA's review of a regulation (typically within 90 days) immediately precedes the rule's publication for public inspection.³

Public Comment Review

When the public comment period is over, the agency is required to review all of the submitted comments and respond to all substantial comments in deciding on the final rule.⁴

Final Rule Issued

The final rule is published in the Federal Register. The preamble of the final rule will include the agency's responses to themes in the public comments and explain the administration's rationale for adopting or disregarding those suggestions from the public. The final rule will include an implementation deadline, which is typically no less than 30-60 days from the date of publication.

NPRM Issued

After OMB review, an agency will publish a proposed regulation as an NPRM in the Federal Register. NPRMs are generally made available on the Federal Register website for **public inspection** a few days before it is officially published. The official publication date is what begins the public comment period, which is typically detailed in the NPRM as 30 or 60 days but can be open for longer at the administration's discretion.

Final Rule Development

The agency, after reviewing and considering all of the submitted comments, writes a final rule. Final rules go through a similar review process as NPRMs, which generally end with a review by OIRA.

OTHER TYPES OF RULEMAKING

- In some cases, including public health emergencies, an administration does not have to follow the usual regulatory process of an NPRM followed by a final rule. For instance, an administration can issue an interim final rule (IFR). An IFR functions like a final rule but has a public comment period after the rule goes into effect and the rule is subject to change based on those comments in a revised final rule.

- The administration can also use subregulatory guidance, in the form of frequently asked question documents, policy notices, program guidelines, interpretive rules, etc. Subregulatory guidance does not have the force of law and may not impose new substantive requirements. This type of guidance is intended to provide additional insight and clarification into the administration's thinking on a topic.

¹ Administrative Procedure Act, Pub. L. No. 79-404, 60 Stat. 237 (1946).

² Ibid.

³ "Executive Order 12866" 58 *Federal Register* 190 (October 4, 1993).

⁴ "A Guide to the Rulemaking Process," prepared by the Office of the Federal Register (2011): https://www.federalregister.gov/uploads/2011/01/the_rulemaking_process.pdf.