

PRIM&R The Federal Rulemaking Process

The rulemaking process is how federal agencies write, revise, or update the specific regulations that carry out laws passed by Congress. This process follows a proposal through public input, review, and revision stages before it becomes a final rule.



1



Pre-rule stage: Agencies list upcoming plans in the Unified Agenda, a biannual public to-do list put together by the Regulatory Information Service Center (RISC) with the White House's Office of Information and Regulatory Affairs (OIRA).



Agencies may also publish an Advance Notice of Proposed Rulemaking (a heads-up and input opportunity before the next stage).



Department of Health and Human Services (HHS) has a pre-rule action in the pipeline ([RIN 0937-AA16](#)) that would propose revisions to 45 CFR 46 (the Common Rule), including “clarifying terminology, expanding exemptions for certain low-risk research activities, and enabling flexibilities for regulatory review of de minimis protocol changes.”

2



Notice of Proposed Rulemaking (NPRM): An agency publishes detailed plans for a new regulation or specific revisions or updates to an existing regulation in the Federal Register, known as a “proposed rule.”



This step opens a public comment period (usually 30 to 60 days) where anyone can submit feedback on the proposed rule.

3



Comment and review period: The agency reads and weighs all comments. Decisions must be based on all information collected during the pre-rule and proposed rule stages, including public comments, data, and expert opinions.



Agencies may hold public hearings so people can speak directly about the rule.

4



Final Rule: The agency publishes the Final Rule in the [Federal Register](#) which details the goals of the rule, the facts and data relied on, responses to major criticisms in the comments, and the effective date.



Most rules take effect 30 days after publication; “major” or “significant” rules wait at least 60 days.

5



After the Final Rule: The rule becomes part of the [Code of Federal Regulations \(CFR\)](#).



Agencies may issue extra guidance to help people follow the new rule.

Adapted from “A Guide to the Rulemaking Process,” prepared by the Office of the Federal Register