

Regulatory Compliance and the Rulemaking Process

Practice pointers on representing clients before regulatory agencies and advocacy during the rulemaking process

1. Varying Levels of Requirements
 - a. Statute
 - i. Passed by Congress
 1. Article 1 Powers in U.S. Constitution – “All legislative Powers herein granted shall be vested in a Congress of the United States, which shall consist of a Senate and House of Representatives.”
 - b. Regulation
 - i. Agencies
 1. Derive Powers from Statute passed from Congress – Enabling legislation.
 - a. Regulations cannot conflict or exceed statutory authority.
 - i. If they do, courts can invalidate.
 2. Agencies are quasi-legislative in creating rules; quasi-executive in enforcing; quasi-judicial in assessing penalties.
 - c. Agency Policy
 - i. Policy statements that inform agency staff and the public regarding agency policy are beneficial to both.
 - ii. Nonbinding. Does not have the force of law.
 - d. Informal Guidance
 - i. Often verbal.
2. General Advice
 - a. Having relationships with the agency is key
 - i. Roles change quickly
 - ii. Have multiple key contacts
 - b. Try to Achieve Agreement Before Escalating
3. Interpretation of Rules
 - a. Ask questions on behalf of clients / members
 - b. When asking for consistency, be ready to comply with the uniform interpretation
 - c. Written guidance is key
 - i. Follow up Regularly
 - ii. Hill pressure, when needed, is effective
4. Rulemaking
 - a. Process outlined by the Administrative Procedures Act
 - i. Generally a Notice of Proposed Rulemaking (NPRM) is required to be listed in the [*Federal Register \(FR\)*](#) (5 U.S.C. § 553(b))
 - ii. Comment period offers opportunity to participate (5 U.S.C. § 553(c))
 1. Typically 30 to 60 days.
 2. Can be longer for complex rulemaking or shorter when justified.

3. Not uncommon to request, and be granted, an extension to comment period timing.
- iii. USDA Considers Comments and Issues a Final Rule
 1. USDA revises the regulation according to feedback and issue a final rule.
 2. Final rule is published in the Federal Register and in USDA's official docket on Regulations.gov.
 3. Effective date is at least 30 days following published date, unless exception applies. (5 U.S.C. § 553(d))
- iv. Final Regulation is codified in the *Code of Federal Regulations*
 1. The Federal Regulations Act of 1936 requires codification by subject.
- b. Exceptions to the rulemaking process.
 - i. Administrative Procedure Act (APA) exceptions permitting agencies to finalize some rules without first publishing a proposed rule in the Federal Register. (5 U.S.C. § 553(b)(3))
 1. Interim Final Rule "good cause" to find that the notice-and-comment process would be "impracticable, unnecessary, or contrary to the public interest."
 - a. Often agency stipulates that it will alter the interim rule if warranted by public comments.
 2. Direct Final Rule: Routine or uncontroversial matters. Will go into effect on a certain date, unless it gets substantive adverse comments during the comment period.
- c. Difference in Types of Rules
 - i. Legislative rules, which are those rules that have gone through the full notice and comment process, have the full effect of law unless they are in conflict with statute. (*see Maryland Gas Co. v. U.S.*, 251 U.S. 342, 349 (1920)).
 1. Receive Chevron deference and court must uphold "reasonable" agency interpretation. (*See e.g. NISH v. Cohen*, 247 F.3d 197, 202 (4th Cir. 2001)).
 - ii. Interpretive rules are only a statement of agency's current interpretation and have no "power to control." (*See Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)).
 1. Courts generally look to (1) process in creating interpretation and (2) degree to which the interpretation is of a "binding character" to determine if Chevron deference applies. (*See Barnhart v. Walton*, 555 U.S. 212 (2002)).
- d. General Advice
 - i. Agency policy outside rulemaking can be quicker and easier.
 1. Lacks force of law and more subject to change.

- ii. Strong consensus going into process improves likelihood of rulemaking success.
- 5. Legislative Change
 - a. First show that the issue could not be addressed outside of Congress.
 - b. Work with the relevant agency while undertaking legislative change
 - i. Congress will ask for their technical guidance.
 - ii. Incorporate suggestions on the front end of the process.

Primary Sources

5 U.S.C. §553. Rule making

(a) This section applies, according to the provisions thereof, except to the extent that there is involved-

- (1) a military or foreign affairs function of the United States; or
- (2) a matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.

(b) General notice of proposed rule making shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law. The notice shall include-

- (1) a statement of the time, place, and nature of public rule making proceedings;
- (2) reference to the legal authority under which the rule is proposed; and
- (3) either the terms or substance of the proposed rule or a description of the subjects and issues involved.

Except when notice or hearing is required by statute, this subsection does not apply-

- (A) to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice; or
- (B) when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.

(c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose. When rules are required by statute to be made on the record after opportunity for an agency hearing, sections 556 and 557 of this title apply instead of this subsection.

(d) The required publication or service of a substantive rule shall be made not less than 30 days before its effective date, except-

- (1) a substantive rule which grants or recognizes an exemption or relieves a restriction;

- (2) interpretative rules and statements of policy; or
- (3) as otherwise provided by the agency for good cause found and published with the rule.

(e) Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.

(Pub. L. 89–554, Sept. 6, 1966, 80 Stat. 383 .)

The Attorney General’s Manual on the Administrative Procedures Act (APA):

Substantive Rules—rules, other than organization or procedural [rules], issued by an agency pursuant to statutory authority and which implement the statute.... Such rules have the force and effect of law....

Interpretative rule—rules or statements issued by an agency to advise the public of the agency’s construction of the statutes and rules which it administers....

General Statements of Policy—statements issued by an agency to advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power.