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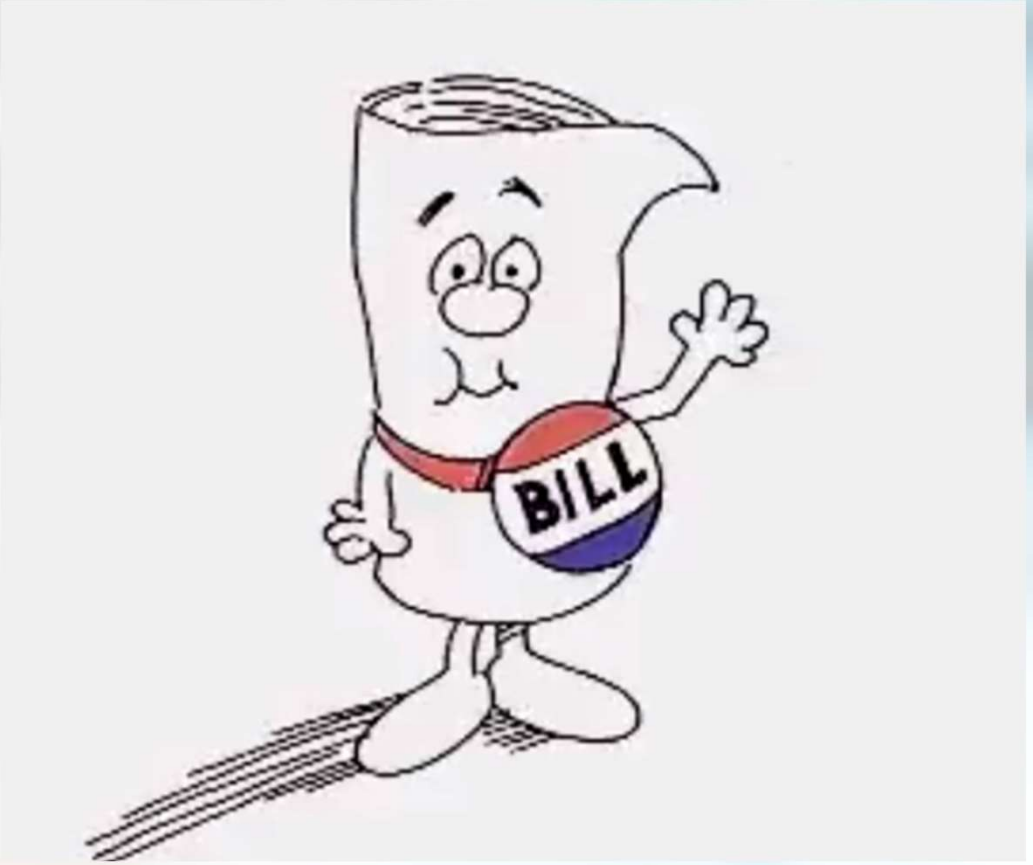
Administrative Procedures Act: Critical Information for Attorneys, aka How a Bill Becomes a Law, Part 2!

Iliana L. Peters, JD, LLM, CISSP

How a Bill Becomes a Law

https://www.cnn.com/2013/01/14/politics/schoolhouse-rock-40/index.html



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How a Bill becomes a Law, Part 1

Federal Legislation

- Industry Groups
- Individuals
- Others

House and Senate

- In consultation with state and federal agencies
- After hearings
- Committee Action
- Floor Action

President

How a Bill becomes a Law, Part 2

- Federal Agency
- Staff Division
- Operating Division
- Political Appointees
- Career Staff

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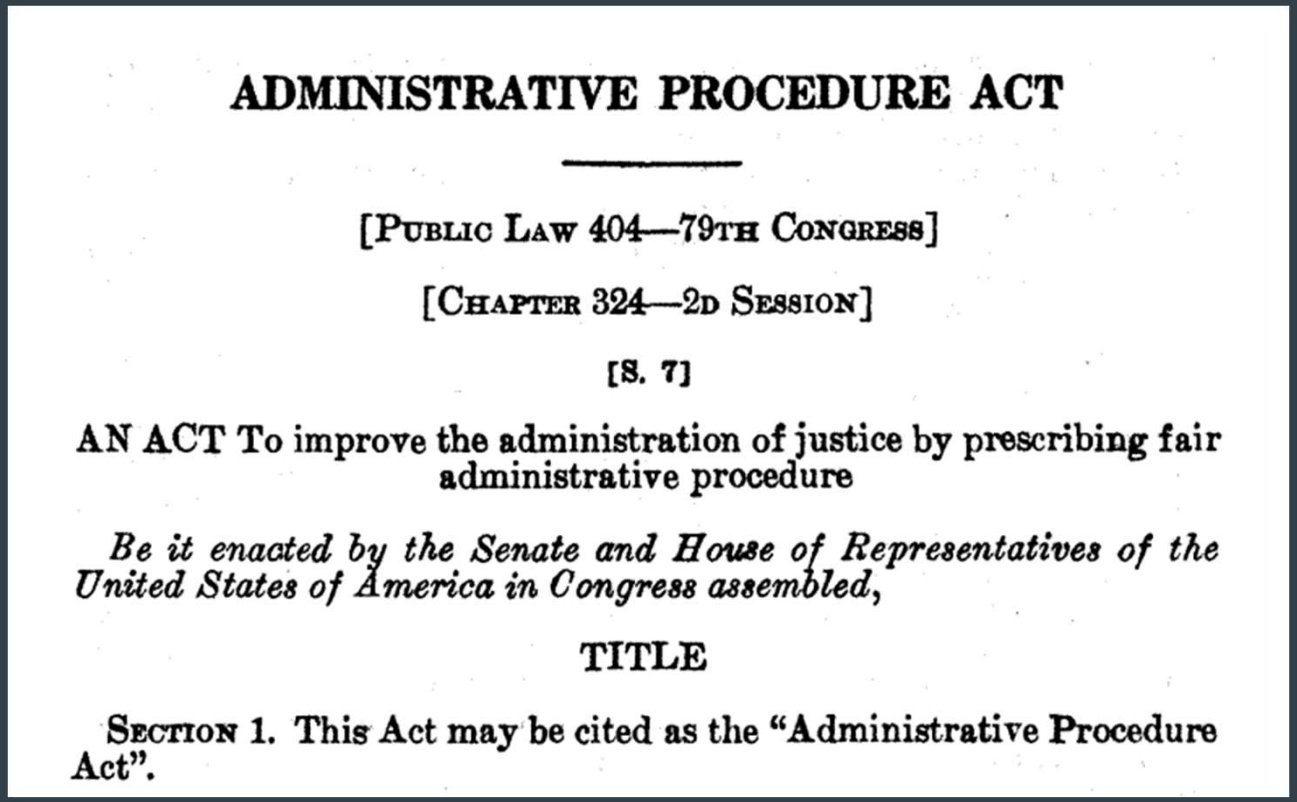
Administrative Procedure Act ("APA")



ADMINISTRATIVE PROCEDURE ACT

[PUBLIC LAW 404—79TH CONGRESS]

[CHAPTER 324—2D SESSION]

[S. 7]

AN ACT To improve the administration of justice by prescribing fair administrative procedure

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

TITLE

SECTION 1. This Act may be cited as the "Administrative Procedure Act".

APA Requirements, Summarized

Request for Information

Notice of Proposed Rulemaking

Interim Final Rule

Comment Period

Final Rule

Federal Rulemaking Procedure

- Agency Draft
- General Counsel Review
- Departmental Review
- Secretary Review
- Office of Management and Budget (“OMB”) Review

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Example: HHS Rulemaking Calendar

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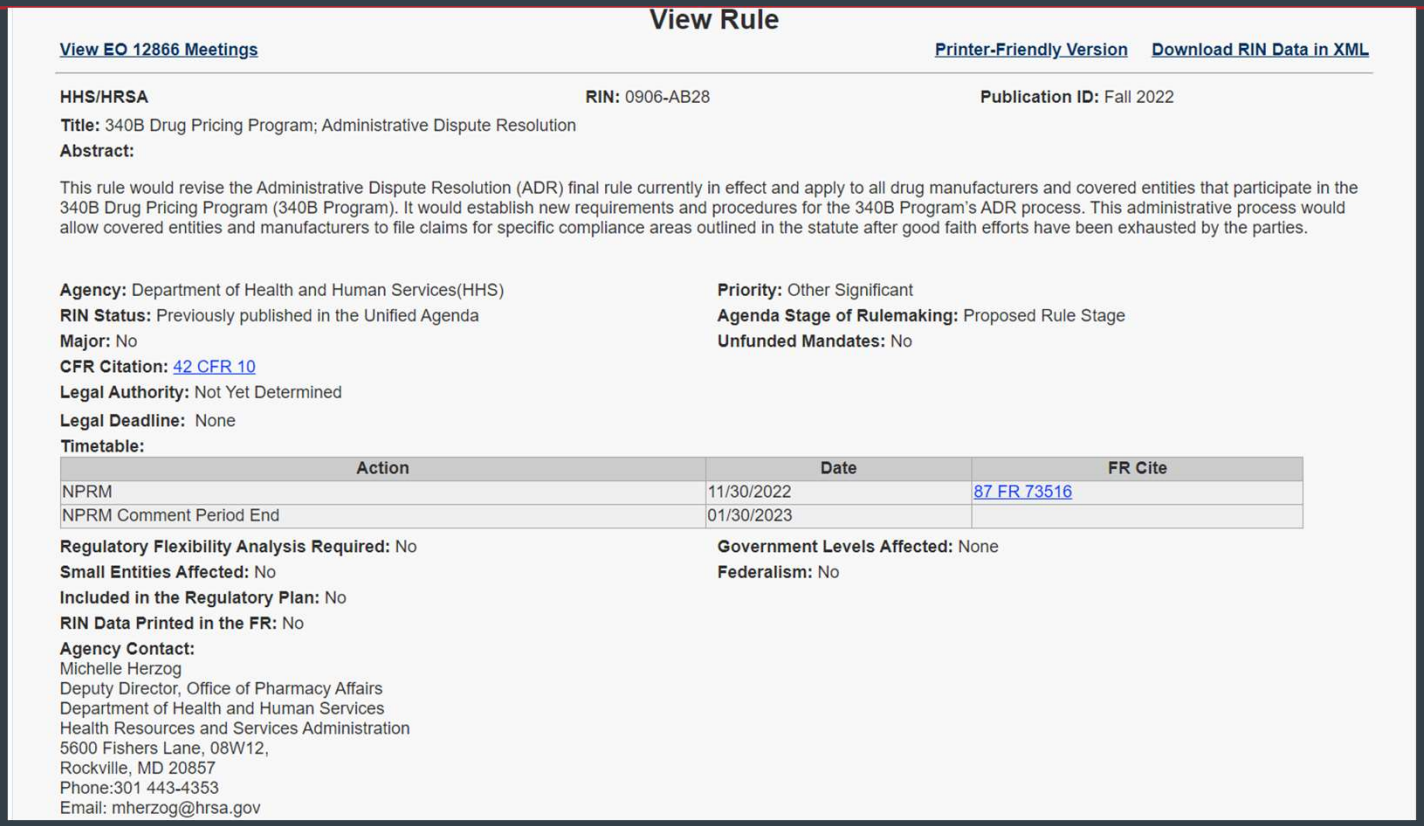
Agency Rule List - Fall 2022

Department of Health and Human Services

Agency	Agenda Stage of Rulemaking	Title	RIN
HHS/HRSA	Proposed Rule Stage	340B Drug Pricing Program; Administrative Dispute Resolution	0906-AB28
HHS/FDA	Proposed Rule Stage	Investigational New Drug Applications; Exemptions for Clinical Investigations to Evaluate a Drug Use of a Product Lawfully Marketed as a Conventional Food, Dietary Supplement, or Cosmetic	0910-AH07
HHS/FDA	Proposed Rule Stage	Post Approval Changes to Approved Applications	0910-AH55
HHS/FDA	Proposed Rule Stage	Current Good Manufacturing Practice for Positron Emission Tomography Drugs	0910-AH58
HHS/FDA	Proposed Rule Stage	Current Good Manufacturing Practice for Outsourcing Facilities	0910-AH61
HHS/FDA	Proposed Rule Stage	Medication Guide; Patient Medication Information	0910-AH68
HHS/FDA	Proposed Rule Stage	Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food	0910-AH77
HHS/FDA	Proposed Rule Stage	Permanent Listing of Color Additive Lakes	0910-AH80
HHS/FDA	Proposed Rule Stage	Amendments to Registration of Food Facilities	0910-AH82
HHS/FDA	Proposed Rule Stage	Requirements for Tobacco Product Manufacturing Practice	0910-AH91
HHS/FDA	Proposed Rule Stage	Administrative Detention of Tobacco Products	0910-AI05
HHS/FDA	Proposed Rule Stage	Protection of Human Subjects and Institutional Review Boards	0910-AI07

Example: RIN 0906-AB28

https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202210&RIN=0906-AB28



View Rule

View EO 12866 Meetings | Printer-Friendly Version | Download RIN Data in XML

HHS/HRSA **RIN:** 0906-AB28 **Publication ID:** Fall 2022

Title: 340B Drug Pricing Program; Administrative Dispute Resolution

Abstract:

This rule would revise the Administrative Dispute Resolution (ADR) final rule currently in effect and apply to all drug manufacturers and covered entities that participate in the 340B Drug Pricing Program (340B Program). It would establish new requirements and procedures for the 340B Program's ADR process. This administrative process would allow covered entities and manufacturers to file claims for specific compliance areas outlined in the statute after good faith efforts have been exhausted by the parties.

Agency: Department of Health and Human Services(HHS)
Priority: Other Significant
RIN Status: Previously published in the Unified Agenda
Agenda Stage of Rulemaking: Proposed Rule Stage
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 10
Legal Authority: Not Yet Determined
Legal Deadline: None
Timetable:

Action	Date	FR Cite
NPRM	11/30/2022	87 FR 73516
NPRM Comment Period End	01/30/2023	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: None
Small Entities Affected: No
Federalism: No
Included in the Regulatory Plan: No
RIN Data Printed in the FR: No

Agency Contact:
Michelle Herzog
Deputy Director, Office of Pharmacy Affairs
Department of Health and Human Services
Health Resources and Services Administration
5600 Fishers Lane, 08W12,
Rockville, MD 20857
Phone:301 443-4353
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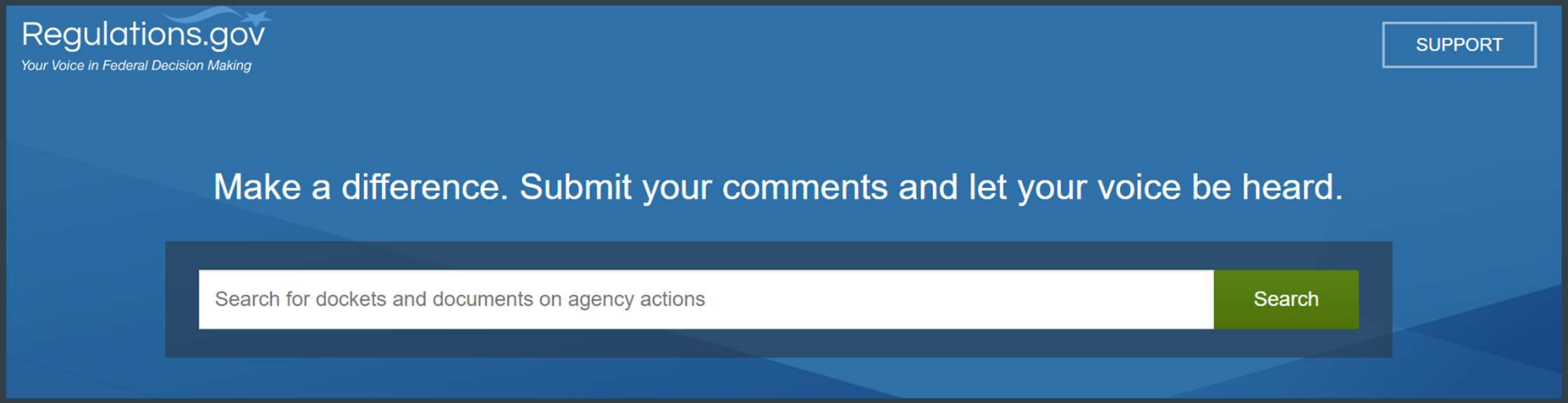

https://www.regulations.gov/

OMB Regulatory Review

https://www.reginfo.gov/public/do/eoReviewSearch

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Office of Information and Regulatory Affairs (OIRA)
Executive Order Submissions Under Review
March 15, 2023

Department of Agriculture

AGENCY: USDA-APHIS
TITLE: Revision to Horse Protection Act Regulations
STAGE: Proposed Rule
RECEIVED DATE: 09/02/2022
RIN: 0579-AE70
ECONOMICALLY SIGNIFICANT: No
LEGAL DEADLINE: None
Status: Pending Review

AGENCY: USDA-APHIS
TITLE: AQI User Fees
STAGE: Proposed Rule
RECEIVED DATE: 02/21/2023
RIN: 0579-AE71
ECONOMICALLY SIGNIFICANT: Yes
LEGAL DEADLINE: None
Status: Pending Review

AGENCY: USDA-FSIS
TITLE: Salmonella in Certain Not-Ready-To-Eat Stuffed Chicken Products
RIN: 0583-ZA21
Status: Pending Review

Example: HIPAA NPRM

View Rule

View EO 12866 Meetings | Printer-Friendly Version | Download RIN Data in XML

HHS/OCR **RIN:** 0945-AA00 **Publication ID:** Fall 2022

Title: HIPAA Privacy: Changes to Support, and Remove Barriers to, Coordinated Care and Individual Engagement

Abstract:

This rule will address proposals to modify the HIPAA Privacy Rule to strengthen individuals' rights to access their own protected health information, including electronic information; improve information sharing for care coordination and case management for individuals; facilitate greater family and caregiver involvement in the care of individuals experiencing emergencies or health crises; address disclosures in emergency or threatening circumstances; and reduce administrative burdens on HIPAA covered health care providers and health plans, while continuing to protect individuals' health information privacy interests.

Agency: Department of Health and Human Services(HHS)
Priority: Economically Significant
RIN Status: Previously published in the Unified Agenda
Agenda Stage of Rulemaking: Final Rule Stage
Major: Yes
Unfunded Mandates: Private Sector
CFR Citation: 45 CFR 160 45 CFR 164
Legal Authority: Health Insurance Portability and Accountability Act of 1996 (HIPAA), sec. 264 (42 U.S.C. 1320d-2 note) Health Information Technology for Economic and Clinical Health (HITECH) Act, sec. 13405 (42 U.S.C. 201 note)
Legal Deadline: None
Timetable:

Action	Date	FR Cite
RFI	11/01/2018	83 FR 64302
RFI Comment Period End	02/19/2019	
NPRM	01/21/2021	86 FR 6446
NPRM Comment Period Extended	03/10/2021	86 FR 13683
NPRM Comment Period End	03/22/2021	
NPRM Comment Period Extended End	05/06/2021	
Final Action	03/00/2023	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Federal, Local, State, Tribal
Small Entities Affected: No
Federalism: No
Included in the Regulatory Plan: No
RIN Information URL: www.hhs.gov/ocr/privacy
RIN Data Printed in the FR: No

AGENCY: HHS-FDA **RIN:** 0910-ZB55 **Status:** Pending Review
TITLE: Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency; Guidance for Industry
STAGE: Notice **ECONOMICALLY SIGNIFICANT:** No
RECEIVED DATE: 03/10/2023 **LEGAL DEADLINE:** None

AGENCY: HHS-OCR **RIN:** 0945-AA20 **Status:** Pending Review
TITLE: Proposed Modifications to the HIPAA Privacy Rule to Support Reproductive Health Care Privacy
STAGE: Proposed Rule **ECONOMICALLY SIGNIFICANT:** Yes
RECEIVED DATE: 01/26/2023 **LEGAL DEADLINE:** None

AGENCY: HHS-ONC **RIN:** 0955-AA03 **Status:** Pending Review
TITLE:ONC Health IT Certification Program Updates, Health Information Network Attestation Process for the Trusted Exchange Framework and Common Agreement, and Enhancements to Support Information Sharing
STAGE: Proposed Rule **ECONOMICALLY SIGNIFICANT:** Yes
RECEIVED DATE: 09/01/2022 **LEGAL DEADLINE:** Statutory

Department of Homeland Security

AGENCY: DHS-FEMA **RIN:** 1660-AB06 **Status:** Pending Review
TITLE: National Flood Insurance Program: Standard Flood Insurance Policy, Homeowner Flood Form
STAGE: Proposed Rule **ECONOMICALLY SIGNIFICANT:** Yes



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