Regulations! Regulations! Read All About It! Insights Into the Regulatory Process

August 4, 2020

Kenya Flash, Librarian for Political Science, Global Affairs, and Government Information
Yale University, kenya.flash@yale.edu

Jennifer Castle, Assistant Professor, Reference and Government Documents Librarian
Tennessee State University, jcastle@tnstate.edu

Yale University

Tennessee State University

Learning Outcomes

- Define pertinent statuses, terms, and ideas within regulatory processes
- Describe the steps of the regulatory process
- Select appropriate sources for locating plans for regulations, and how to analyze regulations

Key Concepts and Ideas

- Regulation
- Rule
- Unified Agenda
- Federal Register
- Federal Register document

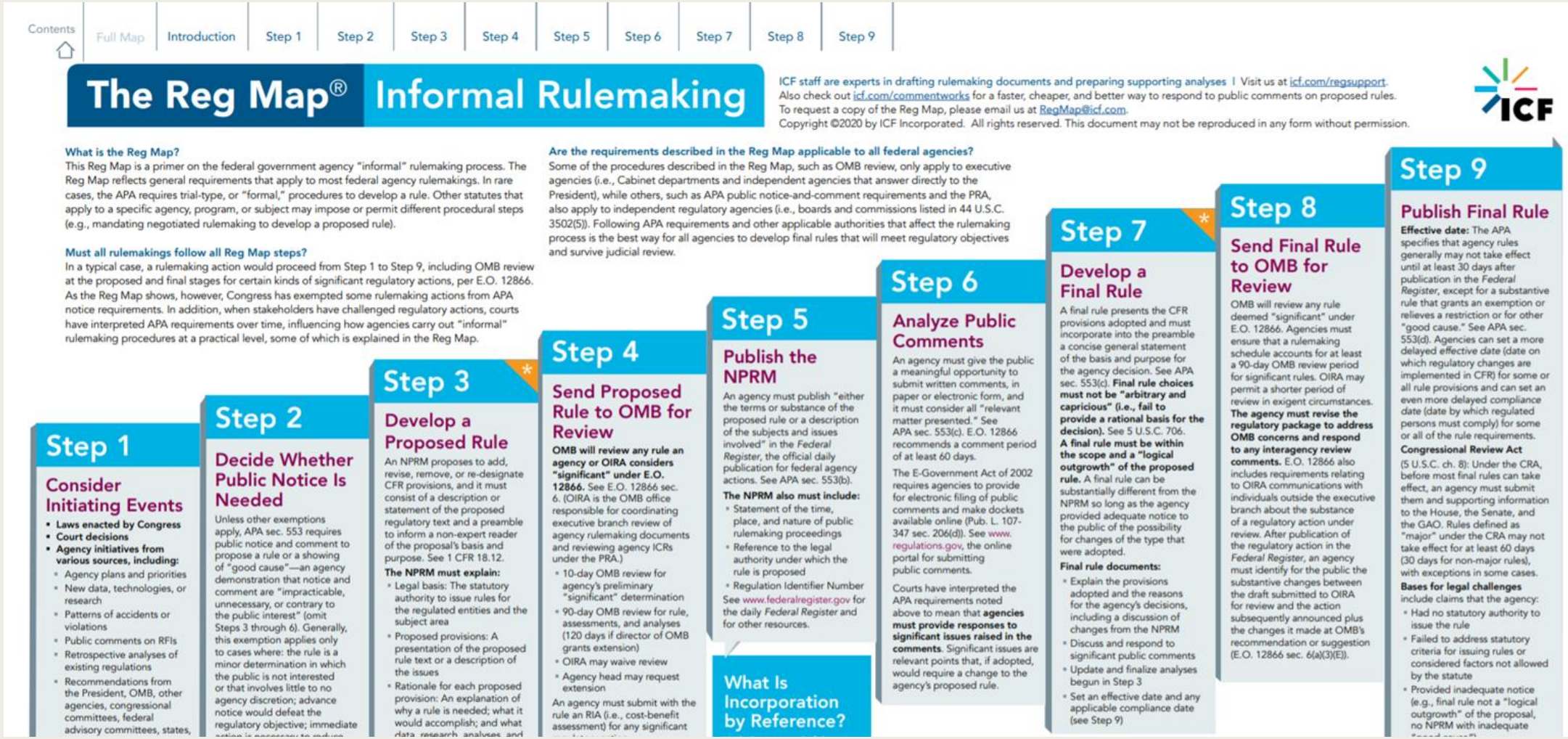
Key Concepts and Ideas

- OIRA
- Code of Federal Regulations
- Regulations.gov
- RegMap

Key Concepts and Ideas

- Administrative Procedure Act of 1942
- EO 12866
- EO 13566

RegMap and Informal Rulemaking



Contents | Full Map | Introduction | Step 1 | Step 2 | Step 3 | Step 4 | Step 5 | Step 6 | Step 7 | Step 8 | Step 9

The Reg Map® Informal Rulemaking

ICF staff are experts in drafting rulemaking documents and preparing supporting analyses | Visit us at icf.com/regsupport.
Also check out icf.com/commentworks for a faster, cheaper, and better way to respond to public comments on proposed rules.
To request a copy of the Reg Map, please email us at RegMap@icf.com.

What is the Reg Map?
This Reg Map is a primer on the federal government agency "informal" rulemaking process. The Reg Map reflects general requirements that apply to most federal agency rulemakings. In rare cases, the APA requires trial-type, or "formal," procedures to develop a rule. Other statutes that apply to a specific agency, program, or subject may impose or permit different procedural steps (e.g., mandating negotiated rulemaking to develop a proposed rule).

Must all rulemakings follow all Reg Map steps?
In a typical case, a rulemaking action would proceed from Step 1 to Step 9, including OMB review at the proposed and final stages for certain kinds of significant regulatory actions, per E.O. 12866. As the Reg Map shows, however, Congress has exempted some rulemaking actions from APA notice requirements. In addition, when stakeholders have challenged regulatory actions, courts have interpreted APA requirements over time, influencing how agencies carry out "informal" rulemaking procedures at a practical level, some of which is explained in the Reg Map.

Are the requirements described in the Reg Map applicable to all federal agencies?
Some of the procedures described in the Reg Map, such as OMB review, only apply to executive agencies (i.e., Cabinet departments and independent agencies that answer directly to the President), while others, such as APA public notice-and-comment requirements and the PRA, also apply to independent regulatory agencies (i.e., boards and commissions listed in 44 U.S.C. 3502(5)). Following APA requirements and other applicable authorities that affect the rulemaking process is the best way for all agencies to develop final rules that will meet regulatory objectives and survive judicial review.

Step 1
Consider Initiating Events
- **Laws enacted by Congress**
- **Court decisions**
- **Agency initiatives from various sources, including:**
  - Agency plans and priorities
  - New data, technologies, or research
  - Patterns of accidents or violations
  - Public comments on RFIs
  - Retrospective analyses of existing regulations
  - Recommendations from the President, OMB, other agencies, congressional committees, federal advisory committees, states,

Step 2
Decide Whether Public Notice Is Needed
Unless other exemptions apply, APA sec. 553 requires public notice and comment to propose a rule or a showing of "good cause"—an agency demonstration that notice and comment are "impracticable, unnecessary, or contrary to the public interest" (omit Steps 3 through 6). Generally, this exemption applies only to cases where: the rule is a minor determination in which the public is not interested or that involves little to no agency discretion; advance notice would defeat the regulatory objective; immediate

Step 3 *
Develop a Proposed Rule
An NPRM proposes to add, revise, remove, or re-designate CFR provisions, and it must consist of a description or statement of the proposed regulatory text and a preamble to inform a non-expert reader of the proposal's basis and purpose. See 1 CFR 18.12.
The NPRM must explain:
- Legal basis: The statutory authority to issue rules for the regulated entities and the subject area
- Proposed provisions: A presentation of the proposed rule text or a description of the issues
- Rationale for each proposed provision: An explanation of why a rule is needed; what it would accomplish; and what

Step 4
Send Proposed Rule to OMB for Review
OMB will review any rule an agency or OIRA considers "significant" under E.O. 12866. See E.O. 12866 sec. 6. (OIRA is the OMB office responsible for coordinating executive branch review of agency rulemaking documents and reviewing agency ICRs under the PRA.)
- 10-day OMB review for agency's preliminary "significant" determination
- 90-day OMB review for rule, assessments, and analyses (120 days if director of OMB grants extension)
- OIRA may waive review
- Agency head may request extension

An agency must submit with the rule an RIA (i.e., cost-benefit assessment) for any significant

Step 5
Publish the NPRM
An agency must publish "either the terms or substance of the proposed rule or a description of the subjects and issues involved" in the *Federal Register*, the official daily publication for federal agency actions. See APA sec. 553(b).
The NPRM also must include:
- Statement of the time, place, and nature of public rulemaking proceedings
- Reference to the legal authority under which the rule is proposed
- Regulation Identifier Number

See www.federalregister.gov for the daily *Federal Register* and for other resources.

What Is Incorporation by Reference?

Step 6
Analyze Public Comments
An agency must give the public a meaningful opportunity to submit written comments, in paper or electronic form, and it must consider all "relevant matter presented." See APA sec. 553(c). E.O. 12866 recommends a comment period of at least 60 days.
The E-Government Act of 2002 requires agencies to provide for electronic filing of public comments and make dockets available online (Pub. L. 107-347 sec. 206(d)). See www.regulations.gov, the online portal for submitting public comments.
Courts have interpreted the APA requirements noted above to mean that **agencies must provide responses to significant issues raised in the comments**. Significant issues are relevant points that, if adopted, would require a change to the agency's proposed rule.

Step 7 *
Develop a Final Rule
A final rule presents the CFR provisions adopted and must incorporate into the preamble a concise general statement of the basis and purpose for the agency decision. See APA sec. 553(c). **Final rule choices must not be "arbitrary and capricious" (i.e., fail to provide a rational basis for the decision).** See 5 U.S.C. 706.
A final rule must be within the scope and a "logical outgrowth" of the proposed rule. A final rule can be substantially different from the NPRM so long as the agency provided adequate notice to the public of the possibility for changes of the type that were adopted.
Final rule documents:
- Explain the provisions adopted and the reasons for the agency's decisions, including a discussion of changes from the NPRM
- Discuss and respond to significant public comments
- Update and finalize analyses begun in Step 3
- Set an effective date and any applicable compliance date (see Step 9)

Step 8
Send Final Rule to OMB for Review
OMB will review any rule deemed "significant" under E.O. 12866. Agencies must ensure that a rulemaking schedule accounts for at least a 90-day OMB review period for significant rules. OIRA may permit a shorter period of review in exigent circumstances.
The agency must revise the regulatory package to address OMB concerns and respond to any interagency review comments. E.O. 12866 also includes requirements relating to OIRA communications with individuals outside the executive branch about the substance of a regulatory action under review. After publication of the regulatory action in the *Federal Register*, an agency must identify for the public the substantive changes between the draft submitted to OIRA for review and the action subsequently announced plus the changes it made at OMB's recommendation or suggestion (E.O. 12866 sec. 6(a)(3)(E)).

Step 9
Publish Final Rule
Effective date: The APA specifies that agency rules generally may not take effect until at least 30 days after publication in the *Federal Register*, except for a substantive rule that grants an exemption or relieves a restriction or for other "good cause." See APA sec. 553(d). Agencies can set a more delayed *effective date* (date on which regulatory changes are implemented in CFR) for some or all rule provisions and can set an even more delayed *compliance date* (date by which regulated persons must comply) for some or all of the rule requirements.
Congressional Review Act
(5 U.S.C. ch. 8): Under the CRA, before most final rules can take effect, an agency must submit them and supporting information to the House, the Senate, and the GAO. Rules defined as "major" under the CRA may not take effect for at least 60 days (30 days for non-major rules), with exceptions in some cases.
Bases for legal challenges include claims that the agency:
- Had no statutory authority to issue the rule
- Failed to address statutory criteria for issuing rules or considered factors not allowed by the statute
- Provided inadequate notice (e.g., final rule not a "logical outgrowth" of the proposal, no NPRM with inadequate

https://www.reginfo.gov/public/reginfo/Regmap/REG_MAP_2020.pdf

Informal Description of Rulemaking

Step 1- Consider initiating event

Step 2- Determine the need for public notice

Step 3- Develop a Proposed Rule

Step 4- Send to Office of Management and Budget (OMB and potentially other agencies) for review

Step 5- Publish the Notice of Public Rulemaking

Informal Description of Rulemaking

Step 6- Analyze public comments

Step 7- Develop a final rule.

Step 8- Send Final Rule to OMB for review.

Step 9- Publish final rule.

Web Resources

- Unified Agenda
- Regulations.gov
- Federal Register
- Electronic Code of Federal Regulations

Unified Agenda

reginfo.gov/public/jsp/Utilities/index.myjsp

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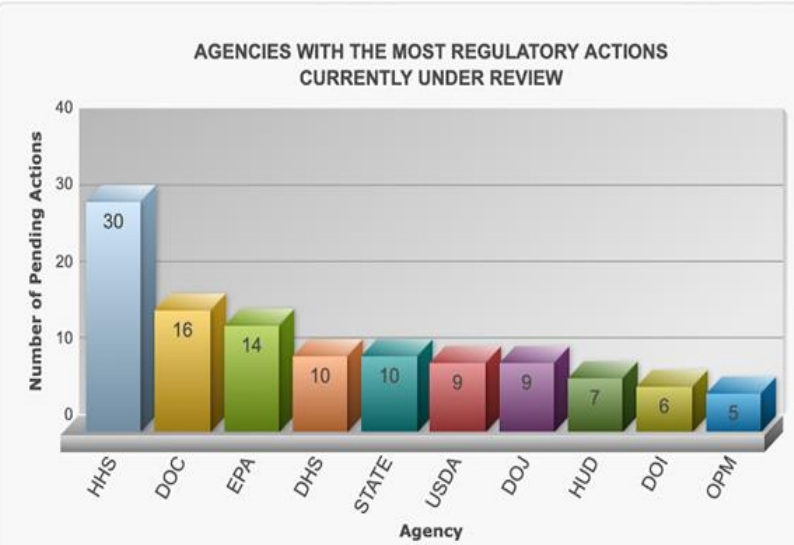
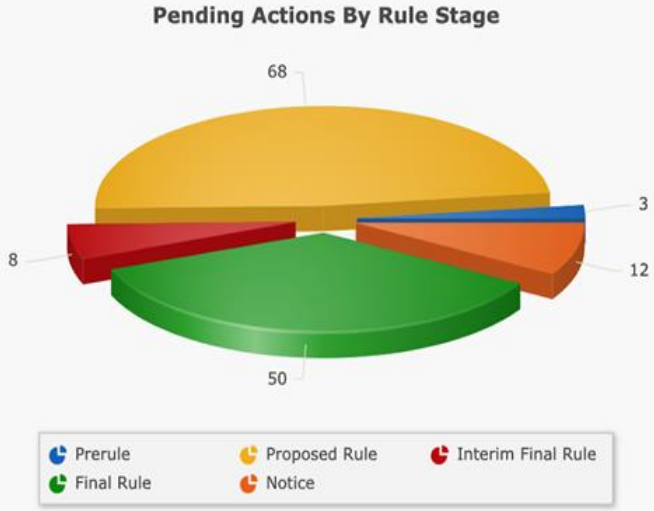


Total Pending Actions: 141



View By Rule Stage

REGULATORY REVIEW

Executive Order 12866 directs agencies to follow certain principles in rulemaking, such as consideration of alternatives and analysis of benefits and costs, and describes OIRA's role in the rulemaking process.

- Regulations under EO 12866 Review

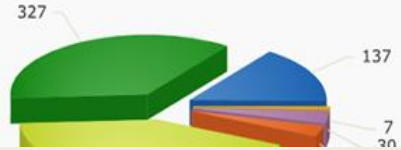
UNIFIED AGENDA and REGULATORY PLAN

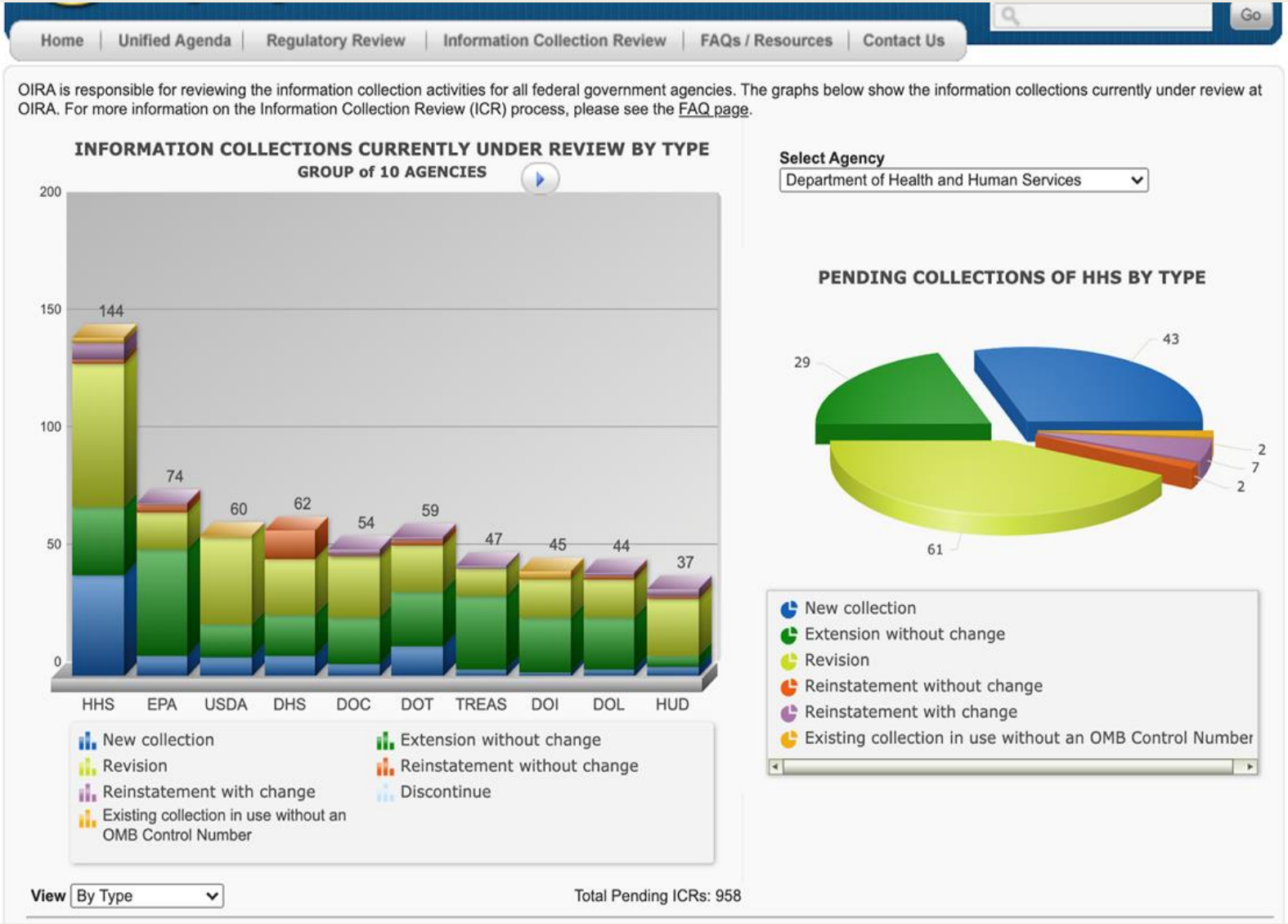
The Unified Agenda and Regulatory Plan provide uniform reporting of data on regulatory and deregulatory actions under development throughout the Federal government, covering over 60 departments, agencies, and commissions.

- The 2020 Spring Agenda was published on

ICR DASHBOARD

INFORMATION COLLECTIONS REVIEW PENDING BY TYPE

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OIRA is responsible for reviewing the information collection activities for all federal government agencies. The graphs below show the information collections currently under review at OIRA. For more information on the Information Collection Review (ICR) process, please see the FAQ page.
INFORMATION COLLECTIONS CURRENTLY UNDER REVIEW BY TYPE
GROUP of 10 AGENCIES
200
150
100
50
0
144
74
60
62
54
59
47
45
44
37
HHS
EPA
USDA
DHS
DOC
DOT
TREAS
DOI
DOL
HUD
New collection
Extension without change
Revision
Reinstatement without change
Reinstatement with change
Discontinue
Existing collection in use without an OMB Control Number
Select Agency
Department of Health and Human Services
PENDING COLLECTIONS OF HHS BY TYPE
43
29
2
7
2
61
New collection
Extension without change
Revision
Reinstatement without change
Reinstatement with change
Existing collection in use without an OMB Control Number
View
By Type
Total Pending ICRs: 958

Spring 2020 Unified Agenda of Regulatory and Deregulatory Actions

The Trump Administration's Unified Agenda of Regulatory and Deregulatory Actions (Agenda) reports on the actions administrative agencies plan to issue in the near and long term. Released by the Office of Information and Regulatory Affairs, the Agenda demonstrates this Administration's ongoing commitment to fundamental regulatory reform and a reorientation toward reducing unnecessary regulatory burdens on the American people.

By amending and eliminating regulations that are ineffective, duplicative, and obsolete, the Administration can promote economic growth and innovation and protect individual liberty.

Fulfilling longstanding principles to review and assess existing regulations, the Agenda includes new deregulatory actions, as well as the withdrawal and reconsideration of other regulatory actions. Agencies are committed to careful assessment of the costs and benefits of each regulatory and deregulatory action and to ensuring that the benefits of regulations substantially justify the costs. The Agenda recognizes that reform will take time and require rigorous analysis, public input, and careful consideration of legal requirements. To this end, the Agenda provides greater information and transparency about regulatory actions proposed by agencies.

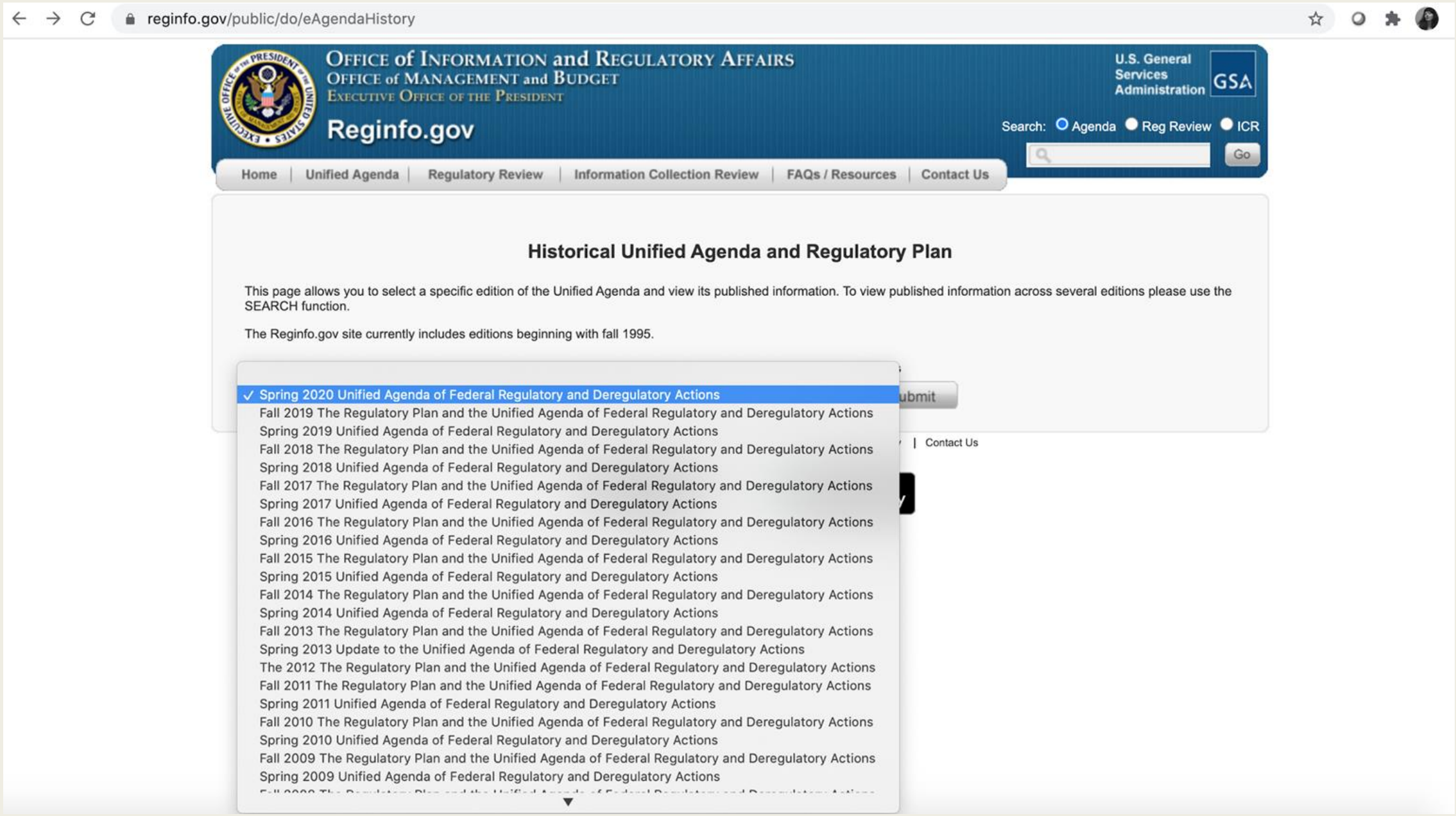
The Agenda represents ongoing progress toward the goals of more effective and less burdensome regulation. This Spring Agenda reflects the following broad regulatory reform priorities:

- ***Advancing Regulatory Reform.*** In this Spring Agenda, agencies continue to identify ineffective regulations for revision and repeal across a variety of sectors. Consistent with Administration priorities, agencies pursue actions that streamline infrastructure development, promote emerging technologies, and provide relief for small businesses.
- ***Public Notice of Regulatory Development.*** In order to provide timely and accurate notice to the public of upcoming deregulatory and regulatory actions, agencies have targeted actions likely to occur in the next 12 months. A clear and accurate Agenda helps avoid unfair surprise and achieves greater predictability of upcoming actions.
- ***Transparency.*** In support of the Administration's commitment to transparency, the Spring Agenda has enhanced search capabilities and functionality. Agencies have also provided consistent and unique identifiers that will allow the public to track regulatory policy from beginning to end.
- ***Consistent Practice across the Federal Government.*** The Agenda reflects core Administration priorities for reducing regulatory burdens across administrative agencies, including in the anticipated deregulatory and regulatory actions from the historically independent agencies.

Spring 2020 Unified Agenda of Regulatory and Deregulatory Actions
Active Regulatory Actions Listed by Agency

Select Agency Submit

(Only agencies with information relevant to this report appear in the list.)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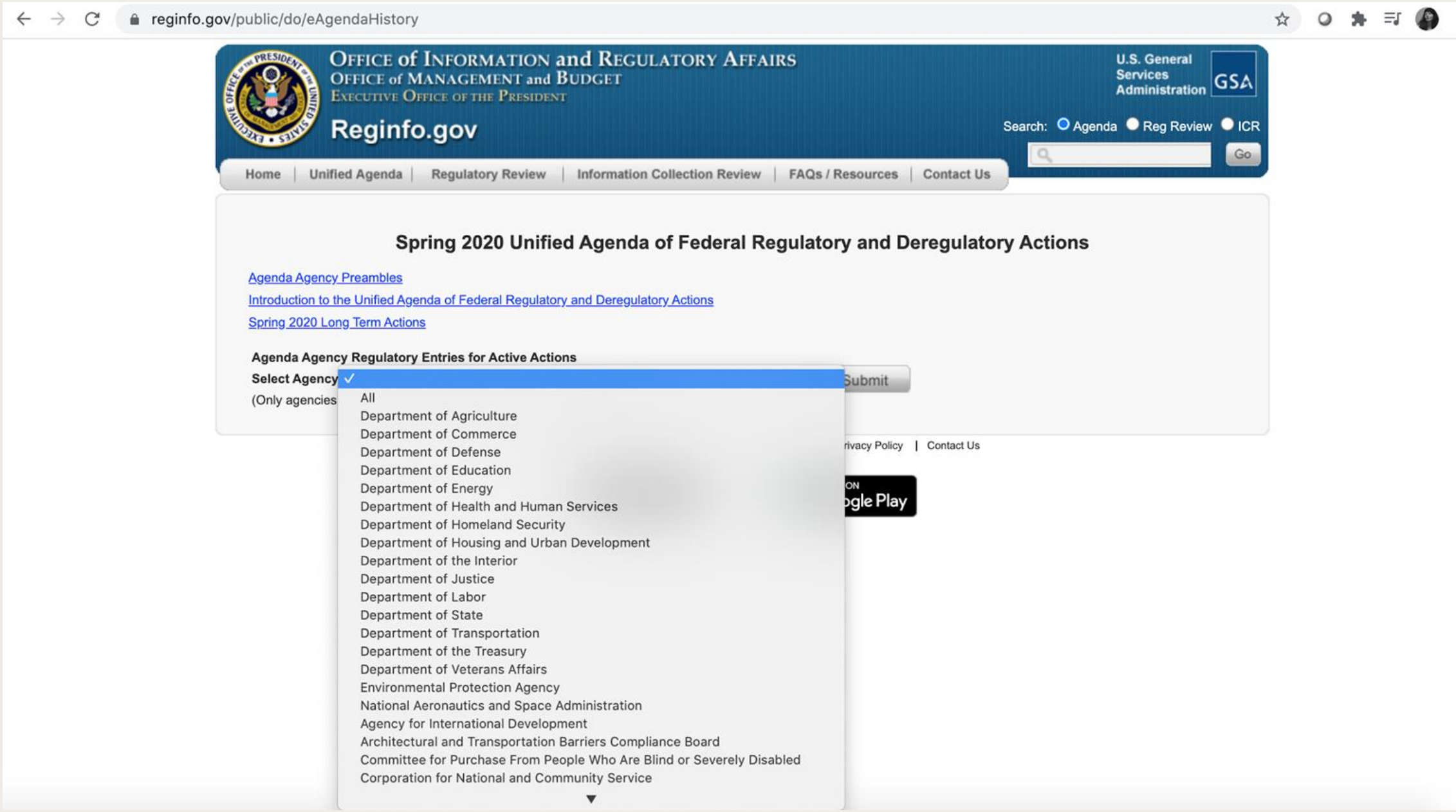
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Agency Rule List - Spring 2020

Department of Health and Human Services

Agency	Agenda Stage of Rulemaking	Title	RIN
HHS/HRSA	Proposed Rule Stage	Countermeasures Injury Compensation Program; Smallpox Countermeasures Injury Table	0906-AB22
HHS/HRSA	Final Rule Stage	National Vaccine Injury Compensation Program: Adding the Category of Vaccines Recommended for Pregnant Women to the Vaccine Injury Table	0906-AB14
HHS/HRSA	Final Rule Stage	Removing Financial Disincentives to Living Organ Donation	0906-AB23
HHS/FDA	Proposed Rule Stage	Postmarketing Safety Reporting Requirements for Human Drug and Biological Products	0910-AA97
HHS/FDA	Proposed Rule Stage	Food Standards: General Principles and Food Standards Modernization	0910-AC54
HHS/FDA	Proposed Rule Stage	Over-the-Counter (OTC) Drug Review--Cough/Cold (Antihistamine) Products	0910-AF31
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	National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers	0910-AH11
HHS/FDA	Proposed Rule Stage	Post Approval Changes to Approved Applications	0910-AH55
HHS/FDA	Proposed Rule Stage	Certain Requirements Regarding Prescription Drug Marketing (203 Amendment)	0910-AH56
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	Nonprescription Drug Product With an Additional Condition for Nonprescription Use	0910-AH62
HHS/FDA	Proposed Rule Stage	Submission of Food and Drug Administration Import Data in the Automated Commercial Environment for Veterinary Devices	0910-AH66
HHS/FDA	Proposed Rule Stage	Medical Devices; Amendments to Medical Device Classification Regulations That Exclude Software Functions In Accordance With the 21st Century Cures Act	0910-AH67
HHS/FDA	Proposed Rule Stage	Medication Guide; Patient Medication Information	0910-AH68
HHS/FDA	Proposed Rule Stage	Streamlining Provisions Requiring Disclosure to and Receipt of Written Assurance From Commercial Customers in the Preventive Controls for Human Food Rule	0910-AH77
HHS/FDA	Proposed Rule Stage	Permanent Listing of Color Additive Lakes	0910-AH80

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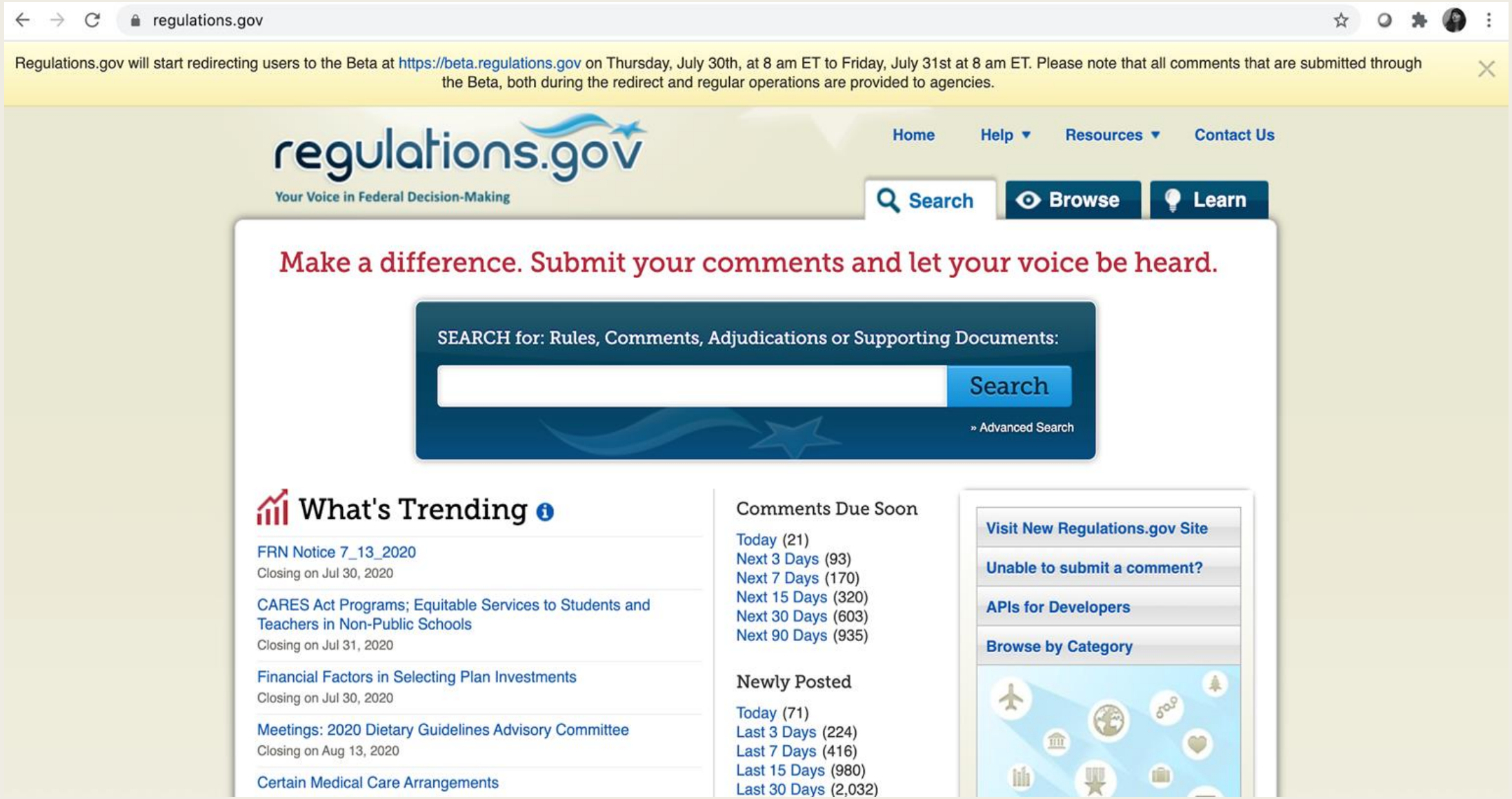
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Closing on Jul 30, 2020
CARES Act Programs; Equitable Services to Students and Teachers in Non-Public Schools
Closing on Jul 31, 2020
Financial Factors in Selecting Plan Investments
Closing on Jul 30, 2020
Meetings: 2020 Dietary Guidelines Advisory Committee
Closing on Aug 13, 2020
Certain Medical Care Arrangements
Comments Due Soon
Today (21)
Next 3 Days (93)
Next 7 Days (170)
Next 15 Days (320)
Next 30 Days (603)
Next 90 Days (935)
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Today (71)
Last 3 Days (224)
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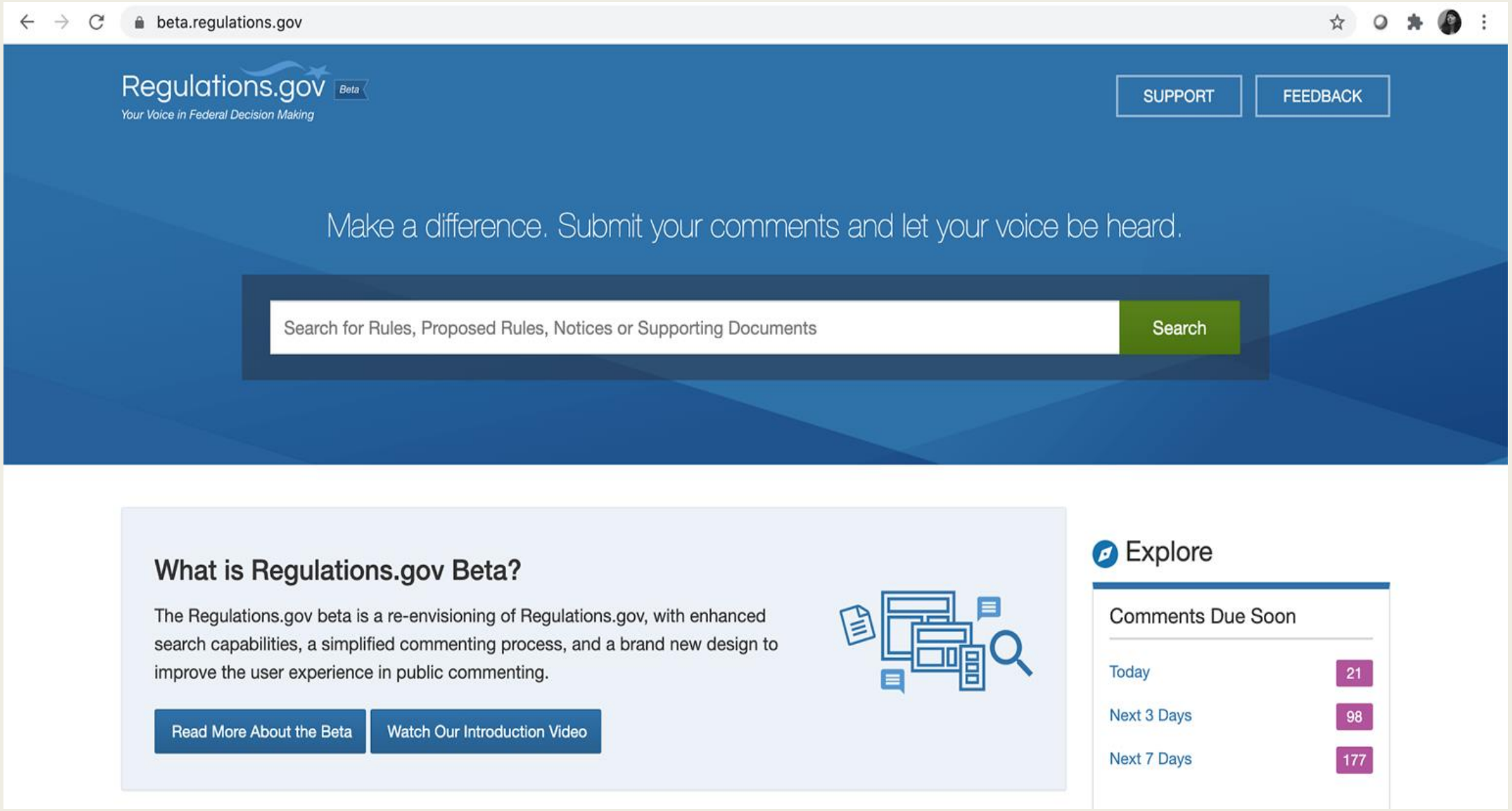
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Next 3 Days 98
Next 7 Days 177

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What's Trending

N — BUREAU OF OCEAN ENERGY MANAGEMENT

Supplement to the Draft Environmental Impact Statement for Vineyard Wind LLC's Proposed Wind Energy Facility...

Comments Due - July 27, 2020

PR — DEPARTMENT OF TRANSPORTATION

Traveling by Air with Service Animals

Comments Due - April 06, 2020

PR — DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

PR — EMPLOYEE BENEFITS SECURITY ADMINISTRATION

Financial Factors in Selecting Plan

Explore

Comments Due Soon

Today	21
Next 3 Days	98
Next 7 Days	177

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Today	71
Last 3 Days	224
Last 7 Days	416

Dockets

Deregulatory	8.17K
Economically Significant	782
Major Rule	808

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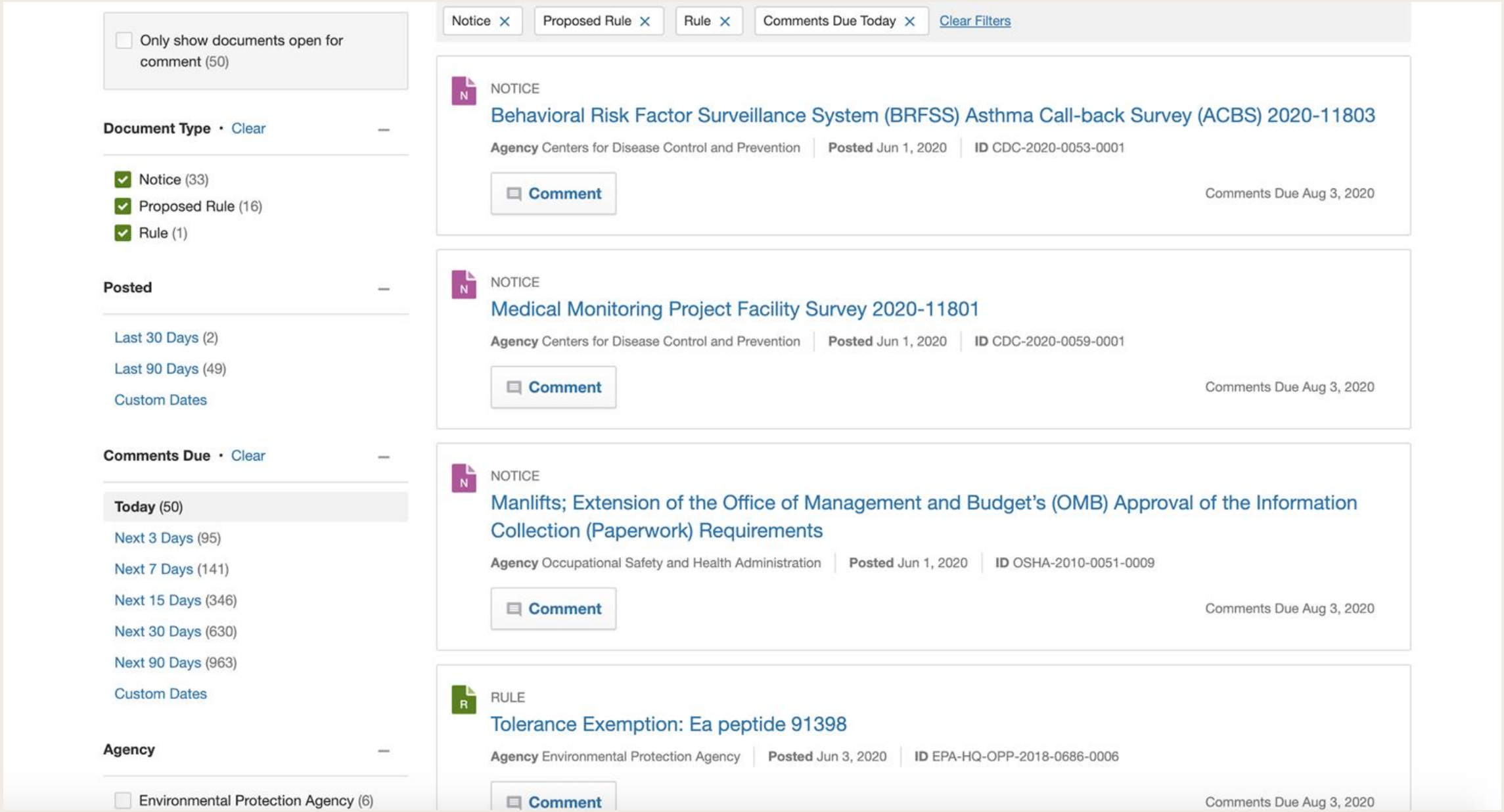
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Notice (33)
Proposed Rule (16)
Rule (1)
Posted
Last 30 Days (2)
Last 90 Days (49)
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Comments Due • Clear
Today (50)
Next 3 Days (95)
Next 7 Days (141)
Next 15 Days (346)
Next 30 Days (630)
Next 90 Days (963)
Custom Dates
Agency
Environmental Protection Agency (6)
Notice ×
Proposed Rule ×
Rule ×
Comments Due Today ×
Clear Filters
NOTICE
Behavioral Risk Factor Surveillance System (BRFSS) Asthma Call-back Survey (ACBS) 2020-11803
Agency Centers for Disease Control and Prevention | Posted Jun 1, 2020 | ID CDC-2020-0053-0001
Comment
Comments Due Aug 3, 2020
NOTICE
Medical Monitoring Project Facility Survey 2020-11801
Agency Centers for Disease Control and Prevention | Posted Jun 1, 2020 | ID CDC-2020-0059-0001
Comment
Comments Due Aug 3, 2020
NOTICE
Manlifts; Extension of the Office of Management and Budget's (OMB) Approval of the Information Collection (Paperwork) Requirements
Agency Occupational Safety and Health Administration | Posted Jun 1, 2020 | ID OSHA-2010-0051-0009
Comment
Comments Due Aug 3, 2020
RULE
Tolerance Exemption: Ea peptide 91398
Agency Environmental Protection Agency | Posted Jun 3, 2020 | ID EPA-HQ-OPP-2018-0686-0006
Comment
Comments Due Aug 3, 2020

Docket (ED-2020-OESE-0091) / Document

Comment Period Ends: **2 Days**

RULE

CARES Act Programs; Equitable Services to Students and Teachers in Non-Public Schools

Posted by the **Department of Education** on Jun 30, 2020

Comment | Share

Document Details | Browse Comments 10.76K

Document ID
ED-2020-OESE-0091-0001

Comments Received
9,956
More Details

Document Details

Comment Due Date
Jul 31, 2020

Content

Action

Interim final rule with request for comments.

Summary

The U.S. Department of Education (Department) issues this interim final rule to clarify the requirement in the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) that local educational agencies (LEAs) provide equitable services to students and teachers in non-public schools under the Governor's Emergency Education Relief Fund (GEER Fund) and the Elementary and Secondary School Emergency Relief Fund (ESSER Fund) (collectively, the CARES Act programs).

Dates

Effective Date: This interim final rule is effective July 1, 2020.

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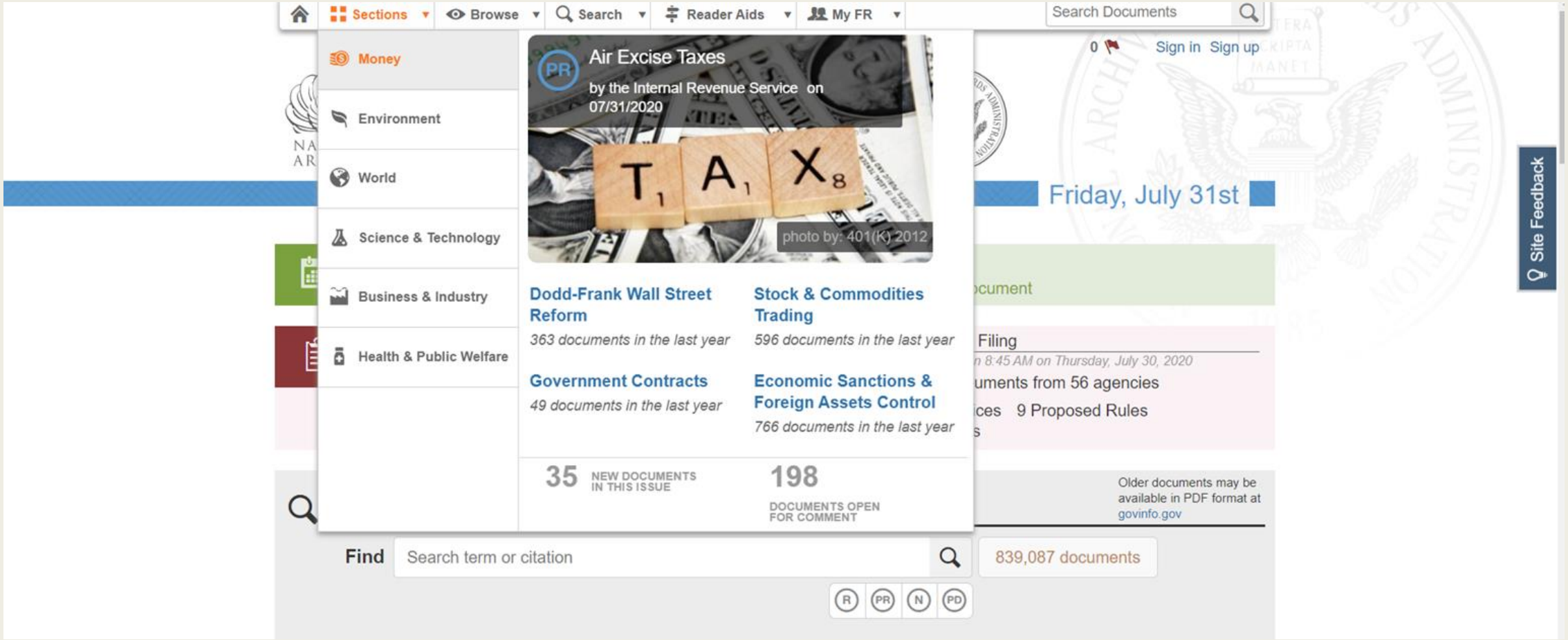
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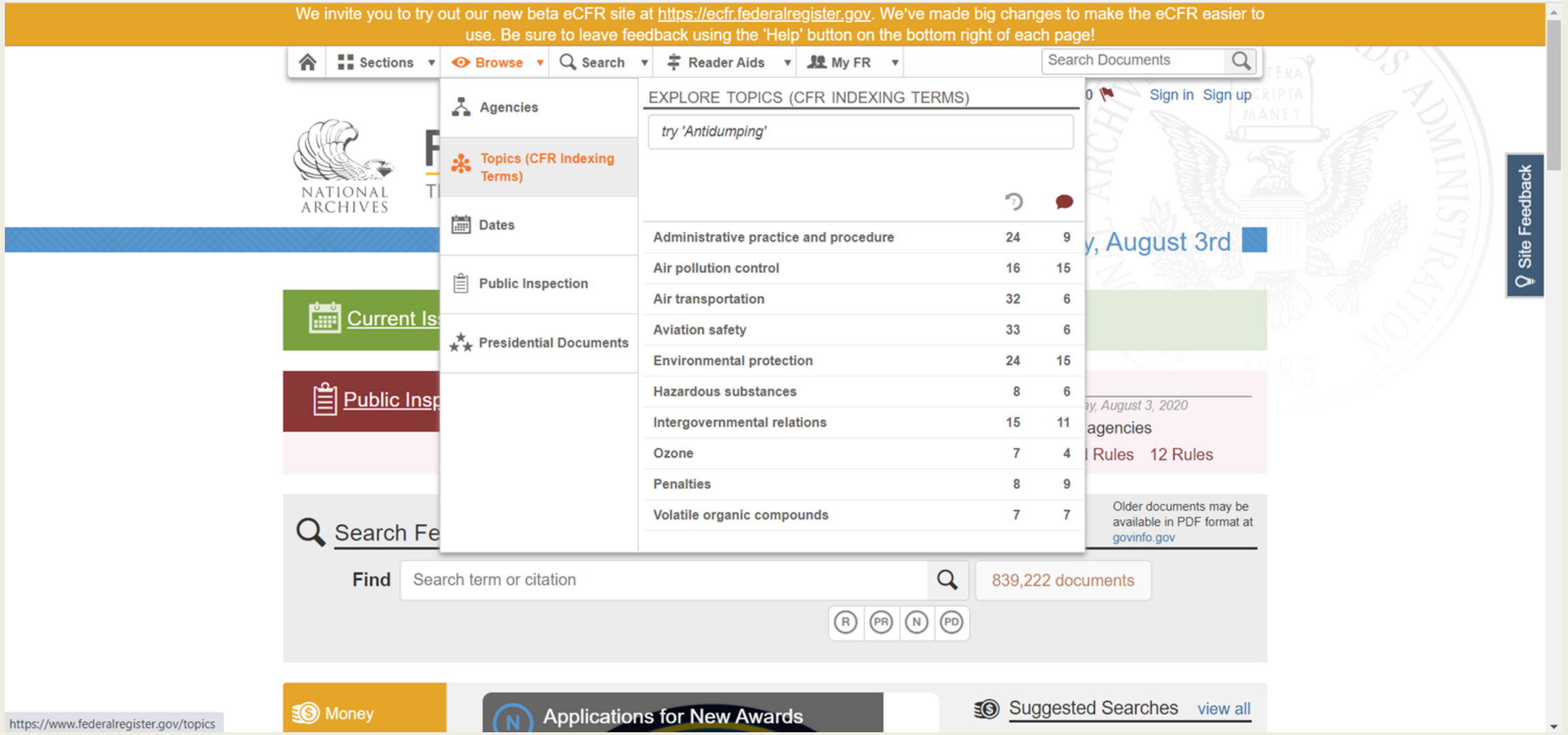
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Executive Orders

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The President of the United States manages the operations of the Executive branch of Government through Executive orders. After the President signs an Executive order, the White House sends it to the Office of the Federal Register (OFR).

The OFR numbers each order consecutively as part of a series and publishes it in the daily Federal Register shortly after receipt. For a table of Executive orders that are specific to federal agency rulemaking, see https://go.usa.gov/xv9cZ.

Donald Trump 175 Barack Obama 276 George W. Bush 291 William J. Clinton 254

Proclamations

view

The President of the United States communicates information on holidays, commemorations, special observances, trade, and policy through Proclamations. After the President signs a Proclamation, the White House sends it to the Office of the Federal Register (OFR).

The OFR numbers each proclamation consecutively as part of a series and publishes it in the daily Federal Register shortly after receipt.

Donald Trump 490 Barack Obama 1228 George W. Bush 941 William J. Clinton 606

Other Presidential Documents

view

The President of the United States issues other types of documents, including but not limited to; memoranda, notices, determinations, letters, messages, and orders. After they are signed, the White House sends it to the Office of the Federal Register (OFR).

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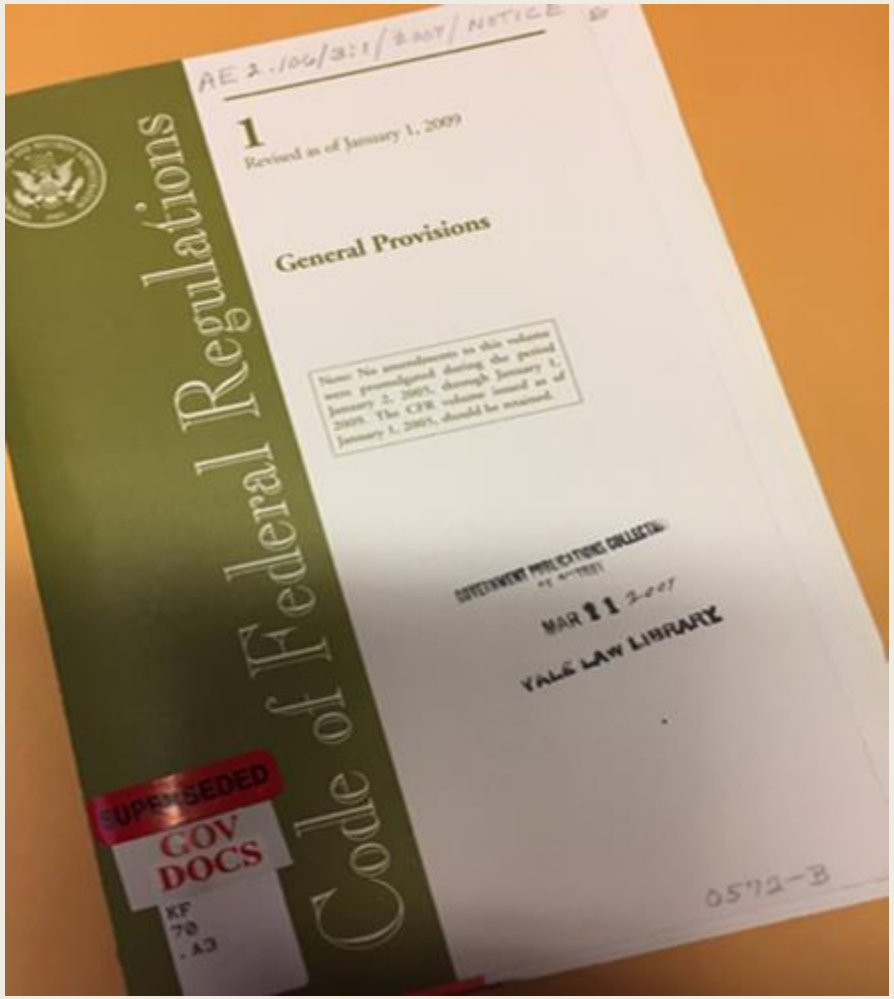
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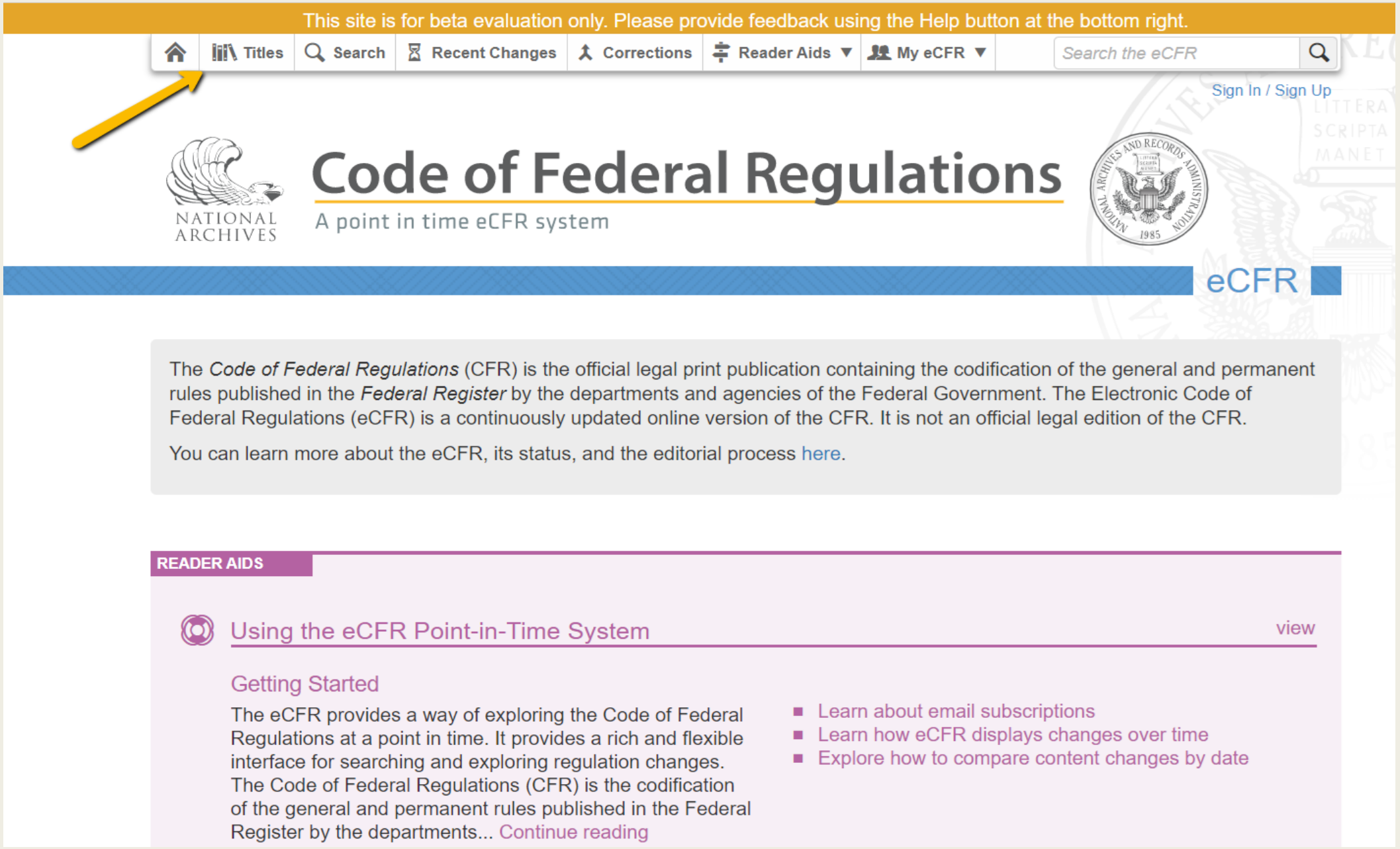
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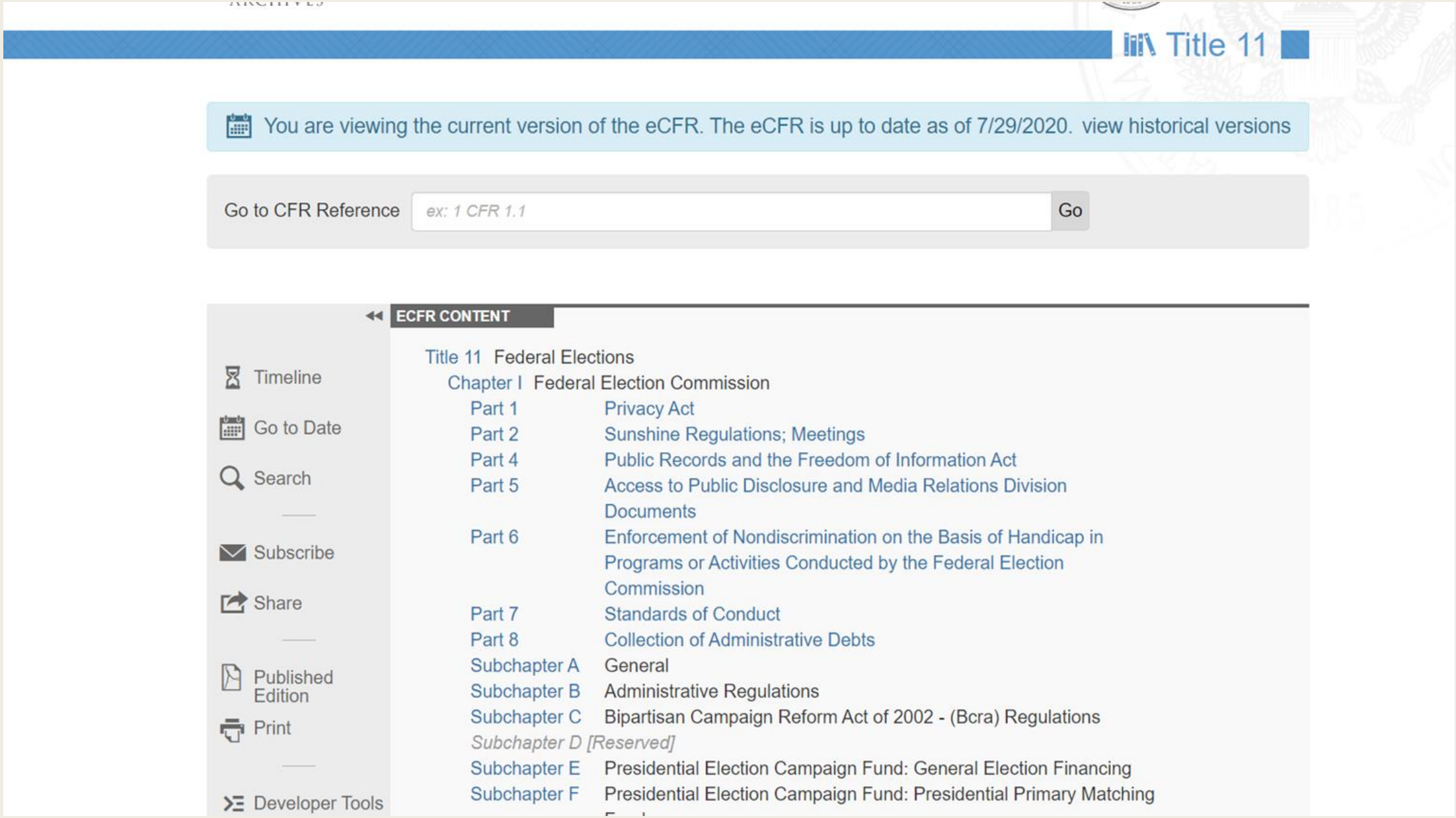
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Contact

- Kenya Flash, Librarian for Political Science, Global Affairs, and Government Information, kenya.flash@yale.edu

- Jennifer Castle, Assistant Professor, Reference and Government Documents Librarian, Tennessee State University, jcastle@tnstate.edu