DEA Regulations, Guidance, and the Regulatory Priorities

Heather Achbach

Deputy Section Chief

Drug Enforcement Administration

Diversion Regulatory Drafting and Policy Support

DIVERSION REGULATORY DRAFTING AND POLICY SUPPORT

Develop and evaluate regulations that implement and interpret the Controlled Substances Act (CSA) in support of the mission of the Diversion Control Division.

Regulations 101

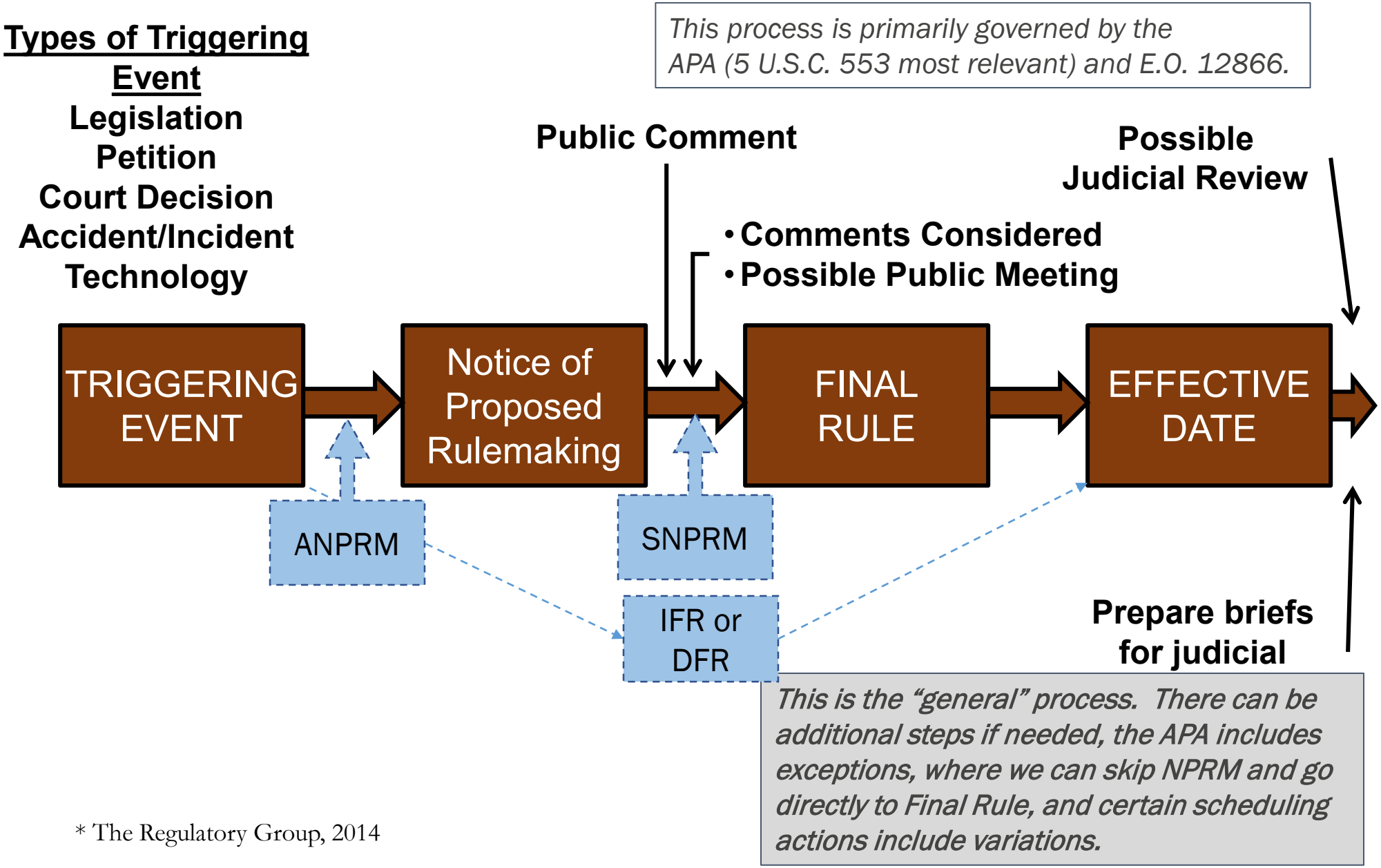
Why does it take so long?

LAWS VS. REGULATIONS

LAWS

REGULATIONS

General Rulemaking Process*



* The Regulatory Group, 2014

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, or external groups
  - Changes in the regulated community
  - Petitions for rulemaking, including petitions for reconsideration

See www.regulations.gov and www.reginfo.gov for intended regulatory and deregulatory actions and for other resources.

Revising or Rescinding an Existing Rule

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 action is necessary to reduce imminent harm to people or property; or Congress implicitly waives notice-and-comment requirements.

"Good cause" options:

- Emergency rules
- Interim final rules (omit Steps 3 through 6 but provide comment period and final rule after Step 9)
- Rules that codify statutory language where agency has no discretion to change the provision
- Direct final rules (streamlined process for non-controversial rules; must be withdrawn

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 data, research, analyses, and assumptions were used to develop the rule

Rule preamble should discuss:

- Regulatory background and history
- Alternatives the agency is considering
- Analyses describing compliance with applicable statutes or executive orders

Analyses begun in Step 3 must be finalized in Step 7.

What Is

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 regulatory action.

Interagency review coordination: OMB may circulate an NPRM to other agencies interested in the content.

OMB will invite the issuing agency to meetings requested by the public to discuss regulatory actions under review per E.O. 12866 sec. 6(b)(4).

E.O. 12866 does not subject independent regulatory agencies to OMB rule review requirements.

See www.reginfo.gov/public to keep up with OMB review

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?

With the approval of the Director of the *Federal Register*, an agency may incorporate material into rules by simply referencing it. Such material must be:

- Published
- Reasonably available to and usable by affected individuals
- Not produced by the agency

Congress authorized this process to reduce the volume of language published in the *Federal Register* and CFR. The legal effect is that the referenced material is treated

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 "good cause")
- Failed to consider public comments
- Reached an "arbitrary and capricious" decision (i.e., provided no rational basis for the action) (see 5 U.S.C. 706)

See www.ecfr.gov for the latest unofficial version of the CFR.

Regulations with Legal Effect Must Be

* Specific Analyses for Steps 3 and 7

Most Frequent Analyses

E.O. 12866 and E.O. 13563, Regulatory Review

RIA required for "significant regulatory actions," which include those that would:

- Have a $100 million or more annual effect on the economy (in current dollars)
- Raise novel legal or policy issues
- Have other significant impacts

If the annual effect is $100 million or more, the rule is "economically significant" and requires:

Regulatory Flexibility Act (5 U.S.C. ch. 6)

Applies to rules that may have a "significant economic impact on a substantial number of small entities" (SEISNOSE), if APA or other statutory notice and comment is required.

An agency must analyze small-entity impacts and mitigate them if possible.

- If there is a SEISNOSE, an agency must

ANALYSES

1. **E.O. 12866 and E.O. 13563 – determination if the rule is a "significant regulatory action"**
   Will it have a $100 million + effect on the economy?
   Does it Raise novel legal/policy issues?
   Are there other significant impacts?
   If the annual effect is less than $100 million agencies must analyze costs & benefits of the selected approach
2. **Regulatory Flexibility Act**
   Determination if the rule will have a "significant economic impact on a substantial number of small entities"
3. **Paperwork Reduction Act**
   if there is a "collection of information" imposed on 10 or more people
4. **E.O. 13132, Federalism**
   Statement required if the rule has federalism implications or would impose unreimbursed costs on state or local governments.
5. **Unfunded Mandates Reform Act**
   Applies if the rule would impose a federal mandate that may result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any year.

TYPES OF RULES: PROPOSED

- **Advanced Notice of Proposed Rulemaking (ANPRM)**
  - A document of choice; not an official part of rulemaking
  - Allows an Agency to obtain public participation in forming a regulation **BEFORE** significant research or investigation has been performed by the Agency
  - Involves the public in a **POTENTIAL** regulatory action **BEFORE** the agency has arrived at even a tentative decision on regulatory change.

- **Notice of Proposed Rulemaking (NPRM)**
  - Informs the public that the Agency is considering a regulatory change
  - Describes the new rule or changes and informs the public how they may participate in the rulemaking process
  - Allows for the public to submit comments:
    - Executive Order 12866- 60 day comment period
    - Public hearing: time and place are stated in the NPRM

TYPES OF RULES: FINAL

- **Interim Final Rule (IFR)**
  - Allows for a rule to be final while still inviting comments from the public
  - Requires a “Good Cause” argument: inviting public comment prior to implementation would be “impracticable, unnecessary, or contrary to the public interest”

- **Direct Final Rule (DFR)**
  - Has a statement saying that the rule will take effect in a certain amount of days unless someone submits a significant adverse or negative comment.
  - If a comment is received, the agency must re-publish as a NPRM
  - Requires a “Good Cause” argument

- **Final Rule (FR)**
  - This is the last stage in the rulemaking process. The agency responds to public comments and makes appropriate revisions
  - Revisions must be within the scope of the proposed rule or a logical outgrowth

THE ADMINISTRATIVE PROCEDURE ACT

The purposes of the act were:

(1) to ensure that agencies keep the public informed of their organization, procedures, and rules,

(2) to provide for public participation in the rule-making process,

(3) to prescribe uniform standards for the conduct of formal rule making and adjudicatory proceedings, and

(4) to restate the law of judicial review.

NOTICE AND COMMENT PROCEDURES

- Interested persons should be given an opportunity to participate in rulemaking when notice is required by the APA.

- Notice and comment process does not apply to interpretive rules.

- A legislative rule requires notice and comment "if Congress has delegated legislative power to the agency and if the agency intended to exercise that power in promulgating the rule."
  - Agency regulations that amend the CFR are considered to be legislative rules that require notice and comment rulemaking.

COMMENTS

- **Responding to Public Comments**

  Don't need to respond individually to comments.

  Do need to respond to significant comments

  (Those which raise relevant points and which, if adopted, would require a change to the proposed rule).

- **Logical Outgrowth Test**

  The proposed rule must provide the public with adequate notice of the possible requirements in the final rule.

  The final rule must be a logical outgrowth of the proposed rule.

DATES

60 Day Comment Period

APA does not require a comment period of a certain length; E.O. 12866 recommends a comment period of 60 days.

Exceptions

- ❑ "good cause."

Administrative Procedure Act

Substantive rules must be published in the Federal Register 30 days before their effective date.

Exceptions

- ❑ When the rule grants or recognizes an exemption or relieves a restriction
- ❑ When rules are exempt from notice and comment.

Congressional Review Act

Non Major rules take effect after the CRA form is delivered to Congress

Major rules must be submitted to Congress 60 days before they go into effect.

Exception

- ❑ Any rule which an agency for good cause finds that notice and public procedure thereon are impractical, unnecessary, or contrary to the public interest

“In the rulemaking process”

When agencies are “in the rulemaking process” there are certain limitations:

- to the extent to which an agency can discuss a pending rule

- with whom and how they can speak with “industry” and interested parties

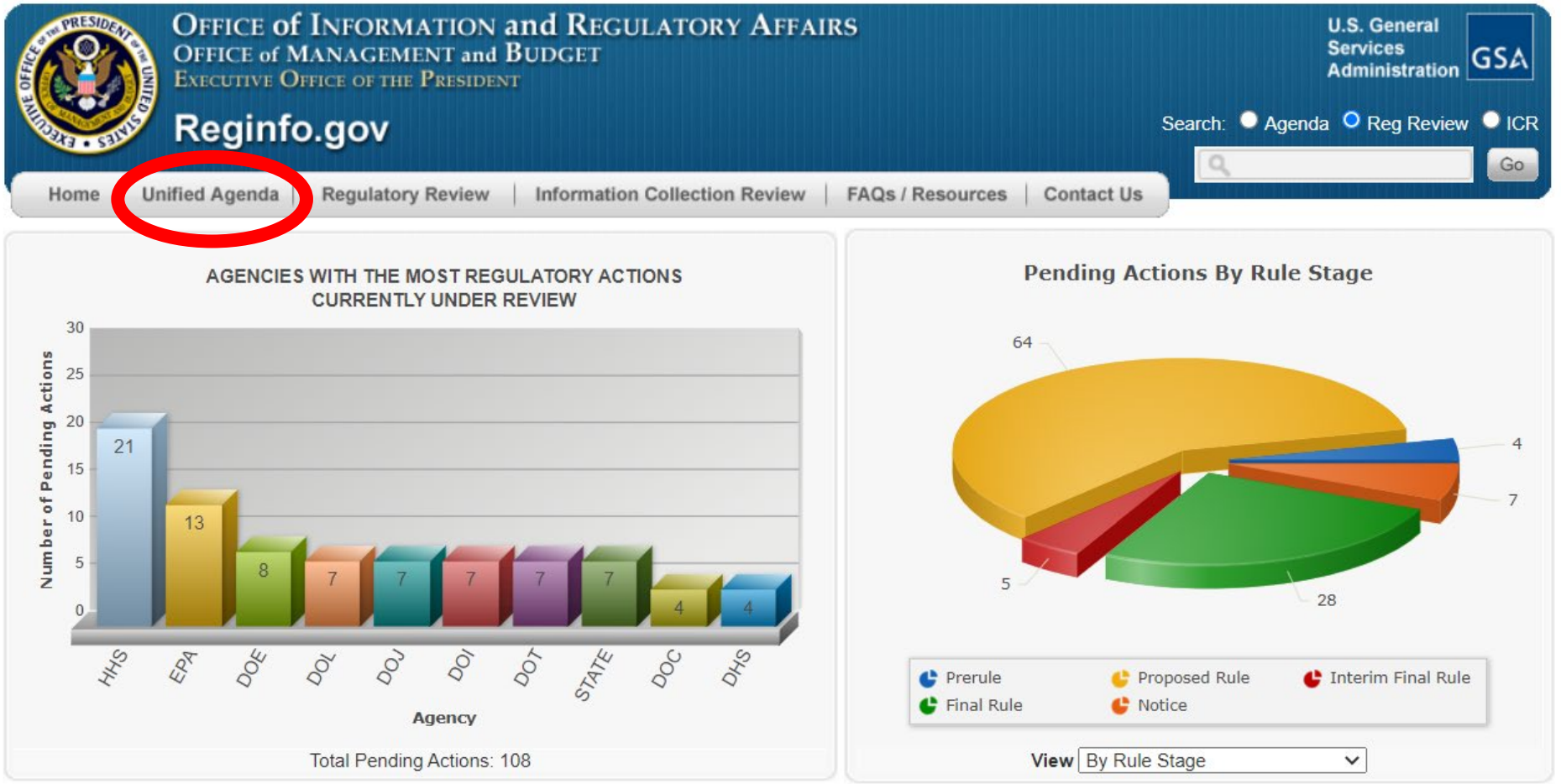
If there is no published NPRM, how does an interested party know if DEA is considering new regulations?

THE UNIFIED AGENDA

- Available at www.reginfo.gov/public/

- The Unified Agenda is a report on the actions administrative agencies plan to issue in the near and long term

THE UNIFIED AGENDA



DEA'S FALL 2022 UNIFIED AGENDA

33 items in the Fall 2022 Unified Agenda, alerting the public of our current regulatory priorities:

- **1 Pre-rule**
- **21 Proposed Rules:**
  - -Special Registration to Engage in the Practice of Telemedicine
  - -Changes to a Prescription
  - -Providing Controlled Substances to Ocean Vessels
  - -Amending Regulations to Conform to the Controlled Substance Ordering System (CSOS) Modernization
  - -Import/Export and Domestic Transactions of Tableting and Encapsulating Machines
- **11 Final Rules**
  - -Suspicious Orders of Controlled Substances
  - -Amending Regulations to Require Electronic Submission of DEA Form 106
  - -Implementation of the Designer Anabolic Steroid Control Act of 2014

Current Regulatory Priorities Related to Supply Chain

DEA REGULATORY PRIORITIES – SUPPLY CHAIN

1. Suspicious Orders Reporting System (SORS)

Would define the term suspicious order and specify the procedures a registrant must follow upon receiving such orders

NPRM published 11/2/2020 (60 days) – 32 comments received
Comment Extension published 2/25/2021 (30 days) – 9 comments received

Currently working on a final rule

DEA REGULATORY PRIORITIES – SUPPLY CHAIN

2. Controlled Substance Ordering System (CSOS) Modernization

Would amend the regulations to conform with the modernization of CSOS and require that applications and related materials be submitted on-line

NPRM published 2/2/2023 (60 days) – 8 comments received

Currently working on a final rule

DEA REGULATORY PRIORITIES – SUPPLY CHAIN

3. Online Only Submission of DEA 106s

Amends the regulations to require that DEA Form 106 (Report of Theft or Loss) be submitted electronically and clarifies the time frame to complete the necessary notifications.

NPRM published 7/29/2020 (60 days) – 22 comments received

Final rule is pending

Guidance Documents

WHAT IS “Guidance”?

- ❑ It’s a <u>TOOL</u> used to supplement or explain statutes or regulations.

- ❑ It <u>COMES IN VARIOUS FORMS</u>
  - but the two main forms (and those specifically mentioned in the APA) are “interpretative” (interpretive) rules and “statements of general policy” (policy statements).

- ❑ Does not require a comment period

- ❑ It’s <u>NOT BINDING</u>* and lacks the force and effect of law
  - Only Agency rules are legally binding

- ❑ A guidance document is an agency statement of general applicability, intended to have future effect on the behavior of regulated parties or to interpret existing statute or agency regulations.

EO13891 – “Promoting the Rule of Law Through Improved Agency Guidance Documents.”

Executive Order issued by President Trump

Published 10/15/2019

Required:

- That agencies establish on their website a single, searchable, indexed database that contains or links to all guidance documents in effect from the agency
- Repealed in 2020 but DEA & DOJ still follow parts related to review and posting

DOJ policy prohibits using guidance as a substitute for regulation.

DEA ACCEPTANCE OF GUIDANCE REQUESTS

DRUG & CHEMICAL EVALUATION SECTION	**571-362-3249**
Drug & Chemical Information, Scheduling Actions, Exempted Lists	DPE@dea.gov
Bulk Chemical Manufacturer Reports	BCMReports@dea.gov
National Forensic Laboratory Information System	NFLIS@dea.gov
LIAISON SECTION	**571-362-3260**
Conferences, Publications, and Customer Service Plan	ODLL@dea.gov
POLICY SECTION	**571-362-3260**
For interpretation and guidance on DEA policies and regulations	ODLP@dea.gov
DEA Policy Questions should be sent in writing	DEA Diversion Control Division Attn: Policy Section 8701 Morrissette Drive Springfield, VA 22152
PHARMACEUTICAL INVESTIGATIONS SECTION	**571-362-1720**
Retail Summary Reports	Targeting&Analysis@dea.gov
Online Reporting: Extortion Scam, RX Abuse, Suspicious Pharmacies	**Submit a Tip to DEA**
CHEMICAL INVESTIGATIONS SECTION	**571-362-3352**
Chemical Regulatory/Registration Questions	DOC@dea.gov
Mail Order Distribution Reports	Mail-Ordersales@dea.gov
Chemical Unusual Order Reporting	CORT@dea.gov

GUIDANCE PORTAL

U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION

DIVERSION CONTROL DIVISION

Guidance Document Portal

Guidance Document Information

Executive Order 13891 requires agencies to put their guidance documents on easily searchable websites so individuals are able to access them, and Department of Justice policy prohibits using guidance as a substitute for regulation. Guidance may not be used to impose new requirements on persons outside the Executive Branch except as expressly authorized by law or expressly incorporated into a contract, grant, or cooperative agreement. See JM 1-19.000.

Guidance documents are not binding and lack the force and effect of law, unless expressly authorized by statute or expressly incorporated into a contract, grant, or cooperative agreement. Consistent with Executive Order 13891 and the Office of Management and Budget implementing memoranda, the Department will not cite, use, or rely on any guidance not so authorized or incorporated that is not accessible through this guidance portal, except to establish historical facts. To the extent any guidance document sets out voluntary standards (e.g., recommended practices), compliance with those standards is voluntary, and noncompliance will not result in enforcement action. Guidance documents may be rescinded or modified in the Department's complete discretion, consistent with applicable laws.

Furthermore, guidance documents may not represent the Department's authoritative or official position and generally are not intended to receive judicial deference. A guidance document may be considered the Department's authoritative or official position only if it is issued in a form understood to reflect the Department's authoritative policy, and only if it emanates from those Department officials whose actions in the relevant context may be said to reflect the considered views of the Department as a whole. See Question 25 of OMB Memorandum M-20-02, Guidance Implementing Executive Order 13891 (October 31, 2019).

Effective February 28, 2020, these documents can also be viewed and commented on at the United States Department of Justice

GUIDANCE PORTAL

	DEA-Registered Authorized Collector Reporting of Theft, Loss, or Missing Sealed Inner Liners that Occurs While in a Common or Contract Carrier's Custody	he EA	09/13/2022	09/16/2022
	DEA-Registered Manufacturer and Distributor Established Controlled Substance Quantitative Thresholds and the Requirement to Report Suspicious Orders	EA s	01/20/2023	01/20/2023

Drug Enforcement Administration
Diversion Control Division
Guidance Document

Title: DEA-Registered Manufacturer and Distributor Established Controlled Substance Quantitative Thresholds and the Requirement to Report Suspicious Orders

Summary: This guidance document clarifies that neither the Controlled Substance Act (CSA) nor the Drug Enforcement Administration (DEA) regulations establish quantitative thresholds or place limits on the volume of controlled substances DEA registrants can order and dispense. This document also reminds all DEA registrants of the requirement to establish systems to identify and report suspicious orders of controlled substances to include Medication for Opioid Use Disorder (MOUD).

Activity: Reporting Suspicious Orders of Controlled Substances Including MOUD

To Whom it Applies: DEA Registrants

Question: Are DEA-registered manufacturers or distributors required by the CSA or DEA regulations to establish limits (quantitative thresholds) on the amounts of controlled substances, including MOUD, that another DEA registrant can order or dispense?

Answer: No. Neither the CSA nor DEA regulations establish quantitative thresholds or limits on the amounts of controlled substances, including MOUD, that DEA registrants may order or dispense, nor do they require registrants to set such thresholds or limits.

The CSA, as amended by the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment Act (SUPPORT Act) requires each DEA registrant to: 1) design and operate a system to identify suspicious orders for the registrant; 2) ensure that the system complies with applicable Federal and State privacy laws; and 3) upon discovering a suspicious order or series of orders, notify the Administrator of the DEA and the Special Agent in Charge of the Division Office of the DEA for the area in which the registrant is located or conducts business. 21 U.S.C. 832(a). Suspicious orders may include, but are not limited to, orders of

WEBSITE Q&AS

Disposal and/or Destruction Q&A

Get Email Updates:

Chemical Control Program
CMEA (Combat Meth Epidemic Act)
Controlled Substance Schedules
COVID-19 Information
DEA TOX Toxicology Testing Program
Drug Disposal Information
Drug and Chemical Information
E-commerce Initiatives
Federal Agencies & Related Links
Federal Register Notices
Guidance Document Portal
National Prescription Drug Take Back Day
NFLIS
Publications & Manuals
Questions & Answers
Synthetic Drugs
Title 21 Code of Federal Regulations
Title 21 USC Codified CSA

Disposal

Question: Who is responsible for **filing a DEA Form 106** if a sealed inner liner is stolen, lost, or missing from a DEA authorized collector's registered location (or authorized long-term care facility) before the sealed inner liner is picked up for destruction or destroyed on-site?

Answer: All DEA registrants, including DEA-registered authorized collectors, are required to notify the DEA Field Division Office in their area, in writing, of any theft or significant loss of any controlled substances within one business day of discovery of the theft or loss; the registrant must also follow up on the written notification by subsequently filing a DEA Form 106 for the theft or significant loss. **21 CFR 1301.74(c)**; **21 CFR 1301.76(b)**. **21 CFR 1301.74(c)(1)-(6)** and **1301.76(b)(1)-(6)** also direct DEA registrants, including DEA authorized collectors, how they may determine whether a loss is significant. *See also* the Federal Register (FR) Final Rule published by DEA on September 12, 2005, titled *Reports by Registrants of Theft or Significant Loss of Controlled Substances*, **70 FR 47094**.

If a sealed inner liner is stolen, lost, or missing from an authorized collector's registered location (or authorized long-term care facility) before the sealed inner liner is picked up for destruction or destroyed on-site as allowed by **21 CFR 1317.05(c)(2)**, the authorized collector has the responsibility to both report the theft or loss as well as file a DEA Form 106 for the sealed inner liner. However, the authorized collector does not have the responsibility to file a DEA Form 106 for the actual contents of the liner because an inner liner's contents are not allowed to be sorted or inventoried after being placed in a collection receptacle, and the sealed inner liner may not be opened once it is removed from the collection receptacle. *See* **21 CFR 1317.60(c)**; **1317.75(c)**.

Pursuant to **21 CFR 1317.40**, DEA has authorized several types of registrants to be collectors after **modifying their registration** in accordance with **21 CFR 1301.51(b)**. Authorized collectors who are DEA registrants are designated as either non-practitioners (i.e., manufacturers, distributors, reverse distributors, and narcotic treatment programs), or practitioners (i.e., hospitals/clinics with an on-site pharmacy and retail pharmacies). **21 CFR 1317.05(c)(2)(iv)-(v)**. Here, non-practitioner collectors are responsible for filing a DEA Form 106 for the sealed inner liner as directed by **21 CFR 1301.74(c)**, and practitioner collectors are responsible for filing a DEA Form 106 for the sealed inner liner as directed by **21 CFR 1301.76(b)**. In addition, DEA-registered authorized collectors must also be in compliance with applicable State, local or tribal laws. **EO-DEA122A, DEA-DC-058, September 15, 2022**

Question: Who is responsible for **filing a DEA Form 106** if, after a sealed inner liner is picked up from a DEA-authorized collector's registered location (or authorized long-term care facility) at the DEA-authorized collector's request, the sealed inner liner is stolen, lost, or missing while in a common or contract carrier's custody?

Answer: All DEA registrants, including DEA-registered authorized collectors, are required to notify the DEA Field Division Office in their area, in writing, of any theft or significant loss of any controlled substances within one business day of discovery of the theft or

QUESTIONS?

THANK YOU!


U.S. Department of Justice
Drug Enforcement Administration
Rx
Diversion Control Division