



**U.S. Department of
Transportation**

**RULEMAKING
HANDBOOK**

May 2022

STATUTES..... 4

I.	Administrative Procedure Act (APA, 5 U.S.C. §§ 551 – 559, 701 – 706).....	4
II.	Regulatory Flexibility Act (5 U.S.C. §§ 601-612).	9
III.	Small Business Regulatory Enforcement Fairness Act (Pub. L. No. 104-121 (1996), Subtitles A-D).....	10
IV.	Congressional Review of Agency Rulemaking (5 U.S.C. §§ 801-808).	12
V.	The Unfunded Mandates Reform Act; Title II – Regulatory Accountability and Reform (2 U.S.C. §§ 1532-1538).	13
VI.	Paperwork Reduction Act (44 U.S.C. §§ 3501-3520).....	15
VII.	Privacy Act (5 U.S.C. § 552a) and Related Requirements.....	16
VIII.	Information Quality Act (Pub. L. No.106-554; § 515).....	16
IX.	Small Business Paperwork Relief Act of 2002.....	17
X.	Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2).	17
XI.	National Environmental Policy Act (NEPA) (42 U.S.C. §§ 4321-4347) and Other Environmental Requirements.	18
XII.	Trade Agreements Act (19 U.S.C. §§ 2531-2533).	19
XIII.	National Technology Transfer and Advancement Act, Section 12(d) (15 U.S.C. § 272 note).	19
XIV.	Assessment of Regulations on Families ((5 U.S.C. § 601 note).	20
XV.	E-Government Act (44 U.S.C. § 3501 note).	20
XVI.	Agency Authorizing Statutes.....	21

EXECUTIVE ORDERS 22

I.	Executive Order 12866: Regulatory Planning and Review (1993).	22
II.	Executive Order 13563: Improving Regulation and Regulatory Review (2011).	25
III.	Executive Order 13272: Proper Consideration of Small Entities in Agency Rulemaking (2002).	27
IV.	Executive Order 13132: Federalism (1999).	28
V.	Executive Order 13175: Consultation and Coordination with Indian Tribal Governments (2000).	29
VI.	Executive Order 12988: Civil Justice Reform (1996).	31
VII.	Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (1994), amended by E.O. 12498, (1995) and E.O. 14008 (2021).	32
VIII.	Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks (1997), amended by E.O. 13229 (2001); E.O. 13296 (2003).	33
IX.	Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use (2001).	33
X.	Other Executive Orders.	34

PRESIDENTIAL DIRECTIVES AND RELATED ACTIONS 35

I.	Plain Language	35
II.	Transparency and Open Government	35
III.	Flexibility and Job Creation.....	37

OMB BULLETINS AND OTHER DIRECTIVES 38

- I. OMB Circular No. A-4, “Regulatory Analysis” (2003). 38
- II. Final Information Quality Bulletin for Peer Review (2004). 39
- III. Agency Good Guidance Practices (OMB Bulletin 07-02; 2007). 41
- IV. Updated Principles for Risk Analysis (M-07-24; 2007). 42

DOT REGULATIONS, ORDERS, MEMORANDA, AND PROCEDURES..... 43

- I. Rulemaking and Guidance Procedures, DOT Order 2100.6A (June 7, 2021). 43
- II. Other Agency Rulemaking Provisions. 49
- III. Dockets. 49
- IV. Related Requirements. E-Government Act (Pub. L. No. 107-347 (2002)) and Privacy Act (5 U.S.C. § 552a). 49
- V. OIRA Memorandum, “Increasing Openness in the Rulemaking Process – Improving Electronic Dockets.” 49

This document is a summary of the requirements imposed on DOT as it implements its responsibilities for rulemaking. This document was originally prepared for the DOT professionals who are involved in the rulemaking process and is not intended to have a substantial future effect on the behavior of regulated parties.

STATUTES

I. Administrative Procedure Act (APA, 5 U.S.C. §§ 551 – 559, 701 – 706).

- A. Coverage. The APA's informal rulemaking requirements are provided in 5 U.S.C. § 553 and apply to all rules unless excepted or a specific statute provides otherwise. "Rule" includes such terms as "regulation" and "amendment." The APA definition of a rule is broad.
1. The APA defines the term "rule" broadly as "the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency and includes the approval or prescription for the future of rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services or allowances therefor or of valuations, costs, or accounting, or practices bearing on any of the foregoing." *See* 5 U.S.C. § 551.
- B. Categories of Rules. There are basically three types. The legal distinctions are not always clear, and an agency statement can contain more than one kind of rule. The categories are:
1. Legislative/Substantive Rules. These are issued under statutory authority. They implement the statute. They have the force and effect of law (*i.e.*, they are binding on the agency, the public, and the courts).
 2. Nonlegislative Rules.
 - a. Interpretive Rules or Guidance. These tell the public what the agency thinks the statutes and the rules it administers mean. Interpretive rules are not binding.
 - b. General Statements of Policy. These tell the public prospectively how the agency plans to exercise a discretionary power. General statements of policy are not binding.
 3. Management and Procedural Rules.
 - a. Management or Personnel. These involve the running or supervising of the agency's business. They concern the agency and do not directly affect the public.
 - b. Organization, Procedure, or Practice. These describe the agency's structure and functions and the way in which its determinations are made.
- C. Exemptions. 5 U.S.C. § 553(a) exempts from the required informal rulemaking procedures rulemakings involving military or foreign affairs functions, or matters

relating to agency management or personnel or to public property, loans, grants, benefits, or contracts. Despite these exceptions, DOT applies notice and comment procedures to rulemakings establishing conditions for financial assistance in the same manner as these procedures are applied to other rulemakings not involving financial assistance.

- D. Formal Rulemaking. When rules are statutorily required to be made on the record after opportunity for an agency hearing, the trial-type or adversary process is referred to as “formal rulemaking” (subject to 5 U.S.C. §§ 556 and 557). An agency can also elect to conduct formal rulemaking even when not required to do so, but because of the additional complexity of the formal rulemaking process, this type of rulemaking is rarely used.
- E. Informal Rulemaking. The process of “notice and comment” rulemaking is referred to as “informal rulemaking” (subject to 5 U.S.C. § 553).
1. Notice of Proposed Rulemaking (NPRM). Subject to certain exceptions identified below, general notice of proposed rulemaking must be issued before any final action can be taken. This document is called a notice of proposed rulemaking, or NPRM.
 - a. Publication. The NPRM must be published in the *Federal Register*, unless there is special service on all persons subject to the regulation or such persons have actual notice.
 - b. Contents.
 - (1) The NPRM must include the following:
 - (A) a statement of the time, place, and nature of the proceedings (for informal rulemaking, this includes the time period and procedure for submitting comments);
 - (B) the legal authority for the proposed rule; and
 - (C) either the terms or substance of the proposed rule or a description of the subjects and issues involved.
 - (2) Public Comment. The agency must invite interested persons to comment on the proposed rule and may provide an opportunity for oral presentations. Public hearings or meetings can make it easier for some people to comment on the rulemaking, offer an opportunity for the agency to ask questions of a commenter, and make it easier for commenters to hear opposing viewpoints.

- (3) Rule Text. Agencies may include the text of the proposed rule in the NPRM. This is not mandatory unless specifically required by statute, but it is usually advisable to improve the quality of public comments.
- (4) Preamble. Any material other than actual rule language is referred to as the preamble.

c. Exceptions. Unless notice or hearing is required by statute, it is not required under the APA for interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice. For rules that do not fall under these exceptions (i.e., for most legislative rules), an agency may publish a final rule without first providing notice and an opportunity to comment only when the agency finds good cause that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, and provides in the final rule the finding and the reasons supporting the finding.

An example of a rulemaking where notice and comment may be impracticable is a rulemaking to address a public health emergency that would have concluded and caused harm to the public before rulemaking could be undertaken (e.g., a Department of Commerce rulemaking to close a fishery because of a red tide event).

Some examples of DOT rulemakings where notice and comment may be unnecessary include implementing nondiscretionary changes required by statute, allowing for electronic submission rather than hand-delivery, fixing misnumbered or removing obsolete regulatory text.

Note that the term “contrary to the public interest” does not in itself provide a separate basis for waiving notice and comment. It is viewed as an umbrella for the “impracticable” and “unnecessary” prongs.

2. Final Rule.

- a. Basis and Purpose. After consideration of public comment, the agency may issue a final rule, which must include a concise general statement of its basis and purpose.
- b. Timing. Unless otherwise set by statute, there is no time limit within which an agency must publish a final rule after publishing an NPRM.
- c. Publication/Availability (5 U.S.C. § 552).

- (1) Procedural rules, substantive rules, policy statements, and interpretations of general applicability. Agencies must

publish these rules in the *Federal Register*. A person may not be required to resort to or be adversely affected by a rule that an agency is required to publish if it is not published, unless the person has actual and timely notice (e.g., personal service) of the rule.

- (2) Interpretations and policy statements of general applicability not published in the *Federal Register*. Agencies must make these documents available for public inspection and copying.
- (3) Interpretations, policy statements, and staff manuals or instructions. If these documents are not published or actual and timely notice is not provided and they affect a member of the public, they must be electronically available before the agency can rely on them, use them, or cite them as precedent.
- (4) Rules of Particular Applicability. The APA does not require publication for rules of particular applicability, but DOT agencies publish them in the *Federal Register* as a matter of practice. Publication serves as legal notice to the affected party and to the general public.

d. Effective Date. 5 U.S.C. 553(d) requires that final rules shall not be made effective in less than thirty days after publication or service except for:

- (1) Substantive rules that grant or recognize an exemption or relieve a restriction.
- (2) Interpretative rules and statements of policy.
- (3) Good Cause. As otherwise provided by the agency for good cause found and published with the rule.

F. Petitions. 5 U.S.C. 553(e) provides the public the right to petition for the issuance, amendment, or repeal of a rule.

G. Exemptions and Waivers. Courts have made it clear that the public has a right to petition for exemption from a rule. Such exemptions are generally granted only for unique circumstances not considered during the rulemaking. In addition, a statute may specifically provide an agency with authority to exempt individuals from particular rules and may even provide the conditions for such an exemption. Some use the term “waiver” interchangeably with “exemption.”

- H. Additional Steps. Agencies can supplement the requirements of the APA. Examples of extra steps DOT uses are:
1. Advance Notice of Proposed Rulemaking (ANPRM). Agencies issue ANPRMs when, *e.g.*, they know there is a problem but do not have sufficient information to know the appropriate solution to propose, or have insufficient information about the rule's expected effects to credibly estimate them (and help ensure accurate and helpful public comments at the NPRM stage). Some agencies are statutorily required to issue ANPRMs in certain circumstances (*e.g.*, 49 U.S.C. § 31136(g) requires the Federal Motor Carrier Safety Administration (FMCSA) to either issue an ANPRM or proceed with a negotiated rulemaking for certain rulemakings).
 2. Supplemental Notice of Proposed Rulemaking (SNPRM). Agencies issue SNPRMs after they have issued an NPRM when, *e.g.*, they wish to obtain public comment on factual information or alternative proposals that were not considered in the NPRM before issuing a final rule. SNPRMs are likely to be helpful when circumstances have changed significantly or significant additional data has become available since the issuance of an NPRM.
 3. Interim Final Rule (IFR). Agencies issue IFRs in limited circumstances when they have met the requirements for issuing a final rule without first issuing an NPRM but seek to obtain public comment on the provisions of that final rule. After reviewing the comments, an agency may modify the interim final rule and issue a "final" final rule. An IFR is not a substitute for an otherwise required NPRM.
- I. Direct Final Rulemaking.
1. Purpose. This is a process used to expedite the issuance of rules for which the agency expects no adverse comment.
 2. Process. Generally, the agency publishes the rule in the *Federal Register* with a statement that, unless adverse comment is received within a certain time period, it will become effective on a specified date. If the agency receives no public comment, it publishes a notice to that effect in the *Federal Register*. If the agency receives adverse comment, the rule is withdrawn and the agency may republish it as an NPRM.
 3. Authority. The agency authority for this process is that notice and comment rulemaking would be unnecessary under the APA good cause exception, but it still provides an expedited process for public comment.
- J. Judicial Review (5 U.S.C. §§ 701-706). If challenged in court under the APA, an agency rulemaking action is subject to standards whereby it can be held unlawful and set aside if it is found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; unconstitutional; or in violation of statute or a procedural

law. The court can also compel agency action unlawfully withheld or unreasonably delayed.

- K. Negotiated Rulemaking Act (5 U.S.C. §§ 561-570a). Agencies can convene advisory committees made up of representatives of interests affected by the issues involved to negotiate an NPRM and a final rule. This act provides agencies the clear statutory authority to employ this process. See section 13(m) of DOT Order 2100.6A for DOT procedures concerning negotiated rulemakings.

II. **Regulatory Flexibility Act (5 U.S.C. §§ 601-612).**

- A. Impacts. Agencies must consider the impact of their rulemakings on small entities (small businesses, small organizations, and local governments). Executive Order 13272 builds on the Act's requirements and is discussed below.
- B. Initial Regulatory Flexibility Analysis (RFA). When 5 U.S.C. § 553 or another law requires an agency to publish an NPRM, 5 U.S.C. § 603 requires an agency to prepare and make available for comment an initial RFA. Section 603 further requires the initial RFA or its summary to be published in the Federal Register at the same time as the NPRM, and requires a copy of the initial RFA to be provided to the Chief Counsel for Advocacy of the Small Business Administration.
 - 1. Contents of initial RFA. Among other things, the agency must estimate the number of small entities to which the rule will apply or explain why an estimate is not available; describe the skills necessary to prepare any reports or records that are proposed to be required; explain what it has done to minimize the significant burdens for small entities; and explain why it chose the alternative it did, as well as explaining why it rejected other alternatives that would have minimized burdens for small entities.
- C. Final RFA. When an agency publishes a final rule that is subject to the informal rulemaking requirements of the APA, 5 U.S.C. § 604 requires the agency to prepare and make public a final RFA, with at least a summary available in the Federal Register.
 - 1. Contents of final RFA. Among other things, the agency must include elements similar to the primary elements of the initial RFA; describe significant issues raised by the public in response to the initial RFA, and a reasoned statement of any changes made in the proposed rule as a result of such comments; and describe any comments filed by the Chief Counsel for Advocacy of the Small Business Administration and explain any changes made as a result of the comments.
- D. Certification. 5 U.S.C. § 605 provides that if the head of an agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities, the analyses otherwise required by the act need not be performed. Such a certification must be published in the Federal Register at the same

time as the corresponding NPRM or final rule, along with a statement providing the factual basis for such certification.

- E. Agenda. 5 U.S.C. § 602 requires agencies to publish semi-annually an agenda of rulemakings having significant economic impacts on a substantial number of small entities. Executive Order 12866, discussed below, expands upon this requirement.
- F. Reviews. 5 U.S.C. § 610 requires that agencies review existing regulations periodically to determine whether changes can be made to lessen or eliminate their impact on small entities.
- G. Judicial Review. 5 U.S.C. § 611 allows for judicial review of agency compliance with most of the Act.
- H. Advocacy Guidance. See “A Guide for Government Agencies – How to Comply with the Regulatory Flexibility Act” (2017).

III. **Small Business Regulatory Enforcement Fairness Act (Pub. L. No. 104-121 (1996), Subtitles A-D).**

A. Compliance Guides (5 U.S.C. § 601 note).

1. Guides. Agencies must prepare and publish one or more guides explaining the actions a small entity is required to take to comply with each rule or group of related rules for which an agency is required to prepare a final regulatory flexibility analysis (FRFA) under the Regulatory Flexibility Act (5 U.S.C. § 604). In other words, a small entity compliance guide is required for any rules for which an agency is unable to certify that the rule would not have a significant economic impact on a substantial number of small entities.
2. Evidence. Although the substance of the guide is not subject to judicial review, its contents may be considered as evidence of the reasonableness or appropriateness of any proposed fines, penalties or damages in any civil or administrative action against a small entity.

B. Informal Guidance (5 U.S.C. § 601 note).

1. Program. Agencies are required to have a program for answering small entity inquiries concerning information on, and advice about, compliance with statutes and regulations within the agency’s jurisdiction, interpreting and applying the law to specific sets of facts supplied by the small entity.

2. Evidence. This guidance may be considered as evidence of the reasonableness or appropriateness of any proposed fines, penalties or damages sought against a small entity in any civil or administrative action.
- C. SBA Enforcement Ombudsman (15 U.S.C. § 657).
1. Ombudsman. The SBA Administrator is required to designate a Small Business and Agriculture Regulatory Enforcement Ombudsman (Ombudsman).
 2. Annual Report. The Ombudsman is required to report annually to Congress and the affected agencies on the enforcement activities of agency personnel, including a rating of the agency's responsiveness to small businesses, based on substantiated comments received from small business concerns and the Regional Small Business Regulatory Fairness Boards (Boards). The Ombudsman must provide agencies an opportunity to comment on draft reports and must include in the report a section with agency comments that are not addressed in revisions to the draft.
- D. Regional Small Business Regulatory Fairness Boards (15 U.S.C. § 657).
1. Boards. The SBA Administrator is required to establish Boards in each SBA regional office; they consist of five members from small business concerns.
 2. Reports to Ombudsman. The Boards provide the Ombudsman with advice on small business concerns about agency enforcement activity; reports on substantiated instances of excessive agency enforcement actions against small business concerns, including their findings or recommendations on agency enforcement policy or practice; and comments on the Ombudsman's annual report.
- E. Rights of Small Entities in Enforcement Actions (5 U.S.C. § 601 note).
1. Reduction or Waiver of Penalties. Each agency that regulates small entities must have a policy or program to provide for the reduction, and under appropriate circumstances for the waiver, of civil penalties for violations of a statutory or regulatory requirement by a small entity.
 2. Considerations, Conditions, or Exclusions. Under appropriate circumstances, an agency may consider ability to pay in determining penalty assessments on small entities. Subject to other statutes, the agency policy or program must have conditions or exclusions.
- F. Other Requirements. Other provisions of the Act applicable to rulemaking are covered in this document under the Regulatory Flexibility Act or the Congressional Review of Agency Rulemaking statute.

- G. DOT Guidance. See the DOT website “Rulemaking Requirements Concerning Small Entities.”

IV. **Congressional Review of Agency Rulemaking (5 U.S.C. §§ 801-808).**

- A. Submission of Rules (5 U.S.C. § 801(a)). The statute requires the submission of all final rules (and supporting documents) to Congress and the Comptroller General before the rules can take effect.
- B. Rule. A “rule” is defined in 5 U.S.C. § 804(3) to be a rule as defined by 5 U.S.C. § 551, with exceptions for rules of particular applicability, rules of agency management or personnel, and rules of agency procedures that do not substantially affect the rights and obligations of non-agency parties.
- C. Effective Date (5 U.S.C. §§ 801(a), (c), (d), 808).
1. Non-Major Rule. Non-major rules must take effect as otherwise provided by law after submission to Congress.
 2. Major Rule.
 - a. General. A major rule cannot take effect for at least 60 days after it is submitted to Congress; there are complex provisions involved that could prevent major rules from becoming effective through the end of a Congress, if a joint resolution is introduced.
 - (1) 5 U.S.C. § 804(2) defines a major rule to be a rule that the Administrator of the Office of Information and Regulatory Affairs (OIRA) determines will have an annual effect on the economy of over \$100 million, will result in a major increase in costs or prices, or will result in significant adverse effects on competition, employment, investment, productivity, innovation, or competitiveness of U.S. firms in domestic and export markets.
 - b. Good Cause. A major rule can take effect earlier if the agency, for good cause, finds that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest. 5 U.S.C. § 808(2).
 - c. Presidential Determination. The President may determine that a rule should take effect regardless of the statute if it is:
 - (1) Necessary because of an imminent threat to health or safety or other emergency;
 - (2) Necessary for enforcement of criminal laws;

- (3) Necessary for National security; or
- (4) Issued pursuant to any statute implementing an international trade agreement.

d. Submission Date. A major rule submitted within 60 session/legislative days before Congress adjourns a session is treated as having been submitted on the 15th session/legislative day of the next session; under these circumstances, the rule can “take effect as otherwise provided by law including” 5 U.S.C. § 801.

- D. Congressional Disapproval Procedures (5 U.S.C. § 801(f)). Congress can always overturn a rule by enactment of legislation, but this statute contains procedures for expedited review and disapproval. Under this statute, Congress can only disapprove the rule; it cannot change it. If a rule is overturned under these procedures, it is “treated as though ... [it] had never taken effect.”
- E. Substantially the Same (5 U.S.C. § 801(b)). If the rule is disapproved, the agency cannot adopt a rule that is substantially the same, unless authorized by a new statute.
- F. Judicial Review (5 U.S.C. §§ 801(g), 805). No determination, finding, action or omission under the statute is subject to judicial review. No court (or agency) may infer any intent from Congressional action or inaction.
- G. OMB Guidance. See OMB memorandum of March 30, 1999, on “Guidance for Implementing the Congressional Review Act.” See also OMB memorandum of April 11, 2019, on “Guidance on Compliance with the Congressional Review Act.”

V. **The Unfunded Mandates Reform Act; Title II – Regulatory Accountability and Reform (2 U.S.C. §§ 1532-1538).**

- A. Written Statements (2 U.S.C. § 1532).
 1. Requirement. Unless otherwise prohibited by law, agencies must prepare a written statement prior to issuing NPRMs and final rules (for which a general notice of proposed rulemaking was published) that include a Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” (See latest DOT Guidance on “Threshold of Significant Regulatory Actions Under the Unfunded Mandates Reform Act of 1995.”) The statement may be included as part of another analysis.
 2. Contents. Each written statement must include, among other things, an analysis of the costs and benefits and a description of prior consultations with, and input from, State, local, or tribal governments.

3. Federal Mandates (2 U.S.C. § 658(6)). These are rules that impose an enforceable duty, except a:
 - a. Condition of Federal assistance.
 - b. Duty arising from participation in a voluntary Federal program (with certain exceptions).
- B. Regulatory Alternatives (2 U.S.C. § 1535). Where a written statement is required, the agency must identify and consider a reasonable number of regulatory alternatives, and from those alternatives select the least costly, most cost-effective or least burdensome alternative that achieves the objective of the rule or explain why it could not.
- C. Preamble Summary (2 U.S.C. § 1532(b)). Each agency must include a summary of any required statement in the NPRM or the final rule preamble.
- D. Report to Congress (2 U.S.C. § 1538). OMB must annually report to Congress on agency compliance with the Act, including a certification, with a written explanation, of agency compliance with the least burdensome option requirement.
- E. Small Government Agency Plans. 2 U.S.C. § 1533 requires that before imposing regulatory requirements that may significantly or uniquely affect small governments, agencies must develop a plan to:
 1. Notify affected small governments of the requirements;
 2. Allow meaningful and timely input by them into the development of the rule; and
 3. Inform, educate, and advise the affected entities of the requirements.
- F. State, Local, and Tribal Government Input.
 1. Process. 2 U.S.C. § 1534 requires agencies to develop an effective process for meaningful and timely input from State, local, and tribal governments in the development of rules with significant intergovernmental mandates.
 2. FACA Exemption. Agency meetings with State, local, or tribal elected officers (or their authorized designees) solely to exchange views, information, or advice relating to the management or implementation of Federal programs that share intergovernmental responsibilities or administration are exempt from the Federal Advisory Committee Act.
- G. Judicial Review (2 U.S.C. §1571). An agency action can be challenged for failure to prepare a written statement or a small government agency plan. Preparation can be

compelled, but inadequacy or failure to prepare cannot be used to stay, enjoin, invalidate or otherwise affect the rule.

- H. OMB Guidance. See OMB memorandum of September 25, 1995, on “Guidelines and Instructions for Implementing Section 204, ‘State, Local, and Tribal Government Input,’ of Title II of Public Law 104-4.”

VI. **Paperwork Reduction Act (44 U.S.C. §§ 3501-3520).**

- A. Burdens. The Act requires that agencies consider the impact of paperwork and other information collection burdens imposed on the public.
- B. Coverage. It applies to all agency collections of information, not just those contained in rulemakings, to both voluntary and mandatory collections, and to agency-directed disclosure to third parties or the public.
- C. OMB Approval. It requires public comment and specific approval by OMB of any new requirements for collection of information imposed on ten or more persons by an agency; without such approval, the agency lacks the authority to enforce any such requirement. OMB approvals expire (typically every 3 years) and, thus, the agency must follow the necessary procedures to renew all ongoing collections.
- D. Enforcement. Agencies must inform respondents that a response is not required unless the collection of information displays a valid OMB control number.
- E. Information Collection Budget (ICB). Annually, each agency must submit an ICB for OMB approval. The ICB covers existing requirements, new proposals, and planned reductions.
- F. OMB Regulations. See 5 C.F.R. Part 1320, “Controlling Paperwork Burdens on the Public,” for detail on these requirements.
- G. Electronic Information. The Government Paperwork Elimination Act (44 U.S.C. § 3504 note) requires that, by October 21, 2003, agencies allow electronic maintenance, submission, or disclosure of information, when practicable as a substitute for paper and for the use and acceptance of electronic signatures, when practicable.
- H. Electronic Signature. The Electronic Signature in Global and National Commerce Act (15 U.S.C. §§ 7001-7031) establishes the legal equivalence, in private commerce, between legally-required written and electronic documents and pen-and-ink and electronic signatures. To the extent Federal law or regulation requires the retention of a document or information, this Act allows electronic retention; agencies are permitted to require paper records in certain circumstances.
- I. OMB Guidance. See OMB/OIRA memorandum of April 7, 2010, on “Information Collection under the Paperwork Reduction Act” implementing the Presidential

Memorandum of January 21, 2009, on “Transparency and Open Government”; and OMB Memorandum of July 22, 2016, on “Flexibilities under the Paperwork Reduction Act for Compliance with Information Collection Requirements.” Additional information and resources can be found at <https://pra.digital.gov/>.

VII. Privacy Act (5 U.S.C. § 552a) and Related Requirements.

- A. Nondisclosure. 5 U.S.C. § 552a(b) prohibits agencies from disclosing any record that is contained in a system of records to any person or another agency, except as authorized in writing by the individual, unless disclosure would meet specified conditions, contained in 5 U.S.C. § 552a(b)(1) – (12), including a routine use described in the system of records.

- B. Privacy Impact Assessments.
 1. FY 2005 Omnibus Appropriations Act, Pub. L. No. 108-447, division H, § 522. Specified agencies, including DOT, must evaluate regulatory proposals involving collection, use, and disclosure of personal information by the Federal Government and conduct a privacy assessment of their proposed rules on the privacy of information in an identifiable form, including the type of personally identifiable information collected and the number of people affected.
 2. OMB Memorandum. See OMB memorandum of February 11, 2005 (M-05-08) from Deputy Director for Management on “Designation of Senior Agency Officials for Privacy.” It discusses senior officials’ role in development and evaluation of regulatory proposals with privacy issues, the need to evaluate the proposal’s impact, and the need to consider alternatives.
 3. DOT Guidance. See the DOT website “DOT Privacy Policy.”
 4. DOT PIA Documents. See the DOT website “Privacy Impact Assessments.”

- C. System of Records Notices (SORN).
 1. DOT SORN Documents. 5 U.S.C. § 552a(e)(4) requires agencies to publish in the Federal Register a notice of the existence and character of the system of records. For a list of Federal Register notices for DOT systems of records, see the DOT website “Privacy Act System of Records Notices.”

- D. DOT Order. See DOT Order 1351.18 (2014), “Departmental Privacy Risk Management Policy,” for supplemental requirements.

VIII. Information Quality Act (Pub. L. No.106-554; § 515).

- A. Agency-Disseminated Information. The Information Quality Act (IQA) directs OMB to provide “guidance to Federal agencies for ensuring and maximizing the quality,

objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies in fulfillment of the purposes and provisions of” the [Paperwork Reduction Act](#). See OMB “Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies,” [67 FR 8452](#) (Feb. 22, 2002). Agencies must have processes for substantiating the quality of the information they have disseminated through documentation or other means appropriate to the information. See also OMB’s “[Final Information Quality Bulletin for Peer Review](#),” (2004) and [OMB and the Office of Science and Technology Policy’s memorandum of September 19, 2007](#), on “Updated Principles for Risk Analysis” (M-07-24).

- B. Agency Guidelines. Agencies must issue guidelines implementing OMB’s guidelines and establishing administrative mechanisms that allow affected persons to seek and obtain correction of the agency information. See “[The Department of Transportation’s Information Dissemination Quality Guidelines](#),” (2019).

IX. Small Business Paperwork Relief Act of 2002.

- A. One Point of Contact ([44 U.S.C. § 3506\(i\)](#)). Each agency (pursuant to 44 U.S.C. § 3502, this includes DOT) must establish one “point of contact ... to act as a liaison between the agency and small business concerns” with respect to information collections and the control of paperwork. The current DOT contact is Joe Solomey, who can be reached at joe.solomey@dot.gov.
- B. Burden Reduction ([44 U.S.C. § 3506\(c\)\(4\)](#)). Each agency must make efforts to further reduce the information collection burden for small business concerns with fewer than 25 employees.
- C. Small Business Paperwork Relief Task Force. See “Report of the Small Business Paperwork Relief Act Task Force” (2004).

X. Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2).

- A. Requirements. Generally, if any agency meets with more than one person (not officers or employees of the Federal government) for receiving group/consensus advice, rather than individual views, that group must be chartered as a Federal advisory committee and must meet certain requirements—such as keeping its meetings open to the public, publishing a Federal Register describing a meeting’s agenda at least 15 calendar days in advance, taking minutes, and having a membership with fairly balanced viewpoints.
 1. Under 49 U.S.C. § 106(p)(5), FAA aviation rulemaking committees are exempt from FACA.
- B. Rulemaking Implications. FACA becomes a factor in rulemaking when a decision maker seeks group advice from specific members of the public on how to handle a particular rulemaking. Often, to get such advice, the decision maker must follow the

procedures specified in DOT Order 1120.3B (1993), referenced below, to charter an advisory committee under FACA or utilize an existing FACA committee, as appropriate.

- C. GSA Regulations. See 41 C.F.R. Part 101-6, Subpart 101-6.10, “Federal Advisory Committee Management” for supplemental requirements.
- D. GSA Guidance. See “Presidential Advisory Commission on Election Integrity Briefing: Federal Advisory Committee Act; Presidential Records Act” (2017).
- E. DOT Order. See DOT Order 1120.3C (2020), “Committee Management Policy and Procedures,” for supplemental requirements.

XI. National Environmental Policy Act (NEPA) (42 U.S.C. §§ 4321-4347) and Other Environmental Requirements.

- A. General. NEPA, numerous other statutes, regulations (see, *e.g.*, Council of Environmental Quality Regulations at 40 C.F.R. §§ 1500-1508 and FHWA/FRA/FTA regulations at 23 C.F.R. Part 771, executive orders, and DOT Order (5610.1C) impose requirements for considering the environmental impacts of agency decisions.
- B. Environmental Impact Statement (EIS). NEPA requires that an EIS be prepared for major Federal actions significantly affecting the quality of the human environment. The agency is required to obtain public comment on a draft EIS before issuing a final EIS.
- C. Environmental Assessment (EA). If an action may or may not have a significant impact, an environmental assessment must be prepared. If, as a result of this study, a Finding Of No Significant Impact (FONSI) is made, no further action is necessary. If it will have a significant effect, then the assessment is used to develop an EIS. It is DOT policy or, in some cases, required by agency regulations to make an EA available to the public. See 23 C.F.R. § 771.119(d).
- D. Categorical Exclusions. Agencies can categorically identify actions (*e.g.*, establishment or modification of terminal control areas) that do not normally have a significant impact on the environment, for which preparation of an EIS or EA is not required. In the rare instances when an action normally classified as categorically excluded could have a significant impact, the agency is required to perform an EA or an EIS. Unless a major Federal action is categorically excluded, an agency must prepare an EA or EIS.
- E. Rules. Rulemaking is a “major” Federal action. Agencies must complete the NEPA documentation before issuing the final rule. Under agency regulations or order, rulemaking may be categorically excluded (see, *e.g.*, 23 C.F.R. §§ 771.115 – 771.117, FAA Order 1050.1F).
- F. Effects. Among other considerations when analyzing effects, agencies must consider beneficial as well as detrimental effects.

- G. Consultation/Coordination/Public Participation. The various requirements imposed on agencies include obligations to consult or coordinate with various other Federal agencies and to provide special opportunities for public comment. Completion of the review/comment period may need to occur prior to issuance of rulemaking documents.
- H. Other Requirements. There are many additional environmental requirements, including some that have substantive effects (*e.g.*, those applying to wetlands).

XII. Trade Agreements Act (19 U.S.C. §§ 2531-2533).

- A. Obstacles to Foreign Commerce. This statute prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. The statute is primarily concerned with products. 19 U.S.C. § 2531(b) makes clear that setting domestic standards, including to protect safety and the environment, are not considered unnecessary obstacles.
- B. Performance Criteria. 19 U.S.C. §2532(3) requires the use of performance rather than design standards, if appropriate.
- C. International Standards. In developing U.S. standards, 19 U.S.C. § 2532(2)(A) requires the consideration of international standards and, if appropriate, that they be the basis for U.S. standards.
- D. Agreement on Technical Barriers to Trade. Article 2 of this international agreement imposes similar requirements, including requiring members to use international standards as the basis for technical regulations, unless they would be ineffective or inappropriate.
- E. OMB/USTR Memorandum. See OIRA Administrator/Deputy United States Trade Representative memorandum of May 19, 2011 (M-11-23), reminding agencies of their obligations under the Act.

XIII. National Technology Transfer and Advancement Act, Section 12(d) (15 U.S.C. § 272 note).

- A. Utilization of Consensus Technical Standards by Federal Agencies. Agencies are required to use technical standards that are developed or adopted by voluntary consensus standards bodies to carry out policy objectives determined by the agencies, unless they are inconsistent with applicable law or otherwise impractical. Agencies may use technical standards that are not developed or adopted by voluntary consensus standards bodies if they transmit an explanation of the reasons for using alternate standards to OMB.

- B. Consultation and Participation. Agencies are required to consult with and—if compatible with agency missions, authority, priorities, and resources—participate with voluntary, private sector, consensus standards bodies.
- C. OMB Circular. See OMB Circular A-119 Revised, “Federal Participation in the Development of and Use of Voluntary Consensus Standards and in Conformity Assessment Activities” (1998), for supplemental information.

XIV. Assessment of Regulations on Families ((5 U.S.C. § 601 note).

- A. Family Policymaking Assessment. Agencies are required to assess policies and regulations that may affect family well-being before implementing them. Several factors are listed for consideration in the assessment.
- B. Written Certification. Agency heads are required to submit a written certification to OMB and Congress that the assessment has been done.
- C. Rationale. Agency heads are also required to provide an adequate rationale for implementing actions that may negatively affect family well-being.
- D. OMB Responsibilities. OMB is required to ensure that policies and regulations are implemented consistent with these requirements. It also must compile, index, and submit annually to Congress the written certifications it receives.
- E. Assessments Requested by Member of Congress. Agencies are required to conduct assessments in accordance with this section’s criteria when requested by a Member of Congress.
- F. Judicial Review. This section is not intended to create any right or benefit enforceable against the United States.

XV. E-Government Act ([44 U.S.C. § 3501 note](#)).

- A. Public Information. To the extent practicable, agencies must provide a website that includes all information about that agency required to be published in the *Federal Register* under 5 U.S.C. § 552(a)(1) and (a)(2). (*N.B.*: § 552(a)(2) does not require publication of any documents.)
- B. Electronic Submission. To the extent practicable, agencies must accept electronically those submissions made under 5 U.S.C. § 553(c).
- C. Electronic Dockets. To the extent practicable, agencies must have an internet-accessible rulemaking docket that includes all public comments and other materials that by agency rule or practice are included in the agency docket.

- D. Privacy Impact Assessments. Agencies must assess privacy impacts before collecting information that will be collected, maintained, or disseminated using information technology and that includes any information in an identifiable form permitting the physical or online contacting of a specific individual, if identical questions have been posed to, or identical reporting requirements imposed on, 10 or more persons, other than Federal agencies or employees.
- E. OMB Memorandum. See OMB memorandum (M-03-22) on the privacy impact assessments required under the statute.

XVI. Agency Authorizing Statutes.

- A. Authorizing Language. An agency cannot issue a regulation unless it has statutory authority to do so. The language in DOT statutes varies:
 - 1. Specific. The authority may be specific (*e.g.*, it may require the installation of emergency locator transmitters in aircraft).
 - 2. General. The authority may be very general (*e.g.*, simply requiring an agency to set “minimum” or “reasonable” standards).
 - 3. Factors to Consider. Some statutes also require that the agency specifically consider certain factors, such as the efficient utilization of navigable airspace, in imposing a requirement.
- B. Potential Conflicts. Some of DOT’s statutory requirements may result in rules that affect another statutory requirement implemented by the same DOT agency (*e.g.*, a NHTSA safety equipment requirement may add weight that will affect the ability to comply with a NHTSA fuel economy requirement). Some may affect rules of other agencies within DOT (*e.g.*, a NHTSA child seat standard may conflict with an FAA standard related to use in an aircraft). Any potential conflicts are handled through agency coordination efforts or OST oversight. Some requirements may affect those of another, non-DOT agency (*e.g.*, an FAA requirement for a wind shear detection device may emit noise and conflict with an EPA standard). These are generally handled through memoranda of understanding between agencies, agency coordination efforts, or OMB oversight.
- C. Procedural Requirements. The statutes may also impose on DOT other procedural (*e.g.*, public hearings) or review (*e.g.*, DOT is required to allow Department of Energy review of automobile fuel economy standards and to provide any response in the preamble if changes are not made) requirements.

EXECUTIVE ORDERS

I. Executive Order 12866: Regulatory Planning and Review (1993).

- A. Regulatory Philosophy and Principles. Section 1 of Executive Order (E.O.) 12866 sets forth regulatory philosophy and principles to which each agency should adhere. Section 1(a) states that Federal agencies should, among other things, choose regulatory alternatives that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires another regulatory approach. In addition, to the extent provided by law and where applicable, section 1(b) requires agencies to, among other things, design their regulations in the most cost-effective manner to achieve the regulatory objective, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs, and tailor their regulations to impose the least burden on society, consistent with obtaining the regulatory objectives.
- B. Unified Agenda of Regulatory and Deregulatory Actions and Regulatory Plan. Section 4(b) of E.O. 12866 requires each agency to prepare a (semiannual) Agenda of all regulatory action under development or review. As part of the Fall Agenda, section 4(c) of E.O. 12866 requires each agency to prepare a Plan of its most important significant regulatory actions.
- C. Review of Existing Regulations. Section 5 of E.O. 12866 requires agencies to submit to OIRA a program for periodic review of existing significant regulations to determine whether to modify or eliminate them. Rules to be reviewed must be included in the agency's Plan. Agencies must also identify legislatively mandated regulations that are unnecessary or outdated.
- D. Public Participation. Section 6(a) of E.O. 12866 requires agencies to provide the public with meaningful participation in the regulatory process. To do this, Section 6(a) recommends agencies seek involvement of those intended to benefit from or be burdened by a regulation prior to issuing an NPRM. There are many ways in which to seek such input, including issuing a Request for Information or advance notice of proposed rulemaking (ANPRM), or holding a public meeting or webinar. The Department's *ex parte* guidance also provides procedures for docketing a communication with an outside party, including docketing a summary memorandum of the communication and the inclusion of any information provided by an outside party in the rulemaking record. These *ex parte* procedures are intended to ensure that the Department's rulemaking processes are open and transparent. In addition, agencies should provide a meaningful opportunity to comment on an NPRM, including a 60-day comment period in most cases. Where appropriate, agencies must use consensual mechanisms for developing regulations, including negotiated rulemaking.
- E. OIRA Review. Section 6 of E.O. 12866 provides guidelines for the centralized review of agency regulations.

1. Definition of “regulation” or “rule.” As defined in section 3(d) of E.O. 12866, a rule means an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency. Rules issued in accordance with formal rulemaking procedures, rules that pertain to a military or foreign affairs function, and rules that are limited to agency organization, management, or personnel matters are excepted from the definition. In addition, the OIRA Administrator may exempt certain categories of regulations from the definition.
2. Coverage. Section 6 of E.O. 12866 requires agencies to submit all significant rulemakings to OIRA for review before issuance. Section 6(b) of E.O. 12866 includes time frames for completing reviews, which is typically 90 days for the review of NPRMs and final rules, along with supporting documentation such as regulatory impact analyses, with a possible 30-day extension.

a. Significant rulemakings are defined in section 3(f) of E.O. 12866 as “any regulatory action that is likely to result in a rule that may:

- (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;
- (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
- (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
- (4) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in this Executive order.”

3. Changes During OIRA Review. Section 6(a)(3)(E)(ii) and (iii) of E.O. 12866 requires that agencies identify for the public substantive changes made to the rulemaking documents after submission to OIRA, specifically identifying those made at the suggestion or recommendation of OIRA.

F. Regulatory Analysis.

1. Assessment. Section 1(b) of E.O. 12866 requires agencies to assess the costs and benefits of intended regulations. For significant regulatory actions reviewed by OIRA, section 6(a)(3)(B)(ii) of E.O. 12866 requires that agencies prepare an

assessment that includes an explanation of the manner in which the regulatory action is consistent with a statutory mandate and, to the extent permitted by law, promotes the President's priorities and avoids undue interference with State, local, and tribal governments in the exercise of their governmental functions. Further, for regulations that are significant because they may have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (an "economically significant" rule), agencies must provide an assessment of the benefits and costs, quantified to the extent feasible, of potentially effective and reasonably feasible alternatives and an explanation of why the planned action is preferable.

2. OMB Guidance. See OMB Circular No. A-4, "Regulatory Analysis" (2003); see Agency Checklist: Regulatory Impact Analysis (2010).

G. Risk Analysis.

1. Assessment. Section 1(b)(4) of E.O. 12866 requires that agencies consider, to the extent reasonable, the degree and nature of the risks posed by substances and activities within the agency's jurisdiction.
2. OMB/OSTP Guidance. See OMB and the Office of Science and Technology Policy's memorandum of September 19, 2007, on "Updated Principles for Risk Analysis" (M-07-24).

H. Disclosure of OIRA Contacts. Section 6(b)(4) of E.O. 12866 includes procedures for how OIRA will disclose communications between OIRA and persons outside of the executive branch.

I. Resolution of Conflicts. Section 7 of E.O. 12866 provides that the President resolves disagreements among agencies or with OMB that cannot be resolved by OIRA.

J. OMB Guidance.

1. OIRA Review. See OIRA Administrator memorandum of September 20, 2001, describing how OIRA carries out its regulatory review and summarizing the principles and the procedures it uses.
2. Electronic Dockets. See OIRA Administrator memorandum of May 28, 2010, on "Increasing Openness in the Rulemaking Process – Improving Electronic Dockets." This memorandum requires that agencies compile and maintain comprehensive electronic regulatory dockets.
3. RINs. See OIRA Administrator memorandum of April 7, 2010, on "Increasing Openness in the Rulemaking Process – Use of the Regulation Identifier Number

(RIN).” This memorandum requires that agencies use RINs on all documents related to a particular rulemaking.

K. White House and OMB Directives.

1. At the beginning of each administration, White House and OMB Directives explain the processes for handling rules during the transition from the previous administration. See, *e.g.*, Presidential Memorandum of January 20, 2021, “Regulatory Freeze Pending Review,” and OMB memorandum of January 20, 2021 (M-21-14), “Implementation of Regulatory Freeze.”
2. The Presidential Memorandum of January 20, 2021, “Modernizing Regulatory Review” directs the Director of OMB to lead an effort to review and evaluate the processes and principles that govern regulatory review and make recommendations to improve them. The memorandum seeks recommendations that will modernize and improve the regulatory review process, including by updating OMB guidance with respect to regulatory analysis, improving consideration of distributional consequences of regulations, and determining the appropriate way to review guidance documents.

L. International Agreements.

1. OIRA. Pursuant to [22 C.F.R. 181.4\(e\)\(2\)](#), agencies are required to consult with OIRA in a timely manner before entering into an international agreement that could reasonably be expected to require (for its implementation) the issuance of a significant regulatory action, as defined in E.O. [12866](#).
2. USTR. Pursuant to [19 U.S.C. § 2541](#), the U.S. Trade Representative (USTR) has responsibility for coordinating U.S. discussions and negotiations with foreign countries for the purpose of establishing mutual arrangements for standards-related activities and requires USTR to consult with any agency having expertise in the subject.

II. Executive Order 13563: Improving Regulation and Regulatory Review (2011).

- A. General Principles (sec. 1). This E.O. supplements and reaffirms E.O. 12866, stressing that, to the extent permitted by law, an agency rulemaking action must be based on benefits that justify its costs, impose the least burden, consider cumulative burdens, maximize benefits, use performance objectives, and assess available alternatives.
- B. Public Participation (sec. 2).
 1. Meaningful Participation. Agencies must, to the extent feasible and permitted by law, provide a meaningful opportunity for public comment (generally 60 days), including through the Internet, with timely and easy access to all pertinent documents. Prior to issuing NPRMs, agencies should seek the views of those

likely to be affected, where feasible and appropriate. See also OIRA Administrator memorandum of March 20, 2012, on “Cumulative Effects of Regulations.” See Section I.D. of this memorandum for appropriate ways to seek such views.

2. Use of the Internet. See also OIRA Administrator memorandum of April 7, 2010, on “Social Media, Web-Based Interactive Technologies, and the Paperwork Reduction Act.”
- C. Integration and Innovation (sec. 3). Agencies must promote coordination, simplification, and harmonization across agencies to reduce redundant, inconsistent, or overlapping rules. They shall also seek to achieve goals designed to promote innovation.
- D. Flexible Approaches (sec. 4). Agencies must consider approaches that reduce burdens and maintain flexibility and freedom of choice.
- E. Science (sec. 5).
1. Objectivity. Agencies must ensure the objectivity of any scientific and technological information and processes supporting their rulemaking. See also the discussion of the Information Quality Act in section VII of Statutes, above.
 2. Related Documents.
 - a. “Scientific Integrity.” See Presidential Memorandum of March 9, 2009, and Director of OSTP memorandum of December 17, 2010.
 - b. “Principles for Regulation and Oversight of Emerging Technologies.” See Director of OSTP, et al. memorandum of March 11, 2011.
 - c. “Implementation of Departmental Scientific Integrity Policy.” See DOT memorandum of April 10, 2012.
- F. Retrospective Analysis (sec. 6).
1. Retrospective Review. Agencies must consider how best to promote retrospective analysis of rules. They must have a plan to periodically review their existing significant regulations to make them more effective or less burdensome. See OIRA Administrator memorandum of June 14, 2011 (M-11-19), on “Final Plans for Retrospective Analysis of Existing Rules.”
 2. Related Documents.
 - a. Paperwork and Reporting. See OIRA Administrator memorandum of February 23, 2011, on “Minimizing Paperwork and Reporting Burdens;

Data Call for the 2011 Information Collection Budget.” This memorandum asks agencies to produce one or more burden reduction initiatives that will have significant progress in the next year with particular focus on relief for small businesses or recipients of Federal benefits. The memorandum offers a variety of approaches that could help.

b. State, Local, and Tribal Governments. See Presidential Memorandum of February 28, 2011, on “Administrative Flexibility, Lower Costs, and Better Results for State, Local, and Tribal Governments.” Agencies must work closely with State, local, and tribal governments to identify regulatory and other barriers in Federally funded programs that prevent efficient and effective use of the funds. By August 28, 2011, agencies are to identify requirements that can be streamlined, reduced, or eliminated.

G. OMB Guidance.

1. General. See OIRA Administrator memorandum of February 2, 2011 (M-11-10), on “Executive Order 13563, ‘Improving Regulation and Regulatory Review.’”
2. Executive Summaries. See OIRA Administrator memorandum of January 4, 2012, on “Clarifying Regulatory Requirements: Executive Summaries.”

III. Executive Order 13272: Proper Consideration of Small Entities in Agency Rulemaking (2002).

- A. SBA’s Office of Advocacy Review (sec. 3(b)). Agencies must notify the Office of the Chief Counsel for Advocacy (Advocacy) of the Small Business Administration (SBA) of draft rules that may have a significant economic impact on a substantial number of small entities when the draft rule is submitted to OIRA of the Office of Management and Budget (OMB) under E.O. 12866 or, if submission to OIRA is not required, at a reasonable time prior to publication of the rule. Advocacy is authorized to submit comments on the draft rule. DOT generally relies on OIRA to ensure that Advocacy is notified of draft rules that may have a significant economic impact on a substantial number of small entities.
- B. Consideration of Advocacy Comments (sec. 3(c)). Agencies must give every appropriate consideration to any Advocacy comments on a draft rule. If consistent with legal requirements, agencies must include in final rule preambles their response to any written Advocacy comments on the proposed rule, unless the agency head certifies that the public interest is not served by such action.
- C. Agency Procedures (sec. 3(a)). Agencies must issue procedures ensuring that the potential impact of their draft rules on small entities are properly considered.
- D. DOT Guidance. See the DOT website “Rulemaking Requirements Concerning Small Entities.”

IV. Executive Order 13132: Federalism (1999).

- A. Principles and Criteria (secs. 2, 3). This E.O. sets forth principles and criteria that agencies must adhere to in policymaking that has federalism implications. These include taking action only when a problem is of national significance and providing the maximum administrative discretion possible where States administer Federal statutes and regulations.
- B. Federalism Implications. The E.O. covers policies with federalism implications. As defined by section 1(a) of E.O. 13132, this means regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.
- C. Preemption (sec. 4).
1. Statutory Construction. Agencies shall construe statutes to preempt State law only where there is express preemption or clear evidence Congress intended preemption, or State action conflicts with Federal action. If the statute does not preempt, agencies shall construe it to authorize preemption only when State action directly conflicts with Federal action or there is clear evidence Congress intended to give authority.
 2. Minimum Necessary. Agencies must restrict regulatory preemption to the minimum necessary to achieve the statutory objectives.
 3. Consultation and Participation. Agencies must consult, to the extent practicable, with State and local officials when possible conflicts are identified and provide them opportunities for appropriate participation in rulemakings.
- D. Consultation (sec. 6).
1. Process. Agencies must have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.
 2. Federalism Official. Agencies must designate an official principally responsible for implementing the E.O.
 3. Compliance Costs and Preemption. To the extent practicable and permitted by law, agencies shall not issue rules with federalism implications that (1) impose substantial direct compliance costs on State and local governments, if not required by statute, unless they comply with a or b, below; or (2) preempt State law, unless they comply with b, below:

a. Funds Provided. The Federal government must provide money for the direct compliance costs of State and local governments.

b. Federalism Summary Impact Statement.

- (1) Consultation. Agencies must consult with State and local officials early in the process of developing the proposed regulation.
- (2) Preamble. In a separately identified portion of the rule's preamble, agencies must provide a federalism summary impact statement describing (a) the prior consultations with State and local officials, (b) the nature of the officials' concerns and the agencies' justification for the rule, and (c) the extent to which the concerns have been met.
- (3) Written Communications. Agencies must make State and local officials' written communications available to OMB.

E. Waivers (sec. 7). As appropriate, practicable, and permitted by law, agencies must streamline the processes for waivers of statutes and rules for State and local governments, consider increasing opportunities for using flexible policy approaches, and make decisions on waivers within 120 days.

F. OMB Review (sec. 8(a)). Agencies submitting to OMB under E.O. 12866 final rules with federalism implications must include a certification from their Federalism Official that this E.O.'s requirements were met in a meaningful and timely manner.

G. Preemption. See Presidential Memorandum of May 20, 2009, on "Preemption." Pursuant to this memorandum, agencies should:

1. Not include statements in regulatory preambles that they intend to preempt State law through regulation, unless such preemption is also included in the codified regulation.
2. Not include preemption provisions in codified regulations unless justified under legal principles governing preemption, including Executive Order 13132.

H. OMB Guidance. See OMB memorandum of October 28, 1999, on "Guidance for Implementing E.O. 13132."

I. DOT Guidance. See DOT Guidance on "Federalism" (1999).

V. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments (2000).

- A. Principles and Criteria (secs. 2 and 3). This E.O. sets forth principles and criteria that agencies must adhere to in policymaking that has tribal implications. These include respecting Indian tribal self-government and sovereignty, consulting with tribal officials on the need for Federal standards, and providing the maximum administrative discretion possible where Indian tribal governments administer Federal statutes and regulations.
- B. Tribal Implications. The E.O. covers policies with tribal implications. As defined by section 1(a) of E.O. 13175, this means “regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.”
- C. Consultation (sec. 5).
1. Process. Agencies must have an accountable process to ensure meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.
 2. Tribal Consultation and Coordination Official. Agencies must designate an official principally responsible for implementing the E.O.
 3. Compliance Costs and Preemption. To the extent practicable and permitted by law, agencies shall not issue rules with tribal implications that (1) impose substantial direct compliance costs on Indian tribal governments, if not required by statute, unless they comply with a or b, below, or (2) preempt tribal law, unless they comply with b, below:
 - a. Funds Provided. The Federal government must provide money for the direct compliance costs of the Indian tribal governments.
 - b. Tribal Summary Impact Statement.
 - (1) Consultation. Agencies must consult with tribal officials early in the process of developing the proposed regulation.
 - (2) Preamble. In a separately identified portion of the rule’s preamble, agencies must provide a tribal summary impact statement describing (a) the prior consultations with tribal officials, (b) the nature of the officials’ concerns and the agencies’ justification for the rule, and (c) the extent to which the concerns have been met.

- (3) Written Communications. Agencies must make tribal officials' written communications available to OMB.
4. Consensus Mechanisms. Agencies must use consensus mechanisms, including negotiated rulemaking, where appropriate, for developing regulations on issues relating to tribal self-government, tribal trust resources, or Indian tribal treaty and other rights.
- D. Waivers (sec. 6). As appropriate, practicable, and permitted by law, agencies must streamline the processes for waivers of statutes and rules for Indian tribes, consider increasing opportunities for using flexible policy approaches, and make decisions on waivers within 120 days.
- E. OMB Review (sec. 7(a)). Agencies submitting to OMB under E.O. 12866 final rules with tribal implications must include a certification from their Tribal Consultation and Coordination Official that this E.O.'s requirements were met in a meaningful and timely manner.
- F. Presidential Memoranda:
1. Government-to-Government Relations with Native American Tribal Governments. This memorandum of April 29, 1994, requires each agency to design solutions and tailor its programs, in appropriate circumstances, to address specific or unique needs of tribal communities and to remove procedural impediments to working directly and effectively with tribal governments.
 2. Tribal Consultation. This memorandum of November 5, 2009 requires each agency to submit to OMB a detailed plan to implement the policies and directives of E.O. 13175, after consultation with Indian tribes and tribal officials. Each agency must also submit to OMB annual progress reports and any updates to the plan.
- G. OMB Guidance. See OMB memorandum of January 11, 2001, on "Guidance for Implementing E.O. 13175, "Consultation and Coordination with Indian Tribal Governments"" and OIRA memorandum of July 30, 2010, on "Guidance for Implementing E.O. 13175, "Consultation and Coordination with Indian Tribal Governments."
- H. DOT Plan. See DOT Tribal Consultation Plan (February 3, 2010).
- I. Alaska Native Corporations. Pursuant to Pub. L. No. 108-199, as amended by Pub. L. No. 108-447, agencies are required to "consult with Alaska Native corporations on the same basis as Indian tribes under" E.O. 13175.

VI. Executive Order 12988: Civil Justice Reform (1996).

- A. Regulatory Requirements (sec. 3(a)). Within budgetary constraints and executive branch coordination requirements, agencies must review existing and new regulations to ensure they comply with specific requirements (*e.g.*, eliminate drafting errors and ambiguity and provide a clear legal standard for affected conduct rather than a general standard) to improve regulatory drafting to reduce needless litigation.
- B. Specific Issues for Review (sec. 3(b)(2)). In conducting the reviews, agencies must make every reasonable effort to ensure that the rule meets specific objectives (*e.g.*, specifies in clear language the preemptive or retroactive effect, if any).
- C. Determination of Compliance (sec. 3(c)). Agencies must determine either that the rule meets the applicable standards or that it is unreasonable to meet one or more of those standards. (Agencies are not required to submit a certification of compliance to OMB.)

VII. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (1994), amended by E.O. 12498, (1995) and E.O. 14008 (2021).

- A. Strategies (E.O. 12898, sec. 1-103). Each agency is required to develop a strategy that identifies and addresses disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low-income populations and identify, among other things, rules that should be revised to meet the objectives of the Order.
- B. Conduct (E.O. 12898, sec. 2-2). Each agency must ensure that its programs, policies, and activities that substantially affect human health or the environment do not exclude persons (including populations) from participating in or getting the benefits of, or subject them to discrimination under, such programs, policies, and activities.
- C. Documents and Hearings (E.O. 12898, sec. 5-5(c)). An agency's public documents, notices, and hearings relating to human health and the environment must be concise, understandable, and readily accessible.
- D. Presidential Memorandum. See Presidential Memorandum of February 11, 1994, on "Environmental Justice" underscoring certain provisions of existing law that can help ensure communities have a safe and healthful environment.
- E. DOT Environmental Justice Strategy (2016). This document contains the Department's commitment to certain principles of environmental justice and identifies the actions the Department will take to implement the E.O.
- F. DOT Updated Environmental Justice Order 5610.2(a). 77 FR 27534 (May 10, 2012). This order sets forth the process that DOT and its operating administrations will use to integrate the goals of the E.O. into their operations.

- G. MOU on Environmental Justice and E.O. 12898. This document is an interagency Memorandum of Understanding to implement E.O. 12898.

VIII. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks (1997), amended by E.O. 13229 (2001); E.O. 13296 (2003).

- A. Policy (E.O. 13045, sec. 1-101). With respect to its rules, to the extent permitted by law and appropriate, and consistent with the agency’s mission, each agency must address disproportionate risks to children that result from environmental health risks or safety risks.
- B. Analysis. For any substantive rulemaking action that is likely to result in an economically significant rule that concerns an environmental health risk or safety risk that an agency has reason to believe may disproportionately affect children, the agency must provide OMB/OIRA:
1. Evaluation: an evaluation of the environmental health or safety effects [attributable to products or substances that the child is likely to come in contact with or ingest] of the planned regulation on children” (E.O. 13045, sec. 5-501(a)).
 2. Alternatives: “an explanation of why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the agency” (E.O. 13045, sec. 5-501(b)).

IX. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use (2001).

- A. Statement of Energy Effects (sec. 2(a)). Agencies are required to prepare and submit to OMB a Statement of Energy Effects for significant energy actions, to the extent permitted by law.
- B. Contents of Statement (sec. 2(b)). Agencies must provide a detailed statement of any adverse effects on energy supply, distribution, or use (including a shortfall in supply, price increases, and increased use of foreign supplies) for the action and reasonable alternatives and their effects.
- C. Publication (sec. 3(b)). Agencies must publish the Statement or a summary in the related NPRM and final rule.
- D. Significant Energy Action (sec. 4(b)). A “significant energy action” is one that is significant under E.O. 12866 and is likely to have a significant adverse energy effect, or is designated by OMB.

- E. OMB Guidance. See OMB memorandum of July 13, 2001, on “Guidance for Implementing E.O. 13211.”

X. Other Executive Orders.

There are other executive orders that may impose procedural and substantive requirements on DOT rulemakings. Please consult with the Office of Regulation to determine if any other Executive Orders apply to a particular rulemaking.

- A. Executive Order 12889: Implementation of the North American Free Trade Agreement (1993). Requires 75-day comment period for proposed Federal technical regulations or sanitary or phytosanitary measure of general application unless technical regulation addresses urgent need related to safety, health, the environment, or consumers; regulation addresses urgent need regarding sanitary or phytosanitary protection; regulation implementing NAFTA Implementation Act; or regulation relating to perishable goods.
- B. Executive Order 12630: Governmental Actions and Interference with Constitutionally Protected Property Rights (1988). Establishes criteria that must be met in order to implement a policy that implicates takings concerns, including conducting a risk assessment, establishing that the action substantially advances safety (“mere assertion” of safety purposes is insufficient) and that its restrictions are not disproportionate to the risk, and estimating the cost to the government if a taking is found.

PRESIDENTIAL DIRECTIVES AND RELATED ACTIONS

I. Plain Language

- A. Presidential Directive (June 1, 1998). Agencies must use plain language in proposed and final rulemaking and other documents. To the extent agencies have the opportunity and resources, they should consider rewriting existing rules in plain language.
- B. Guidance to Accompany the Presidential Directive (July 1998). This document directed Agencies to designate a senior official responsible for implementing plain language and prepare a plain language action plan. It also provided guidance on writing in plain language.
- C. DOT Guidance. See the DOT website “[Plain Language](#)” circulated with Secretarial memorandum on “Plain Language” dated April 5, 1999.
- D. Plain Writing Act (2010). This statute, which is intended to promote clear government communication, does not apply to regulations. However, E.O.s [12866](#), [13563](#), and [12988](#) do impose requirements for plain language. The statute does cover documents that explain to the public how to comply with a requirement that the Federal Government administers or enforces. See [Administrator of OIRA memorandum of April 13, 2011 \(M-11-15\)](#), on “Final Guidance on Implementing the Plain Writing Act of 2010.” The memorandum notes that guidance and rulemaking preambles are covered by the Act.

II. Transparency and Open Government

- A. Presidential Memorandum (January 21, 2009). This memorandum requires agencies to harness new technologies to put information online, offer Americans increased opportunities to participate in policymaking, and use innovative tools, methods, and systems to cooperate with other government agencies and the public. It also requires agencies to solicit public feedback on how they can improve in these areas.
- B. Disclosure and Simplification. See OMB Director memorandum of December 8, 2009, on “Open Government Directive” and OIRA Administrator memorandum of June 18, 2010, on “Disclosure and Simplification as Regulatory Tools.” The latter memorandum provides principles designed to assist agencies in their efforts to issue information disclosure to achieve their regulatory objectives.
- C. RINs. See OIRA Administrator memorandum of April 7, 2010, on “Increasing Openness in the Rulemaking Process – Use of Regulation Identifier Number (RIN).” To help the public more easily find documents related to a rulemaking in its various stages, agencies should use RINs on all relevant documents throughout the lifecycle of a rulemaking. This includes NPRMs, final rules, and (to the extent they are associated with a rulemaking), notices, guidance, environmental impact statements, regulatory impact analyses, information collections, and supporting materials, as well as the metadata/text in the *Federal Register* and Regulations.gov.

- D. Electronic Dockets. See OIRA Administrator memorandum of May 28, 2010, on “Increasing Openness in the Rulemaking Process – Improving Electronic Dockets.”
1. Comprehensive Dockets. Agencies must compile and maintain comprehensive electronic regulatory dockets that include supporting materials, such as notices, significant guidance, environmental impact statements, regulatory impact analyses, and information collections, which should be available during the notice and comment process.
 2. Machine Readable. Documents in the docket should be in a format that enables full-text searches.
 3. Timely Postings. Public comments are expected to be posted to the docket in a timely manner.
 4. Compliance with Law. Agencies must ensure that they comply with all applicable laws and policies, including those on national security, information security, confidentiality, privacy, and intellectual property.
 5. Taxonomy. Agencies must use a common taxonomy for documents, sub-documents, and non-rulemaking document types.
- E. Regulatory Compliance. A Presidential Memorandum of January 11, 2011, on “Regulatory Compliance” requires greater disclosure of agency regulatory compliance information.
1. Accessible, Downloadable, and Searchable Information. Agencies with broad regulatory compliance and administrative enforcement responsibilities must make information about their regulatory compliance and enforcement activities easily accessible, downloadable, and searchable on-line.
 2. Cross-Agency Comparisons and Sharing of Information. The Federal Chief Information Officer and the Chief Technology Officer must make compliance/enforcement information available in ways that facilitate cross-agency comparisons and share such information across the government, to promote flexibility and coordinated enforcement.
- F. Social Media, Web-Based Interactive Technologies, and the Paperwork Reduction Act. See OIRA Administrator memorandum of April 7, 2010, on this subject. It clarifies the application of the Paperwork Reduction Act to agency use of social media and web-based interactive technologies. Although certain uses of these tools are excluded from coverage under the Act, agencies need to carefully review the constraints discussed in this memorandum.

- G. Export and Trade Promotion, Public Participation, and Rulemaking. See OIRA Administrator/Deputy United States Trade Representative memorandum of May 19, 2011 (M-11-23), on this subject. It highlights the importance of regulatory transparency and openness in promoting international trade and describes existing agency obligations that can help reduce trade barriers.

III. Flexibility and Job Creation

- A. Presidential Memorandum of January 18, 2011, on “Regulatory Flexibility, Small Business, and Job Creation.” This memorandum directs agencies, “when initiating rulemaking that will have a significant economic impact on a substantial number of small entities, to give serious consideration to whether and how it is appropriate, consistent with law and regulatory objectives, to reduce regulatory burdens on small businesses, through increased flexibility.”
- B. Possible Forms of Flexibility.
1. Extended compliance dates.
 2. Performance standards.
 3. Simplification of reporting and compliance.
 4. Different requirements for small businesses.
 5. Partial or total exemptions.
- C. Justification. When not providing such flexibility for other than legal limitations, an agency should explicitly justify its decisions in the proposed or final rule.

OMB BULLETINS AND OTHER DIRECTIVES

I. OMB Circular No. A-4, “Regulatory Analysis” (2003).

- A. General. This circular provides guidance on the development of regulatory analyses and on the regulatory accounting statements for each major final rule required under the Regulatory Right-to-Know Act.
- B. Benefit-Cost Analysis (BCA) and Cost-Effectiveness Analysis (CEA).
1. Major Health and Safety Rulemakings. A BCA and CEA are necessary.
 2. Other Major Rulemakings. A BCA is necessary; a CEA should also be provided, if some primary benefits cannot be monetized.
 3. Qualitative Discussion. If quantification cannot be produced, qualitative discussion should be presented.
- C. Discount rate. Agencies should use a discount rate of 7 percent as a base case under OMB Circular A-94 but should provide estimates of net benefits using both 3 percent and 7 percent.
- D. Uncertainties. Agencies should provide a formal quantitative analysis of the relevant uncertainties about benefits and costs for rules involving annual effects of \$1 billion or more, using appropriate statistical techniques to determine a probability distribution of relevant outcomes.
- E. Sensitivity Analysis. Agencies should examine how results vary with plausible changes in assumptions, data, and alternative analytical approaches.
- F. OMB Guidance.
1. Checklist. See “Agency Checklist: Regulatory Impact Analysis.” It provides a checklist for compliance with E.O. 12866 and OMB Circular A-4.
 2. Frequently Asked Questions. See “Regulatory Impact Analysis: Frequently Asked Questions (FAQs).”
 3. International Effects. See OIRA Administrator/Deputy United States Trade Representative memorandum of May 19, 2011 (M-11-23), on “Export and Trade Promotion, Public Participation, and Rulemaking.”
- G. Modernizing Regulatory Review.
1. On January 20, 2021, the President issued a memorandum for executive departments and agencies titled “[Modernizing Regulatory Review](#).” It directs the Director of OMB, in consultation with agencies, to produce a set of

recommendations for improving and modernizing regulatory review. These recommendations should provide concrete suggestions on how the regulatory review process can promote public health and safety, economic growth, social welfare, racial justice, environmental stewardship, human dignity, equity, and the interests of future generations. The recommendations should also include proposals that would ensure that regulatory review serves as a tool to affirmatively promote regulations that advance these values. In addition, they should be informed by public engagement.

H. DOT Guidance.

1. Value of Statistical Life and Injuries. See “Departmental Guidance on Valuation of a Statistical Life in Economic Analysis.” This page provides the value for a statistical life (adjusted annually) and injuries that DOT uses in economic analyses of DOT rulemaking actions.
2. Value of Travel Time. See “Departmental Guidance for the Valuation of Travel Time in Economic Analysis” (1997) and “Revised Departmental Guidance-Valuation of Travel Time in Economic Analysis” (2016). These documents contain procedures and empirical estimates for calculating the value of time saved or lost by users of the transportation system.

II. Final Information Quality Bulletin for Peer Review (2004).

A. Review.

1. Influential Scientific Information. To the extent permitted by law, each agency must conduct a peer review of all influential scientific information that the agency intends to disseminate. This is information that could have a clear and substantial impact on important public policies or private sector decisions.
2. Highly Influential Scientific Information. Additional requirements apply to highly influential scientific information that could have an impact exceeding \$500 million in any year or is novel, controversial, or precedent-setting or has significant interagency interest.

B. Dissemination. “Dissemination” is an agency initiated or sponsored distribution of information to the public. Among other things, dissemination excludes information distributed for peer review in compliance with this Bulletin or shared confidentially with scientific colleagues, provided that the distributing agency includes an appropriate and clear disclaimer on the information.

C. Peer Review Mechanism.

1. Influential Scientific Information. The choice of the peer review mechanism for influential scientific information is based on the novelty and complexity of the

information, the importance of the information to the decision, the extent of prior peer review, and the expected benefits and costs of the review and transparency factors. The options range from the use of agency personnel who have not participated in the development of the product being reviewed to independent third parties.

2. Highly Influential Scientific Information. Additional requirements are imposed on the mechanism used for peer review of highly influential scientific information. Employees of DOT can be used only under exceptional circumstances, when approved by the Secretary or Deputy Secretary and when employed by a DOT agency different from the one disseminating the information. Whenever feasible and appropriate, the agency must provide an opportunity for public comment during the peer review, including a public meeting with the peer reviewers.

D. Timing.

1. General. Although the Bulletin does not require a peer review to be conducted at a specific time during the rulemaking process, it does state that “it is most useful to consult with peers early in the process of producing information.”
2. Critical Information. It also notes that, when the information “is a critical component of rule-making, it is important to obtain peer review before the agency announces its regulatory options.”
3. Public Participation. Agencies may decide that peer review should precede an opportunity for public comment, but there are situations where public participation in peer review is an important aspect of obtaining a high-quality product.

E. Reports and Agency Responses.

1. Influential Scientific Information. The peer reviewers must prepare a report, which must be posted on the agency’s website along with related materials, discussed in the preamble to any related rulemaking, and included in the administrative record.
2. Highly Influential Scientific Information. Additional requirements are imposed on the reports for this information and the agency must prepare a written response to the report explaining any agreements or disagreements, the actions the agency is undertaking in response, and the reason the agency believes those actions satisfy the key concerns in the report. The agency response must be posted on its website along with related material.

- F. Planning. Each agency must post on its website, and update at least every six months, an agenda of its peer review plans, setting out what will be reviewed and how, including opportunities for public participation.

G. Exemptions. The exemptions include the following:

1. Negotiations involving treaties where there is a need for secrecy or promptness.
2. Individual agency adjudication or permit proceedings “unless the peer review is practical and appropriate and ... the influential dissemination is scientifically or technically novel or likely to have precedent-setting influence on future adjudications and/or permit proceedings.”
3. Regulatory impact analyses or regulatory flexibility analyses subject to E.O. 12866, except for underlying data and analytical models used.
4. Information disseminated in connection with routine rules that materially alter entitlements, user fees, or loan programs, or the rights and obligations of recipients thereof.

III. **Agency Good Guidance Practices (OMB Bulletin 07-02; 2007).**

- A. General. This bulletin establishes requirements for the development, issuance, and use of significant guidance documents by agencies. See additional DOT requirements for issuing guidance that are set forth in DOT Order 2100.6A.
- B. Coverage. The bulletin applies to significant guidance documents (which includes the subset of economically significant guidance documents). The bulletin provides definitions as used in the bulletin:
 1. *Agency* means the Department level at DOT.
 2. *Guidance document* --
 - a. Means either a generally applicable interpretation of or a policy statement on, a statutory or regulatory issue or a policy statement on a technical issue.
 - b. To be covered, it must be prepared by the agency and distributed to the public or regulated entities.
 - c. If it responds to an individual person or entity, it is not covered unless it is intended to have a precedential effect (*e.g.*, if it is posted on the internet).
 - d. The definition is not limited to written materials.
 3. *Significant* and *economically significant guidance document* have essentially the same meaning as legislative rules under E.O. 12866, except that a legislative rule

is one that is likely to result in a rule that may have the effect described, whereas guidance may reasonably be anticipated to have that effect.

- C. Approval Procedures. Each agency must have written procedures for the approval by appropriate senior agency officials of significant guidance documents.
- D. Standard Elements. Agencies must provide specified, standard elements in each significant guidance document.
- E. Public Access for Significant Guidance Documents.
 - 1. Access. Each agency must have a website providing the public with specified information about significant guidance documents.
 - 2. Feedback.
 - a. Comments and Requests. Each agency must provide a process for the public to submit electronic comments on – and electronic requests for issuance, reconsideration, modification, or rescission of – significant guidance documents. Agencies are not required to respond to the comments.
 - b. Complaints. Each agency must designate an office(s) to receive and address public complaints that it is not complying with the OMB Bulletin or is improperly treating a significant guidance bulletin as a binding requirement.
- F. Notice and Public Comment for Economically Significant Guidance Documents.
 - 1. Public Comment on Draft. For economically significant guidance documents, each agency must invite public comment on a draft before issuing the guidance. The agency must respond to the public comments.
 - 2. Exemptions. In consultation with OIRA, the agency head may identify particular documents or categories for which these requirements are not feasible or appropriate.
- G. Emergencies. For emergencies or legal deadlines that would not allow normal review procedures, each agency must notify OIRA as soon as possible and comply with the bulletin to the extent practicable.

IV. Updated Principles for Risk Analysis (M-07-24; 2007).

- A. General. This memorandum is intended to reinforce generally-accepted principles for risk analysis upon which a wide consensus now exists, to assist and guide agencies.

This memorandum builds upon OIRA Administrator memorandum of January 12, 1995, on “Principles for Risk Analysis.”

- B. General Principles. Risk analysis is a tool that must adapt to scientific advances and be consistent with statutes and administration priorities. Agencies must consider risks to the extent reasonable and should distinguish between the risk assessment and risk management (which may change behavior in ways that alter risks). The depth of the analysis should be commensurate with the nature and significance of the decision.
- C. Principles for Risk Assessment. Agencies should use the best reasonably attainable scientific information; characterizations of risks should be qualitative and quantitative and broad enough to inform the range of policies to reduce risks; judgments should be explicit and their influence articulated; all appropriate hazards should be included, with attention given to subpopulations that may be particularly susceptible to such risks and/or may be more highly exposed; the use of peer review should be maximized; and agencies should use consistent approaches in evaluating risks.
- D. Principles for Risk Management. Agencies should analyze the distribution of risks and the costs and benefits of risk management strategies; and the alternative selected should provide the greatest net improvement in total societal welfare when accounting for a broad range of relevant social and economic considerations.
- E. Principles for Risk Communication. Agencies should have an open, two-way exchange between professionals (including policy makers and experts) and the public; goals should be clear, and risk assessments and risk management decisions communicated accurately and objectively in a meaningful manner; the basis for significant assumptions, data, models, and inferences should be explained; the sources, extent and magnitude of significant uncertainties should be described; appropriate risk comparisons should be made, considering such factors as public attitudes toward voluntary and involuntary risk; and the public should be provided timely public access to relevant supporting documents and a reasonable opportunity to comment.
- F. Principles for Priority Setting Using Risk Analysis. Agencies should compare risks and group them in categories of concern (*e.g.*, high, moderate, and low); set priorities for risk management to achieve the greatest net improvement in societal welfare first; inform priority-setting by consideration of views from a broad range of individuals, with consensus views being reflected where possible; and coordinate risk reduction efforts with other agencies, where feasible and appropriate.
- G. DOT Order. See DOT Order 1351.18 (2014), “Departmental Privacy Risk Management Policy,” for supplemental requirements.

DOT REGULATIONS, ORDERS, MEMORANDA, AND PROCEDURES

I. Rulemaking and Guidance Procedures, DOT Order 2100.6A (June 7, 2021).

A. Policies and Procedures for Rulemaking.

1. Coverage. This order applies to all generally applicable DOT rulemakings, but excludes those related to military or foreign affairs functions, agency management or personnel, and Federal procurement.
2. Policies. Section 8 of the order explains several policies governing DOT regulations. It states that the Department issues regulations for the primary purpose of ensuring the United States transportation system is the safest and most efficient in the world, while also addressing the urgent challenges facing the Nation including stimulating economic recovery and growth, remedying inequitable distribution of transportation benefits and impacts, mitigating environmental harms, reducing greenhouse gas emissions, and building a resilient transportation system..
3. Responsibilities. Section 6 of the order describes the responsibilities of individuals involved in the rulemaking process in the Office of the Secretary (OST) and operating administrations (OAs). The Secretary of Transportation supervises the overall planning, direction, and control of the Department's Regulatory Agenda. The General Counsel of DOT is the chief legal officer of the Department with final authority on all questions of law and serves as the Department's Regulatory Policy Officer pursuant to section 6(a)(2) of Executive Order 12866. DOT's Assistant General Counsel for Regulation supervises the Office of Regulation within the Office of the General Counsel (OGC), oversees the process for DOT rulemakings, and provides legal advice on compliance with all APA and other administrative law requirements.
4. Regulatory Leadership Group. Section 7 of the order describes the composition and functions of the Regulatory Leadership Group (RLG), which, among other things, provides substantive direction on individual regulations prior to publication of documents at each stage in the rulemaking proceeding to ensure all DOT regulations reflect senior departmental leaders' goals and priorities.
5. Initiating Office Responsibilities. Section 8 of the order requires that any operating administration or rulemaking component of the Office of the Secretary that seeks to develop a rulemaking must submit a Rulemaking Initiation Request to the Office of Regulation, with limited exceptions. The General Counsel will approve or deny Rulemaking Initiation Requests.
6. General Rulemaking Procedures. Section 10 of the order sets requirements for the process by which DOT rulemakings are developed and promulgated. The following are some of the most significant topics covered:
 - a. Departmental Review. The order requires all rulemakings that are significant under E.O. 12866 or otherwise of special note to the

Department to be reviewed and cleared by the Office of the Secretary, with certain exceptions.

- (1) Section 10(a)(2) of the order explains that a rulemaking “of special note to the Department” means a regulatory action, designated as such by the General Counsel, that may reasonably be anticipated to:
 - (A) relate to a major program, policy, or activity of the Department or a high-profile issue pending for decision before the Department;
 - (B) involve one of the Secretary’s top policy priorities;
 - (C) garner significant press or congressional attention; or
 - (D) raise significant questions or concerns from constituencies of importance to the Department, such as Committees of Congress, States or Indian tribes, the White House or other departments of the Executive Branch, courts, consumer or public interest groups, labor, cities and counties, or leading representatives of industry.
- (2) The exceptions from Office of the Secretary review and Secretarial approval are for:
 - (A) emergency FAA rules pursuant to sections 49 U.S.C. sections 106(f)(3)(B)(ii) and 46105(c); and
 - (B) rules that do not raise novel legal or policy issues and are:
 - (a) modifications to existing regulations consisting of amendments that are ministerial in character and not legally discretionary;
 - (b) technical or editorial corrections to rules or notices that do not materially affect the substance of the underlying rulemaking document;
 - (c) final rules that are limited to the adoption of statutory language, without interpretation; and

(d) final rules for which no substantive comments were received and which do not differ from a proposed rule that was not designated “of special note to the Department.”

- b. Review of Existing Regulations. The order describes and sets requirements for the process by which departmental regulations are reviewed on a 10-year cycle.
 - c. Supporting Economic Analysis. The order requires rulemakings to include assessments of potential costs and benefits. Further, the order provides guidance that economic analyses should quantify to the extent practicable the benefits, costs, and any significant distributional impacts in accordance with the requirements of section 6(a)(3)(B) and (C) of Executive Order 12866 and OMB Circular A-4. When equity or environmental metrics of interest have been identified, the economic analysis should characterize any equity or environmental impacts. If quantification is not possible, impacts should be described qualitatively.
7. ANPRMs and NPRMs. The order sets minimum requirements for the contents of ANPRMs and NPRMs.
 8. Final Rules. The order sets minimum requirements for the contents of final rules, such as a requirement that a final rule contain an explanation of any changes from the rule as proposed in the NPRM and a justification of why the changes were needed or appropriate.
 9. Exemptions from public comment. The order provides the circumstances in which final rules may be issued without notice and an opportunity to comment, consistent with the Administrative Procedure Act and other applicable law. It further provides that when a DOT operating administration (OA) or component of the Office of the Secretary issues an interim final rule, it should proceed at the earliest opportunity to replace the IFR with a final rule that responds to any comments received on the IFR.
 10. Public Comment. The order advises that absent special considerations, the comment period should be at least 30 days for nonsignificant rules and at least 60 days for significant rules.
 11. Negotiated Rulemakings. The order states that DOT encourages the use of negotiated rulemaking when appropriate, in order to promote consensus, enable DOT to receive data efficiently, simplify implementation, reduce the likelihood or scope of a litigation challenge, and result in a more effective or durable final rule. The order also sets forth procedures for the use of negotiated rulemaking, consistent with the Negotiated Rulemaking Act.
 12. Public Contacts.

a. In General. OAs and OST components are encouraged to conduct outreach and provide access equitably to stakeholder groups and provide robust opportunities for discussion early in, and throughout, the rulemaking process. OAs and OST components should ensure that outreach includes providing adequate opportunities for stakeholders who may not have access to extensive legal and lobbying support. Note that while informal communications between agency personnel and individuals outside of the Federal Executive branch have traditionally been an important and valuable aspect of rulemaking and other DOT actions, they also have the potential to create an inference of improper influence on DOT decision-making, raise questions of fairness and equity, and frustrate judicial review of DOT actions (based on the need for a complete record).

Procedures. DOT has developed guidelines for the conduct of these informal communications – commonly referred to as *ex parte* communications – that apply to all DOT employees, both policy officials and career staff. [Guidance on Ex Parte Communications | US Department of Transportation](#)

In summary:

(1) DOT's *ex parte* guidance applies from approval of a RIN request through publication of a final rule, and through disposition of any petition for reconsideration.

(2) DOT personnel may have meetings or other contacts with members of the public throughout the rulemaking process, and must ensure, through appropriate affirmative outreach where necessary, that the opportunity to engage in *ex parte* communications is equitable to all parties, including stakeholders who might otherwise be less represented in that process.

(3) DOT is in listening mode for any *ex parte* communication and may not discuss or negotiate concerning the substance of a rulemaking.

(4) The party requesting the *ex parte* communication should be asked to submit a memorandum memorializing the communication unless the OST Office or OA determines in advance that it should prepare the memorandum.

(5) This memorandum, as well as the substance of material information submitted by the public as part of an *ex parte* communication, must be included in the public rulemaking docket so that all interested parties have notice of and an opportunity to comment on the information.

B. Policies and Procedures for Guidance.

1. Definition. Section 12 of the order defines “guidance document” as a new, or amendment to an existing, statement of agency policy or interpretation concerning a statute, regulation, or technical matter within the jurisdiction of the agency that does not have the force or effect of law. Section 12 also includes a list of documents that are not subject to the order’s guidance procedures, which include rules, agency adjudication decisions, internal legal advice and legal interpretations, legal briefs and filings, positions taken during litigation or enforcement actions, and solicitations and awards of contracts or grants.
2. Review and Clearance. Section 13 of the order sets requirements for internal review and clearance of guidance.
3. Requirements. Section 14 of the order specifies several requirements that a guidance document must meet. For example, the document must contain the term “guidance” or its functional equivalent; it must avoid using mandatory language such as “shall” or “require” unless it is describing an established requirement; and it must state clearly that the contents of the document do not have the force of law and do not bind the public in any way.
4. Public Access. Section 15 of the order requires each OA and OST component responsible for issuing guidance documents ensure that such documents are accessible to the public in electronic form on its web site.
5. Guidance Documents that are of special note to the Department.
 - a. Definition. Section 16 of the order specifies that a guidance document is of special note to the Department if it can be reasonably expected to:
 - (1) relate to a major program, policy, or activity of the Department or a high-profile issue pending for decision before the Department;
 - (2) involve one of the Secretary’s top policy priorities;
 - (3) garner significant press or congressional attention; or
 - (4) raise significant questions or concerns from constituencies of importance to the Department, such as Committees of Congress, States or Indian tribes, the White House or other departments of the Executive Branch, courts, consumer or public interest groups, labor organizations, cities and counties, or leading representatives of industry
 - b. Requirements. Section 17 explains that if there is a reasonable likelihood the guidance document may be considered “of special note to the Department” or if the OA or OST component is uncertain whether the

guidance document may qualify as such, the OA or OST component should email a copy of the proposed guidance document (or a summary of it) to the Office of Regulation for review and further direction. If a guidance document is determined to be of special note to the Department, it must be approved by the Secretary before issuance. Further, the Office of Regulation (in coordination with the OA or OST component) that it is appropriate to coordinate with OMB.

II. Other Agency Rulemaking Provisions.

Some of the DOT operating administrations and OST have published regulations setting forth their specific procedures for implementing the APA. For example, they may provide an address for filing petitions for rulemaking and indicate how long the agency generally takes to review such petitions, or they may indicate that late-filed comments may be considered if they do not delay the issuance of a final rule.

III. Dockets.

- A. **Documents.** DOT agencies place each rulemaking and supporting document (*e.g.*, proposed and final rule, economic or environmental analyses and information collection materials) and all public comments received, including late-filed comments and any other relevant information received, in a public docket located at Regulations.gov. They may also place other documents (*e.g.*, technical studies) in the docket. Generally, they do not place internal correspondence with other executive branch agencies in the docket, but they do place information in the docket noting any changes made to draft rulemaking documents during interagency review under E.O. 12866.

IV. Related Requirements. E-Government Act (Pub. L. No. 107-347 (2002)) and Privacy Act (5 U.S.C. § 552a).

V. OIRA Memorandum, “Increasing Openness in the Rulemaking Process – Improving Electronic Dockets.”