



Good Regulatory Practices in the United States

Office of Information and Regulatory Affairs
U.S. Office of Management and Budget

Agenda

- ❑ Legal Framework for Rulemaking in the U.S.
- ❑ Interagency Coordination of Rulemaking
 - ❑ OMB and the Office of Information and Regulatory Affairs
 - ❑ Executive Orders 12866 and 13563
- ❑ Regulatory Impact Analysis
 - ❑ OMB Circular A-4
- ❑ Regulatory Transparency and Participation
 - ❑ Administrative Procedure Act of 1946

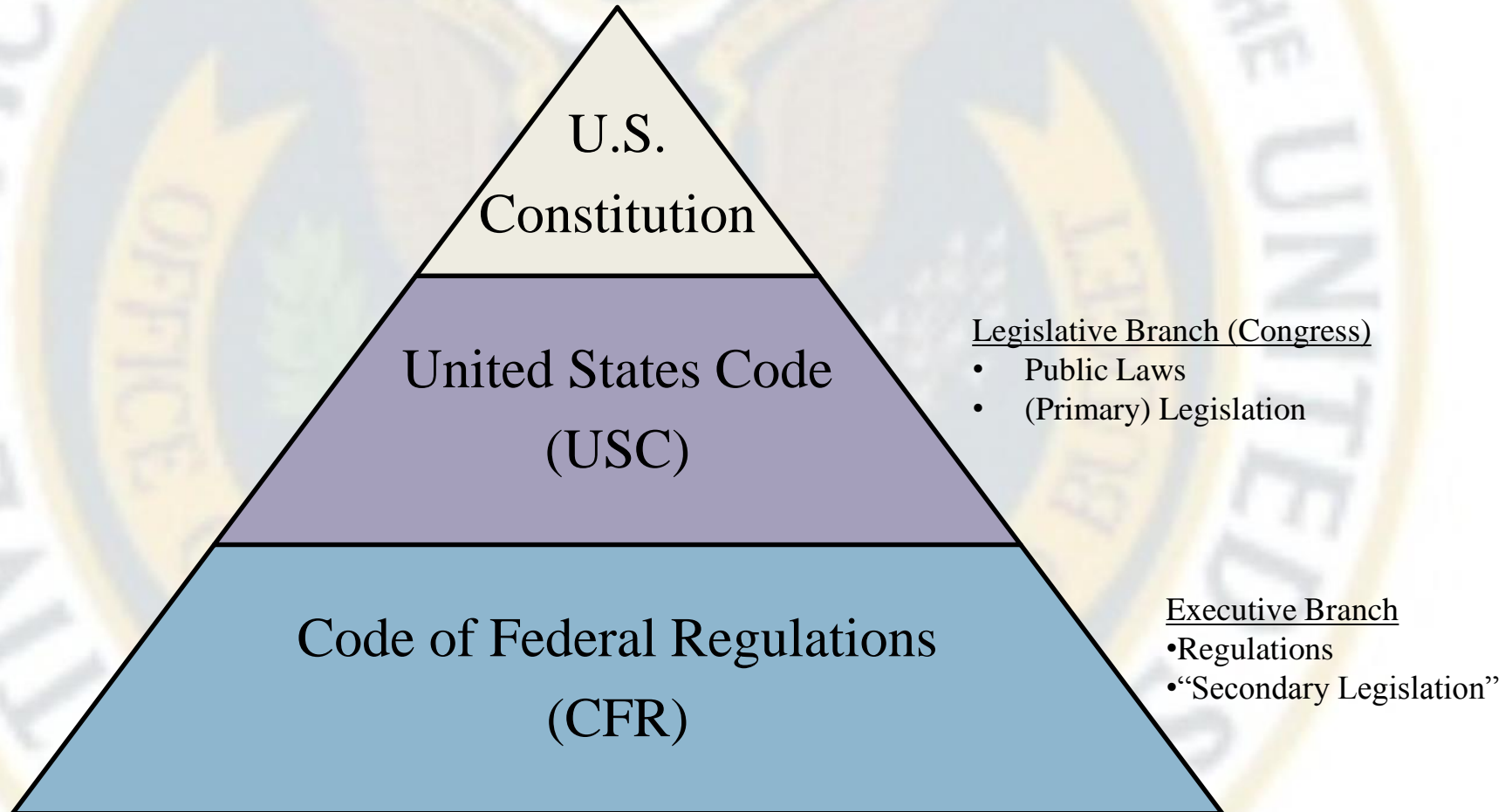
On Regulation

Supreme Court Justice Felix Frankfurter explained regulatory action this way:

- Hardly a measure passes Congress the effective execution of which is not conditioned upon rules and regulations emanating from the enforcing authorities. These administrative complements are euphemistically called “filling in the details” of a policy set forth in statutes. But the “details” are of the essence; they give meaning and content to vague contours.¹

¹Frankfurter, Felix. *The Task of Administrative Law*, 75 U. Pa. L. Rev. 614 (1927)

Legal Framework for Rulemaking in the United States



Regulations in the U.S.

- ❑ The Executive Branch can make law.
 - ❑ Congress delegates authority to Executive Branch agencies to implement statutes through rulemaking.
 - ❑ Some statutes are so broad that agencies can make new programs without new statutes.
- ❑ Many important public policy decisions are made during rulemaking.
 - ❑ Regulatory enforcement and allocation of resources.
 - ❑ Grants, loans, and loan guarantees.
 - ❑ Rights and responsibilities of the 50 States and the public.

U.S. Rulemaking Process

Legislative Branch

Executive Branch

Judicial Branch

www.Congress.gov

1. Congress passes law authorizing or requiring regulation.

www.RegInfo.gov

2. Agency drafts a proposed regulation.

3. If "significant," OMB reviews draft proposed regulation.

4. Agency publishes notice of proposed rulemaking (NPRM).

www.Regulations.gov

5. Public reviews NPRM/docket and submits comments to agency.

6. Agency reviews public comments drafts a final regulation.

7. If "significant," OMB reviews and draft final regulation.

www.FederalRegister.gov
www.Regulations.gov

8. Agency publishes final regulation.

9. Regulation takes effect.

www.RegInfo.gov
www.Regulations.gov

Unified Agenda & Regulatory Plans

www.FederalRegister.gov
www.Regulations.gov

www.RegInfo.gov

Congress reviews regulation.

Disapproval resolution passed.

Regulation takes effect.

Regulation challenged in court.

Court "vacates" all or part of rule.

Office of Management and Budget (OMB)

- ❑ OMB assists the President in the development and implementation of budget, program, management, and regulatory polices.
 - ❑ Develops the President's annual budget submission to Congress.
 - ❑ Assists the President in managing the Executive Branch, developing the Administration's position on legislation before Congress and executing the law.
 - ❑ Provides high quality regulatory analysis.
- ❑ History
 - ❑ 1921: Bureau of the Budget (BoB) established within the Treasury Department.
 - ❑ 1939: BoB moved from Treasury to the Executive Office of the President.
 - ❑ 1970: BoB reorganized into the Office of Management and Budget.

Interagency Coordination of Rulemaking: Office of Information and Regulatory Affairs

- ❑ Role of the Office of Information and Regulatory Affairs
 - ❑ OIRA was established by the Paperwork Reduction Act of 1980, partially in response to the explosion in regulation that occurred in the 1970s and earlier in the U.S.
 - ❑ As part of the Office of Management and Budget, OIRA is a central body that has special standing with the agencies.
 - ❑ OIRA is the lead division of OMB for regulatory oversight and interagency review of “significant” regulations.
 - ❑ OIRA also develops and oversees government-wide policies in the areas of information collection, information policy, privacy, and statistical and science policy.

Office of Information and Regulatory Affairs



Interagency Coordination of Rulemaking: Presidential Oversight

- ❑ President Ford: Required, for the first time, regulatory impact analysis (RIA) requirement for major regulations (over \$100 million in impact).
- ❑ President Carter: Established the Regulatory Analysis Review Group.
- ❑ President Reagan: Solidified regulatory oversight authority within the White House, issuing Executive Order 12291, which required OMB review and approval of rules.
- ❑ President George H.W. Bush: Continued the Reagan Executive Order.
- ❑ President Clinton: Issued Executive Order 12866, which focused OMB oversight on “significant” rules and increased the disclosure of contacts with outside parties.
- ❑ President George W. Bush: Maintained the Clinton Executive Order that requires the agencies to do RIAs and send significant regulations to OMB for review.
- ❑ President Obama: Issued Executive Order 13563, which affirms EO 12866 and outlines his regulatory strategy to support continued economic growth and job creation.

Executive Order 12866: “Regulatory Planning and Review”

- ❑ Issued by President Clinton in October 1993.
 - ❑ Governs OIRA’s centralized, interagency review of draft regulations.
- ❑ Establishes principles of regulation.
 - ❑ Regulation must be consistent with law.
 - ❑ Regulations must identify nature and significance of problem.
 - ❑ Alternatives to address the problem must be identified and assessed.
 - ❑ The costs and benefits of each alternative must be assessed.
 - ❑ The alternative selected should maximize net benefits to society.
- ❑ These principles guide OIRA’s review of regulations.

What regulations must OIRA review?

❑ “Significant” Rules

- ❑ Create a serious inconsistency or otherwise interfere with another agency’s actions.
- ❑ Materially alter the budgetary impact of Federal programs.
- ❑ Raise novel legal or policy issues.
- ❑ OIRA reviews 500-700 proposed and final regulations per year—those we determine to be significant—out of about 6,500 that are published in the *Federal Register*.

❑ “Economically Significant” Rules

- ❑ Subset of “significant” rules.
- ❑ 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.
- ❑ About 70-100 of the regulations reviewed are “economically significant.”

EO 12866: Important Requirements and Scope

- ❑ EO 12866 has deadlines for OIRA review (usually 90 days).
- ❑ EO 12866 requires economic analysis.
 - ❑ Economically significant regulations require more analysis than smaller rules.
 - ❑ OIRA examines the RIA and the regulation and makes suggestions to improve both the RIA and the rule's cost-effectiveness, ensure adherence to the Executive Order's principles, and consistency with the President's priorities.
- ❑ Independent Regulatory Agencies are not covered.
 - ❑ For example, Consumer Product Safety Commission, Federal Communications Commission, and the financial regulators.

Possible Actions at the End of OIRA Review

- ❑ Allow the agency to issue the rule.
 - ❑ A rule is usually sent directly to the *Federal Register* at the conclusion of review.
- ❑ Agency withdrawal of the rule.
 - ❑ If we are unable to resolve issues during the review process, or the agency needs more time to make changes, the agency can withdraw the rule.
- ❑ “Return Letter”
 - ❑ OIRA may return a regulation for agency reconsideration to address OIRA concerns.
 - ❑ Very public and very rare.

Executive Order 13563: “Improving Regulation and Regulatory Review”

- ❑ Issued by President Obama in January 2011.
 - ❑ Reaffirms the principles, processes, and structures of EO 12866.
 - ❑ Calls for public participation to promote an open exchange with stakeholders.
 - ❑ Directs agencies to harmonize, simplify, and coordinate rules to reduce costs and to promote simplicity.
 - ❑ Considers flexible approaches that reduce burdens and maintain freedom of choice for the public (e.g., public warnings or provisional information).
 - ❑ Calls for scientific integrity.
 - ❑ Directs agencies to conduct retrospective analysis of existing rules and produce preliminary plans for periodic review.

Regulatory Impact Analysis (RIA)

❑ Basic Goals

- ❑ Maximize net benefits to society—or at least ensure that benefits justify costs.
- ❑ Promote economic efficiency by regulating only where markets fail, and when regulating, by using cost-effective and market-based approaches.
- ❑ Increase the transparency of the regulatory system.

❑ RIA assesses the anticipated consequences a regulation and estimates associated benefits and costs.

- ❑ Helps to organize and consolidate all the possible impacts and elements for decisions at various stages of policy development.
- ❑ Provides clear and transparent methodologies and criteria for new or existing regulations.

What is RIA?

- ❑ Elements of a Regulatory Impact Analysis
 - ❑ Statement of need for the proposed rule that identifies the nature and significance of the problem (e.g., identification of the market failure).
 - ❑ Examination of alternative approaches to addressing the problem.
 - ❑ Analysis of the costs and benefits of each alternative.
- ❑ RIA is a flexible and adaptable tool that should always:
 - ❑ Be proportional to the situation.
 - ❑ Follow consistent guidance for complexity and level of analysis.
- ❑ OMB Circular A-4: Guidelines for the Conduct of Regulatory Analysis (September 2003)

Why Does Regulatory Analysis Matter?

- ❑ Good analysis helps provide a reasonable basis for rulemaking.
 - ❑ Evidence- and science-based decision making.
- ❑ Good analysis is critical to inform stakeholders:
 - ❑ Decision-makers
 - ❑ Interested/Affected Parties (regulated entities and stakeholders)
 - ❑ Congress
 - ❑ The Public

Regulatory Transparency and Participation

❑ Administrative Procedure Act of 1946 (APA)

- ❑ The APA requires that agencies go through a notice and comment process open to all members of the affected public, both U.S. and foreign.
- ❑ Before agencies can issue a final regulation, they must respond to the public comments, make sure that the final regulation is a logical out-growth of the proposal and the administrative record, and is not arbitrary or capricious.

❑ *Federal Register*

- ❑ The official daily publication for rules, proposed rules, and notices of Federal agencies and organizations
- ❑ Executive orders and other presidential documents are also published in the *Federal Register*.

Regulatory Transparency and Participation: Notice of Proposed Rulemaking (NPRM)

Preamble

- Legal authority for the regulation.
- A summary of the provisions in the regulatory proposal.
- A description of alternatives to the agency's proposal.
- Solicitation for public comments on the issues raised.
- Various legal and analytical assessments.

Regulatory Text

- Draft text that the agency proposes be codified in the Code of Federal Regulations (i.e., law).

Regulatory Transparency and Participation: Public Comments

- ❑ The APA requires agencies to provide an opportunity for the public to submit “written data, views or arguments.”
- ❑ The APA does not require a minimum comment period.
 - ❑ Executive Orders 12866 and 13563 direct agencies to provide at least 60 days for public comment.
 - ❑ Agencies often provide 30 days.
 - ❑ Agencies will provide longer comment periods when stakeholders may need more time to understand and analyze a complex regulatory proposal.
- ❑ APA Good Cause Exemption
 - ❑ The agency may find “good cause” that notice and comment would “impracticable, unnecessary, or contrary to the public interest.”
 - ❑ The agency must explain its rationale for finding good cause in the preamble to the interim final rule.

Regulatory Transparency and Participation: Final Rule

Preamble

- Discussion of changes from the NPRM and why they were made.
- Responses to public comments on the NPRM.
- A description of alternatives to the agency's proposal.
- Various legal and analytical assessments.

Regulatory Text

- The text that will be codified in the Code of Federal Regulations (i.e., law).

Effective Date

- The APA requires at least 30 days from publication
- There are exceptions (including “good cause”).

Regulatory Transparency and Participation: The “Administrative Record”

- ❑ All and only the information that
 - ❑ the agency relied on to develop the regulation; and
 - ❑ the courts can rely on during judicial review.
- ❑ Contents
 - ❑ The proposed and final regulations.
 - ❑ Supporting information, data, and research, including RIAs.
 - ❑ All public comments and notes of public hearings and meetings with outside parties.

Regulatory Transparency and Public Participation: Regulations.gov

The screenshot displays the Regulations.gov website. At the top, the logo "regulations.gov" is accompanied by the tagline "Your Voice in Federal Decision-Making". Navigation links for Home, Help, Resources, and Feedback and Questions are visible. A search bar and buttons for Browse and Learn are also present.

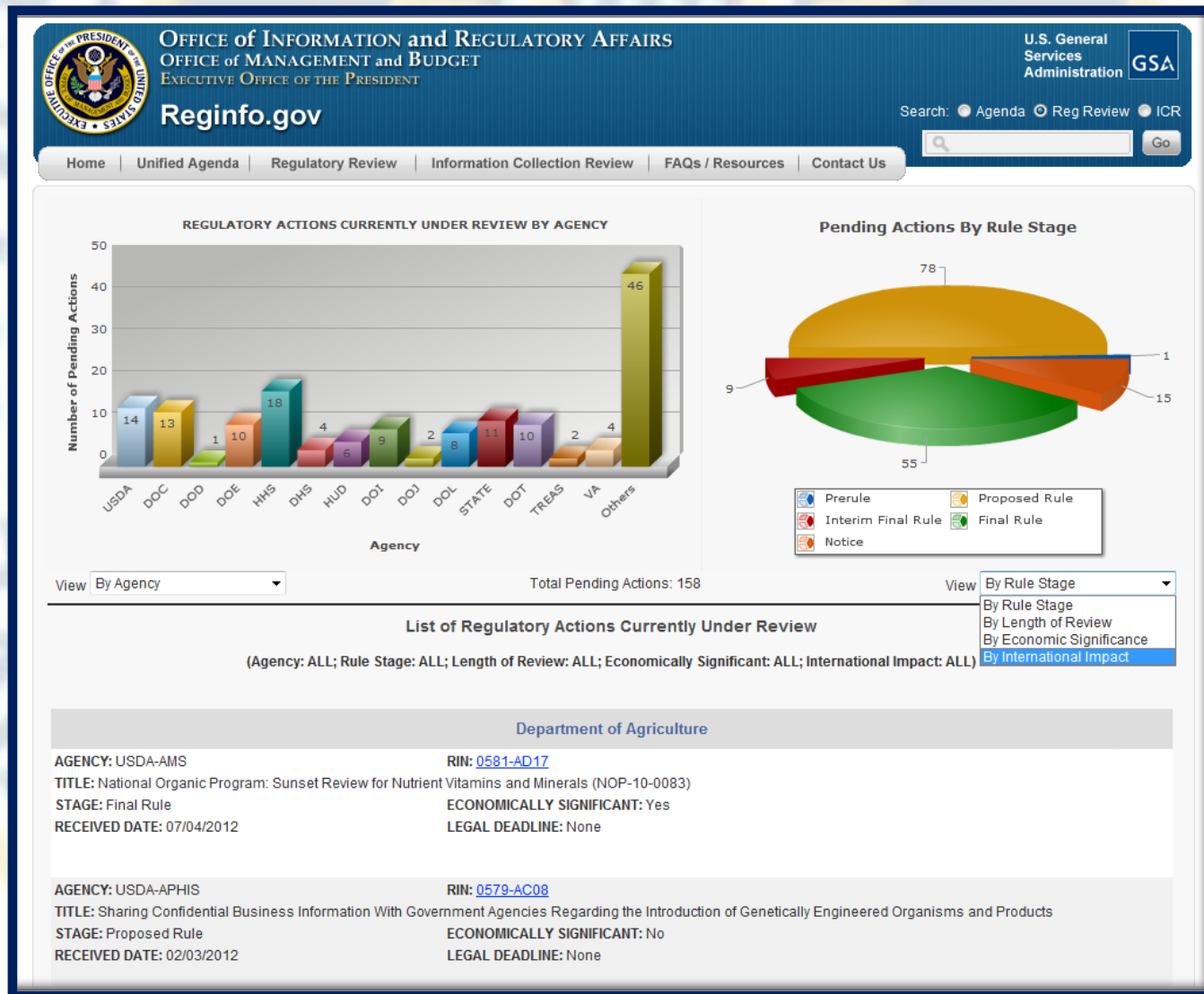
The main content area is divided into several sections:

- Participate Today!**: Encourages users to submit comments on proposed regulations and provides instructions on how to use the site.
- SEARCH for: Rules, Comments, Adjudications or Supporting Documents:**: A search bar with a "Search" button and a link to "Advanced Search".
- What's Trending**: A list of trending regulations with their closing dates, such as "Medicare Programs: Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule and..." closing on Sep 06, 2013.
- Comments Due Soon**: A list of regulations with their comment counts and due dates, such as "Today (33)", "Next 3 Days (71)", "Next 7 Days (246)", "Next 15 Days (463)", "Next 30 Days (842)", and "Next 90 Days (1,238)".
- Newly Posted**: A list of newly posted regulations with their counts and dates, such as "Today (84)", "Last 3 Days (307)", "Last 7 Days (552)", "Last 15 Days (1,142)", "Last 30 Days (2,193)", and "Last 90 Days (6,440)".
- Are you new to the site?**: A section with links to help new users get started, including "What can I find on this site?", "How do I find a rule?", "How do I submit a comment?", "How do I find my comment?", and "Do my comments make a difference?".
- Newly Redesigned Comment**: A section featuring an image of a laptop displaying the comment form and the text "Comment on a regulation today with the new form!".
- Site Enhancements**: A list of site updates, including "Unified Agenda Spring 2013", "Developers", "A Commenter's Checklist", and "President's Executive Order".

The footer contains navigation links for Home, About Us, Resources, Help, and Connect With. The "Connect With" section includes social media icons for RSS, Facebook, Twitter, and YouTube, along with a "Feedback and Questions" button and links for Privacy Notice, User Notice, and Accessibility Statement.

At the bottom, there are "Partner Sites" links (We the People, Federal Register, Reginfo, Thomas, USA.gov, E-Gov, Opengov) and a "Participate Today!" button.

Regulatory Transparency and Public Participation: Regulatory Review Dashboard



Regulatory Transparency and Participation: Disclosure of Information Under EO 12866

❑ Unified Agenda and Regulatory Plan

- ❑ The Unified Agenda of Regulatory and Deregulatory Actions is the semi-annual publication about agencies' upcoming regulatory actions.
- ❑ The annual Regulatory Plan explains the regulatory priorities of agencies.
- ❑ Both are available on the Regulations.gov and RegInfo.gov.

❑ Communications with Outside Parties

- ❑ Meetings with outside parties – OIRA and the issuing agency will meet with external stakeholders regarding rules under review. OMB's website notes which outside groups have met with OIRA, including the participants, and docket written materials provided to OIRA during the meeting.
- ❑ All written information given to us while a rule is under review is sent to the agency, placed in OIRA's docket, and posted online.

Conclusions

- ❑ A firm and enduring commitment to good regulatory practices from the center of government is a necessary condition for a successful regulatory program.
- ❑ An effective regulatory program should ensure that economic analysis is conducted to promote economic efficiency and inform policy decisions and public stakeholders.
- ❑ Regulatory transparency, public participation in rulemaking, and accountability are required to address concerns about undue influence by special interests, allow all interested parties to be heard, and maintain political support for regulatory reform.

References

❑ Internal Coordination of Rulemaking

- ❑ Office of Information and Regulatory Affairs: http://www.whitehouse.gov/omb/infoREG_default
- ❑ Executive Order 12866: <http://www.whitehouse.gov/OMB/infoREG/eo12866.pdf>
- ❑ Executive Order 13563: http://www.whitehouse.gov/sites/default/files/omb/infoREG/eo12866/eo13563_01182011.pdf

❑ Regulatory Impact Analysis

- ❑ OMB Circular A-4: <http://www.whitehouse.gov/sites/default/files/omb/assets/omb/circulars/a004/a-4.pdf>

❑ Regulatory Transparency and Participation

- ❑ Administrative Procedure Act: <http://www.archives.gov/federal-register/laws/administrative-procedure/>
- ❑ Federal Register: www.FederalRegister.gov
- ❑ Public Participation in the Regulatory Process: www.regulations.gov
- ❑ Regulatory Review Dashboard: <http://www.reginfo.gov/public/jsp/EO/eoDashboard.jsp>