

# Regulatory Analysis Requirements

## A Review and Recommendations for Reform

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This draft report was prepared for the consideration of the Administrative Conference of the United States. The views expressed are those of the author and do not necessarily reflect those of the members of the Conference or its committees.

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## Introduction

Numerous analytical rulemaking requirements have been established incrementally during the last 40 to 50 years through a series of presidential and congressional initiatives. Concerns have been raised that the cumulative and uncoordinated nature of these and other requirements have slowed down the rulemaking process without improving the quality of the resultant regulations.<sup>1</sup> Others have pointed out that even if one believes that the analytical requirements are effective, “the patchwork of statutes and executive orders by which these analysis requirements have been imposed and the interrelations between these various statutes and executive orders have created a confusing labyrinth through which agencies seeking to adopt rules must grope.”<sup>2</sup>

The Administrative Conference of the United States (ACUS) has previously recommended procedures for performing regulatory analyses, and ways to make those analyses more transparent to the public.<sup>3</sup> In 1993, ACUS noted that “[i]nformed observers generally agree that the rulemaking process has become increasingly less effective and more time-consuming.”<sup>4</sup> ACUS therefore recommended that, among other things, “Congress should reconsider the need for continuing statutory analytical requirements that necessitate broadly applicable analyses or action to address narrowly-focused issues.”

Similarly, in 1992 the American Bar Association (ABA) recommended that the President and Congress “exercise restraint in the overall number of required rulemaking impact analyses [and] assess the usefulness of existing and planned impact analyses.” The ABA went on to say that “the steady increase in the number and types of cost-benefit or rulemaking review requirements has occurred without any apparent consideration being given to their cumulative effect on the ability of agencies to carry out their statutory obligations.” In 2008, the ABA reiterated its concerns:

Over time, both Congress and the executive have laden the process of informal rulemaking with multiple requirements for regulatory analysis. Viewed in isolation, a good case can be made for each of these requirements. Their cumulative effect, however, has been unfortunate. The addition of too many analytical requirements can detract from the seriousness with which any one is taken, deter the initiation of needed rulemaking, and induce agencies to rely on non-regulatory pronouncements that may be issued without public comment procedures but have real-world effects.<sup>5</sup>

The ABA recommended that Congress and the President should “work to replace the current patchwork of analytical requirements found in various statutes and Executive Orders with one coordinated statutory structure.” Similarly, in 2009, a group of individuals organized by OMB Watch recommended to the incoming Obama

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<sup>1</sup> See, for example, Thomas O. McGarity, “Some Thoughts on ‘Deossifying’ the Rulemaking Process,” *Duke Law Journal*, vol. 41 (1992), pp. 1385-xx; and Thomas O. McGarity, “The Expanded Debate Over the Future of the Regulatory State,” *University of Chicago Law Review*, vol. 63 (1996), pp. 1463 – xx.

<sup>2</sup> Mark Seidenfeld, “A Table of Requirements for Federal Administrative Rulemaking,” *Florida State University Law Review*, vol. 27 (2000), p. 534.

<sup>3</sup> See, for example, ACUS Recommendations 79-4 and 85-2, available at <http://www.acus.gov/acus-recommendations/>.

<sup>4</sup> ACUS Recommendation 93-4.

<sup>5</sup> ABA Section of Administrative Law and Regulatory Practice, “Improving the Administrative Process: A Report to the President-Elect of the United States,” *Administrative Law Review*, vol. 61 (2008), pp. 239-240 (2008).

Administration that the analytical requirements be “rationalized, simplified, and in many cases deleted.”<sup>6</sup>

Others have also examined the growing set of rulemaking requirements and recommended simplification. For example, in 2011, Stuart Shapiro concluded that the rulemaking process contained “many requirements of dubious utility” but that consumed increasing amounts of agency resources.<sup>7</sup> He suggested that a single statutory requirement for cost-benefit analysis and the elimination of other statutory and executive order requirements “would streamline, defragment, and ‘clarify’ the regulatory process and regulations themselves.”<sup>8</sup>

These comments and recommendations notwithstanding, Congress and various Presidents have continued to add new analytical requirements to the rulemaking process, and many more requirements were proposed during the first session of the 112<sup>th</sup> Congress.<sup>9</sup> Commenting on one bill that would make major changes to the rulemaking process (H.R. 3010, the Regulatory Accountability Act of 2011), the ABA’s Section of Administrative Law and Regulatory Practice said it was “gravely concerned” about a revision of the rulemaking process that “not only failed to consolidate existing analysis requirements, but greatly augmented the analysis burdens associated with completing a rulemaking proceeding.”<sup>10</sup> The Section went on to say the following:

These incremental requirements would in all likelihood significantly hamper agencies’ ability to respond to congressional mandates to issue rules, or to delegations of rulemaking authority. Moreover, they would likely augment the tendency of agencies to use “underground rules” (a.k.a. “regulation by guidance”) or case-by-case adjudication to formulate policy without having to surmount the additional hurdles presented by [the proposed revisions].

## Objectives, Scope, and Methodology

The primary objective of this report is to identify the analytical requirements that executive branch agencies currently must comply with in the federal rulemaking process, and determine whether those requirements could or should be consolidated or otherwise reformed to make the rulemaking process more efficient and effective. The report focuses primarily on the analytical requirements that are “crosscutting” in that they apply to a large number of executive branch agencies, but it will also note some (but not all) of

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<sup>6</sup> Gary D. Bass, et al., *Advancing the Public Interest Through Regulatory Reform: Recommendations for President-Elect Obama and the 111<sup>th</sup> Congress*, November 2008, p. 22.

<sup>7</sup> Stuart Shapiro, “Defragmenting the Regulatory Process,” *Risk Analysis*, vol. 31 (2011), pp. 893-901.

<sup>8</sup> *Ibid.*, p. 898.

<sup>9</sup> U.S. Congressional Research Service, *Regulatory Reform Legislation in the 112<sup>th</sup> Congress*, CRS Report R41834, by Curtis W. Copeland, August 24, 2011.

<sup>10</sup> American Bar Association, Section of Administrative Law and Regulatory Practice, “Comments on H.R. 3010, the Regulatory Accountability Act of 2011,” October 24, 2011, available at [http://www.americanbar.org/content/dam/aba/administrative/administrative\\_law/commentson3010\\_final\\_nocover.auth\\_checkdam.pdf](http://www.americanbar.org/content/dam/aba/administrative/administrative_law/commentson3010_final_nocover.auth_checkdam.pdf).

the agency- or issue-specific requirements. This report will also attempt to determine whether these analytical requirements have measurably slowed down the rulemaking process. The terms “regulatory impact analysis” (RIA) or “economic analysis” are used in this report to refer to a variety of analyses that are required before agencies issue final rules, including (but not limited to) cost-benefit analysis (sometimes referred to as “benefit-cost analysis”).

To help provide context for these objectives, the report first discusses the number of rules and “major” rules (e.g., those with an annual effect on the economy of \$100 million or more) that have been issued in recent years, noting the different types of major rules that federal agencies issue. Major rules are focused on in this report because some analytical requirements only apply to such rules, and they are more likely to trigger other requirements than rules that are not considered major. The report also distinguishes “analytical requirements” from other “rulemaking requirements” that do not require some type of analysis or assessment. It then examines the major rules that were published in the *Federal Register* during calendar year 2010 (the most recent full year when the research began) to determine which analytical requirements the agencies mentioned in the preambles, and which requirements they indicated triggered an analysis. The major rules published in 2010 were identified using the Government Accountability Office’s (GAO) rules database that was developed pursuant to the Congressional Review Act (CRA, 5 U.S.C. §§ 801-808).<sup>11</sup>

Finally, structured interviews were conducted with officials in some of the agencies that issued the 2010 major rules, as well as some agencies that did not issue such rules that year. Interviews were conducted with officials in the following departments and agencies: the Departments of Agriculture (USDA), Commerce (DOC), Energy (DOE), Health and Human Services (HHS), the Interior (DOI), and Transportation (DOT); the Environmental Protection Agency (EPA); the Securities and Exchange Commission (SEC), the Federal Communications Commission (FCC), and the Food and Drug Administration (FDA). In these departments and agencies, particular major rules were discussed with agency officials, addressing such issues as why certain analytical requirements were and were not considered applicable to the rules; whether the analytical requirements had measurably slowed rulemaking, whether all or some of the analytical requirements could or should be consolidated into a single statute or executive order; and the effect that the requirements had on the amount of time needed to issue rules. Interviews were also conducted with officials at GAO, the Small Business Administration’s (SBA) Office of Advocacy, and with representatives of other organizations that have been interested in these issues (e.g., the Mercatus Center at George Mason University, the Center for Progressive Reform, Resources for the Future, and OMB Watch). The Office of Information and Regulatory Affairs (OIRA) at the Office of Management and Budget (OMB) declined to participate in the study, and the Chamber of Commerce did not respond to multiple requests for an interview.

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<sup>11</sup> The GAO database may be accessed at <http://gao.gov/legal/congressact/fedrulen.html>.

# Final Rules and Major Final Rules

The Congressional Review Act requires each federal agency (including cabinet departments, independent agencies, and independent regulatory agencies) to send its covered final rules to the Comptroller General at GAO and to both houses of Congress before the rules can take effect.<sup>12</sup> Section 804(3) of the CRA generally defines a covered “rule” by referring to the definition in Section 551 of the APA, which says that a rule is

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 therefore or of valuations, costs, or accounting, or practices bearing on any of the foregoing.<sup>13</sup>

The CRA does, however, exclude certain types of rules from its coverage:

(A) any rule of particular applicability, including a rule that approves or prescribes for the future rates, wages, prices, services, or allowances therefore, corporate or financial structures, reorganizations, mergers, or acquisitions thereof, or accounting practices or disclosures bearing on any of the foregoing; (B) any rule relating to agency management or personnel; or (C) any rule of agency organization, procedure, or practice that does not substantially affect the rights or obligations of non-agency parties.<sup>14</sup>

These limits notwithstanding, the scope of the CRA is extremely broad, including rules that are exempt from notice-and-comment rulemaking procedures (e.g., interpretive rules, statements of policy, and rules that are considered “proprietary” or that fall under the “military” or “foreign affairs” exemptions in the APA).<sup>15</sup>

The CRA generally requires agencies to delay the effective dates of “major” final rules until 60 days after the date that the rules are published in the *Federal Register* or submitted to Congress, whichever is later.<sup>16</sup> The Act also requires the Comptroller General to provide a report to the congressional committees of jurisdiction within 15

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<sup>12</sup> 5 U.S.C. § 801(a)(1)(A). For more information on the CRA, see U.S. Congressional Research Service, *Disapproval of Regulations by Congress: Procedure Under the Congressional Review Act*, CRS Report RL31160, by Richard S. Beth, October 10, 2001, available at <http://www.au.af.mil/au/awc/awcgate/crs/rl31160.pdf>; and Morton Rosenberg, “The Congressional Review Act After 15 Years: Background and Considerations for Reform,” September 16, 2011, available at <http://www.acus.gov/wp-content/uploads/downloads/2011/09/COJR-Draft-CRA-Report-9-16-11.pdf>. In this report, “independent agencies” refers to agencies that answer directly to the President, but are not part of cabinet departments (e.g., the Environmental Protection Agency). “Independent regulatory agencies” refers to the boards and commissions identified as such in the Paperwork Reduction Act (44 U.S.C. 3502(5)), such as the Securities and Exchange Commission.

<sup>13</sup> 5 U.S.C. § 551(4).

<sup>14</sup> 5 U.S.C. § 804 (3)(A-C).

<sup>15</sup> Jeffrey S. Lubbers, *A Guide to Federal Agency Rulemaking*, 4<sup>th</sup> ed., (Chicago, IL: 2006), p. 187.

<sup>16</sup> 5 U.S.C. § 801(a)(3).

calendar days after each major rule is submitted or published, with the report summarizing the issuing agency’s compliance with relevant rulemaking requirements.<sup>17</sup> The Act defines a “major rule” as

any rule that the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget finds has resulted in or is likely to result in—(A) an annual effect on the economy of \$100,000,000 or more; (B) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (C) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. The term does not include any rule promulgated under the Telecommunications Act of 1996 and the amendments made by that Act.<sup>18</sup>

No data are available on the number of major final rules published prior to March 1996, when the CRA was enacted.<sup>19</sup> As **Table 1** below indicates, GAO’s database of rules submitted to the Comptroller General shows that in the first 11 full calendar years after the CRA was enacted (1997 through 2007), federal agencies published between 50 and 80 major rules each year in the *Federal Register*. The number of major rules issued during a single calendar year first exceeded 80 in 2008 (the last full year of the George W. Bush Administration), when 95 major rules were published. In calendar year 2009, the first calendar year of the Obama Administration, federal agencies issued 84 major final rules. However, 11 of those 84 rules were actually issued in early January 2009, during final days of the Bush Administration.<sup>20</sup> During calendar year 2010, federal agencies published 100 major final rules. In calendar year 2011, the number of major rules fell to 76.

**Table 1. Number of Final Rules and Major Final Rules by Calendar Year: 1997-2011**

Calendar Year	Number of Final Rules	Number of Major Final Rules
1997	3,960	61

<sup>17</sup> 5 U.S.C. § 801(a)(2)(A). To access these reports, see <http://www.gao.gov/decisions/majrule/majrule.php>. In the reports, GAO generally summarizes the agencies’ economic analyses, and does not prepare its own analysis.

<sup>18</sup> 5 U.S.C. § 804(2).

<sup>19</sup> The definition of a “major rule” in the CRA was taken from Executive Order 12291, which was abolished when Executive Order 12866 was issued in September 1993. Data from the Regulatory Information Service Center (at <http://www.reginfo.gov>) indicates that OIRA reviewed an average of 67 “economically significant” or “major” regulatory actions per year from 1982 through 1996, but that average includes both proposed and final rules.

<sup>20</sup> Of the 16 major rules that were published in the *Federal Register* during January 2009, the GAO database indicates that 11 of them were published on or before January 21, 2009. Although President Obama was sworn into office on January 20, 2009, the rules that were published on January 21 (including one major rule) had already been submitted to the Office of the Federal Register.



Calendar Year	Number of Final Rules	Number of Major Final Rules
1998	4,420	76
1999	4,373	51
2000	4,113	77
2001	3,454	70
2002	3,608	51
2003	3,785	50
2004	3,703	66
2005	3,352	56
2006	3,083	56
2007	2,971	61
2008	3,117	95
2009	3,492	84
2010	3,271	100
2011	3,453	76

Source: GAO rules database, available at <http://www.gao.gov/fedrules/>.

**Table 2** below shows the number of final rules and major final rules by cabinet department and agency from 2004 through 2011.<sup>21</sup> The table indicates that the number of rules and major rules issued has varied considerably by department and agency, and that the number of final rules that an agency issues is not necessarily an indication of how many major rules the agency will issue. For example, although the Department of Commerce (DOC) published nearly 2,500 final rules during this period, only 6 of those rules (0.2%) were considered “major.” In contrast, the Department of Health and Human Services (HHS) issued 726 final rules from 2004 through 2011, of which 168 (23.4%) were considered major rules.

**Table 2. Number of Final Rules and Major Final Rules by Department or Agency: Calendar Years 2004-2011**

Department/Agency	Number of Final Rules	Number of Major Final Rules
Agriculture (USDA)	1,419	53

<sup>21</sup> The starting point of 2004 was selected because that was the first full year that the Department of Homeland Security was in existence, and government organization has been relatively stable since that date.

Department/Agency	Number of Final Rules	Number of Major Final Rules
Commerce (DOC)	2,442	6
Defense (DOD)	708	14
Education (ED)	159	17
Energy (DOE)	235	22
Health and Human Services (HHS)	726	168
Homeland Security (DHS)	6,156	21
Housing and Urban Development (HUD)	161	8
Interior (DOI)	612	55
Justice (DOJ)	161	7
Labor (DOL)	197	19
State (DOS)	112	2
Treasury (TREAS)	809	9
Transportation (DOT)	6,225	32
Veterans Affairs (DVA)	182	8
Environmental Protection Agency (EPA)	3,582	46
Federal Communications Commission (FCC)	821	14
Federal Reserve System (FRS)	83	18
Nuclear Regulatory Commission (NRC)	146	10
Other Independent Agencies and Government Corporations	1,600	65
Total	26,536	594

**Source:** GAO rules database, available at <http://www.gao.gov/fedrules/>.

**Note:** Agencies in the “Other Independent Agencies and Government Corporations” grouping include the Federal Deposit Insurance Corporation, the General Services Administration, and the Social Security Administration. DOD rules include those that GAO reports separately for the Department of the Air Force and the Department of the Army.

## Why Rules Are Considered “Major”

As noted previously, the Congressional Review Act generally defines a “major rule” as one that OIRA concludes is likely to result in at least one of the following: (1) an annual “effect on the economy” of \$100 million or more; (2) a “major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions;” or (3) “significant adverse effects on competition, employment,

investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.”<sup>22</sup>

Within the first of these three definitional categories, a rule could have a \$100 million annual “effect on the economy” in any of several ways.<sup>23</sup> For example, if a rule is expected to have \$100 million in compliance costs in any one year, it would likely be considered a “major” rule. If a rule is expected to produce economic benefits in any one year that are valued at \$100 million, that rule would also likely be considered “major.” Other rules that increase or decrease federal grants, subsidies, or other types of “transfer” payments by at least \$100 million in any year, or rules that increase federal fees or other revenues by at least \$100 million in a year, would also appear to meet this definition of a major rule. In addition, a rule would also be a “major rule” if is expected to yield a \$100 million “consumer surplus” during a year by triggering consumer spending.

**Table 3** below, drawn from a 2011 report from the Congressional Review Service (CRS),<sup>24</sup> takes the 100 major rules that were published during calendar year 2010 and, using information in GAO’s reports on the major rules and information in the preambles to the rules themselves, illustrates which of the various definitions of a “major rule” appear to be applicable to them (i.e., why the rules were considered “major”). The table divides the category of “\$100 million annual effect on the economy” into five subcategories (regulatory costs, regulatory benefits, transfers, consumer surplus, and fees and revenues). In some cases, more than one category or subcategory applies to a single rule. For example, if a rule was expected to result in at least \$100 million in annual compliance costs and was also expected to result in at least \$100 million in annual benefits, then both subcategories would appear to apply. Therefore, the number of explanations provided overall (and sometimes by agency) exceeds the number of rules issued. However, if a rule appeared to be major because it had \$100 million or more in annual compliance costs, CRS did not also code it as having a “major” increase in costs or prices.

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<sup>22</sup> 5 U.S.C. § 804(2). The definition of a “major rule” is very similar to the definition of an “economically significant” rule under Executive Order 12866 (which is defined as a rule that 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”).

<sup>23</sup> See, for example, “Regulatory Impact Analysis: Frequently Asked Questions (FAQs),” February 7, 2011, available at [http://www.whitehouse.gov/sites/default/files/omb/circulars/a004/a-4\\_FAQ.pdf](http://www.whitehouse.gov/sites/default/files/omb/circulars/a004/a-4_FAQ.pdf), which says that a rule can meet the \$100 million threshold as benefits, costs, or transfers.

<sup>24</sup> U.S. Congressional Research Service, *REINS Act: Number and Type of “Major” Rules in Calendar Year 2010*, by Curtis W. Copeland and Maeve P. Carey, April 2011.

**Table 3. Why Rules Appeared to be “Major” by Agency: Calendar Year 2010**

\$100 Million Annual Effect on the Economy Due to...						
Agency (Number of Major Rules)	Regulatory Costs	Regulatory Benefits	Transfers	Consumer Surplus	Fees and Revenues	Major Increase in Costs/ Prices
USDA (6)	—	—	5	—	—	1
DOD (4)	—	—	4	—	—	—
ED (5)	1	—	4	—	—	—
DOE (4)	2	3	1	—	—	—
HHS (21)	6	2	16	—	—	—
DHS (3)	—	—	1	—	2	—
HUD (1)	—	1	—	—	—	—
DOI (7)	1	1	—	6	—	—
DOJ (3)	2	3	—	—	—	—
DOL (3)	2	2	—	—	—	1
DOS (1)	—	—	—	—	1	—
DOT (4)	4	4	—	—	—	—
TREAS (3)	—	2	—	—	—	1
DVA (2)	—	—	2	—	—	—
CPSC (1)	1	—	—	—	—	—
EPA (8)	7	8	—	—	—	—
FRS (5)	—	1	—	—	—	4
NRC (1)	—	—	—	—	1	—
SEC (9)	2	1	—	—	—	6
TREAS/ DOL/ HHS (6)	—	—	4	—	—	3
TREAS/ FRS/ FDIC (1)	—	—	—	—	—	1
FRS/ FTC (1)	1	—	—	—	—	—
EPA/ DOT (1)	1	1	—	—	—	—
<b>Total (100)</b>	<b>30</b>	<b>29</b>	<b>37</b>	<b>6</b>	<b>4</b>	<b>17</b>

**Source:** CRS, based on information in GAO’s major rule reports and the rules themselves.

**Notes:** A rule may appear to be “major” for more than one reason (e.g., annual regulatory costs and benefits are each expected to exceed \$100 million). Therefore, the number of rules issued by an agency may be less than the number of explanations provided. Agencies are presented first by cabinet department, then by independent agency, and finally by groups of agencies that issued certain rules. Agency abbreviations not previously identified are CPSC (Consumer Product Safety Commission), FDIC (Federal Deposit Insurance Corporation), and FTC (Federal Trade Commission).

Overall, 37 of the 100 rules appeared to be “major” only because they were expected to produce \$100 million in costs, \$100 million in benefits, or (most frequently) both; 34 of the rules appeared to only involve some type of transfer of funds from one party to

another, most commonly the transfer of federal funds to the recipients of those funds (e.g., grants, food stamps, Medicare or Medicaid funds, special pay for members of the military, and crop payments); 16 rules appeared to be major only because they were expected to result in increased costs or prices (but not at or above the \$100 million threshold); 6 rules appeared to only involve “consumer surplus” issues; 4 rules appeared to only involve changes to federal fee structures; and 3 rules appeared to be major for multiple reasons. More detailed descriptions of the 2010 rules within each of these “major” categories are discussed in **Appendix 1** to this report.

## “Rulemaking Requirements” Versus “Analytical Requirements”

A threshold issue in this research was to determine what should be considered an “analytical requirement” in the rulemaking process. During the past 65 years, Congress and various Presidents have put in place an array of rulemaking requirements that all or most executive branch agencies must follow when issuing regulations. Several individuals and organizations have published lists of those requirements. For example,

- In 2000, Mark Seidenfeld published a “Table of Requirements for Federal Administrative Rulemaking” in which he delineated “all of the requirements that an agency seeking to adopt a rule must follow.”<sup>25</sup>
- In a 2009 report, GAO listed 17 rulemaking statutes and executive orders that were cited in 10 or more of 139 major rules.<sup>26</sup>
- ICF International created a “Reg Map” that lists dozens of rulemaking requirements. (A 2-foot by 2-foot post of the Reg Map is available from ICF,<sup>27</sup> or from a website maintained by the Regulatory Information Service Center at the General Services Administration.<sup>28</sup>)
- Some federal agencies have published their own lists of rulemaking requirements, which typically include (but are not limited to) analytical requirements. For example, the Assistant General Counsel for Regulation and Enforcement at DOT compiled a 47-page listing of governmentwide and agency-specific rulemaking requirements, which is accessible on the DOT website.<sup>29</sup>

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<sup>25</sup> Mark Seidenfeld, “A Table of Requirements for Federal Administrative Rulemaking,” *Florida State University Law Review*, vol. 27 (2000), pp. 533-545.

<sup>26</sup> U.S. General Accounting Office, *Federal Rulemaking: Improvements Needed to Monitoring and Evaluation of Rules Development as Well as to the Transparency of OMB Regulatory Reviews*, GAO-09-205, April 20, 2009.

<sup>27</sup> See <http://www.icfi.com/insights/products-and-tools/reg-map>.

<sup>28</sup> <http://www.reginfo.gov/public/reginfo/Regmap/index.jsp>.

<sup>29</sup> See [http://regs.dot.gov/docs/Rulemaking\\_Requirements\\_05312011.pdf](http://regs.dot.gov/docs/Rulemaking_Requirements_05312011.pdf).

However, some of the crosscutting statutes and executive orders included in these lists are primarily procedural in nature, requiring agencies to allow the public to participate in the rulemaking process, to consult with certain groups, or to establish certain policies and processes. They do not specifically require agencies to prepare some kind of analysis or assessment. For example:

- The Administrative Procedure Act of 1946 (APA, 5 U.S.C. §§ 551-559) generally requires agencies to publish a notice of proposed rulemaking (NPRM), give “interested persons” an opportunity to comment, publish a final rule (accompanied by a concise statement of basis and purpose), and not make that final rule effective until at least 30 days after its publication. An agency may avoid notice and comment and the 30-day delay in effective date if (among other things) the agency concludes there is “good cause” to do so.<sup>30</sup> Section 706(2)(A) of the APA instructs courts reviewing regulations to set aside any agency action found to be “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.”
- The Negotiated Rulemaking Act of 1990 (5 U.S.C. §§ 561-570a) encourages agencies to consider convening a negotiated rulemaking committee before developing and issuing a proposed regulation under the APA.
- The Congressional Review Act (CRA, 5 U.S.C. §§ 801-808) requires agencies to submit their final rules to the Government Accountability Office (GAO) and both houses of Congress before they can take effect, and generally requires agencies to delay the effective dates of “major rules” (e.g., those with at least a \$100 million annual effect on the economy) for 60 days after the date of publication and submission to GAO and Congress.<sup>31</sup>
- Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001, generally known as the “Data Quality Act” or the “Information Quality Act” (IQA), directed OMB to issue government-wide guidelines that “provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies.” The IQA also instructed agencies to issue their own guidelines not more than one year after the issuance of OMB’s government-wide guidelines, and to establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency.
- Section 206 of the E-Government Act of 2002 generally requires agencies to (1) ensure that a publicly accessible website includes all information about that

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<sup>30</sup> To conclude that there is “good cause” to avoid notice and comment, Section 553(b) of the APA requires the agency to conclude that it is “impracticable, unnecessary, or contrary to the public interest.”

<sup>31</sup> Section 801(a)(1)(B) of the Congressional Review Act does require agencies to submit to GAO and make available to Congress any cost-benefit or other type of analysis that has been prepared, but the act does not require agencies to prepare those analyses.

agency that is required to be published in the *Federal Register*, (2) accept public comments on proposed rules “by electronic means,” and (3) ensure that a publicly accessible federal website contains “electronic docket” for proposed rules containing all comments submitted on the rules as well as “other materials that by agency rule or practice are included in the rulemaking docket under [the APA], whether or not submitted electronically.”

- The Small Business Paperwork Relief Act of 2002 (P.L. 107-198) required each agency to establish a single point of contact to act as a liaison for small business concerns with regard to information collection and paperwork issues. It also directed agencies to make a special effort to reduce information collection burdens for small businesses with fewer than 25 employees. OMB was directed to publish in the *Federal Register* and make available on the Internet an annual list of the compliance assistance resources available to small businesses.<sup>32</sup> The Act also required agencies to report to Congress on the amount of penalty relief provided to small businesses, and established a task force to study the feasibility of streamlining information collection requirements on small businesses.<sup>33</sup>
- Executive Order 12889 on the North American Free Trade Agreement<sup>34</sup> generally requires agencies subject to the APA to provide at least a 75-day comment period for any “proposed Federal technical regulation or any Federal sanitary or phytosanitary measure of general application.”
- Executive Order 12988 on civil justice reform<sup>35</sup> generally requires agencies to review proposed regulations to eliminate drafting errors and ambiguity, write rules to minimize litigation, and provide a clear legal standard for affected conduct. Rules are also to define key terms and clearly specify any preemptive or retroactive effects.

Other broadly applicable statutes and executive orders can affect the rulemaking process, but do not specifically require some type of analysis. For example:

- The Federal Advisory Committee Act (FACA) of 1972 (5 U.S.C. App. II) established requirements to ensure that agencies using advisory committees receive impartial and relevant expertise. Specifically, FACA requires that the advice provided by advisory committees be objective and accessible to the public. With certain exceptions, each advisory committee meeting is presumptively open to the public. Adequate advance notice of the meetings must be published in the *Federal Register*, and all papers, records, and minutes of the meetings must

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<sup>32</sup> These lists of compliance assistance resources are available at <http://www.sba.gov/category/navigation-structure/starting-managing-business/starting-business/business-law-regulations/contact-government-agency/fe>.

<sup>33</sup> See <http://www.whitehouse.gov/sites/default/files/omb/assets/omb/inforeg/sbpr2004.pdf> for a copy of the task force’s June 28, 2004, final report.

<sup>34</sup> Executive Order 12889, “Implementation of the North American Free Trade Agreement,” 58 *Federal Register* 69681, December 30, 1993.

<sup>35</sup> Executive Order 12988, “Civil Justice Reform,” 61 *Federal Register* 4729, February 7, 1996.

generally be made available to the public. FACA also requires that the advisory committees be fairly balanced in regard to the points of view of affected interests and the functions performed. The Act defines an advisory committee as any committee or similar group (1) established or used to obtain advice or recommendation for one or more federal agencies or the President and (2) that is not composed wholly of full-time federal officers or employees.

- The Trade Agreements Act of 1979 (19 U.S.C. §§ 2531-2533) prohibits agencies from setting regulatory standards that create “unnecessary obstacles to foreign commerce” of the United States. The Act specifically states that legitimate domestic objectives such as safety or health are not considered unnecessary obstacles. The statute also requires, where appropriate, the use of performance standards rather than design standards and the consideration of international standards as the basis of domestic standards.
- Section 12(d) of the National Technology Transfer and Advancement Act (15 U.S.C. 272 note), adopted in March 1996, generally requires federal agencies to “use technical standards that are developed or adopted by voluntary consensus standards bodies” to carry out policy objectives unless doing so is “inconsistent with applicable law or otherwise impractical.” Agencies are also required to consult with and (if in the public interest and compatible with agency missions, authority, priorities, and resources) participate with voluntary private sector consensus bodies.
- Executive Order 13212<sup>36</sup> generally requires agencies to take actions to accelerate the completion of energy-related projects.

## **Crosscutting Analytical Requirements**

On the other hand, a number of crosscutting statutes and executive orders require some type of analysis or assessment for certain rules.

### **National Environmental Policy Act**

The National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. §§ 4321-4347) requires federal agencies to include in every recommendation or report related to “major Federal actions significantly affecting the quality of the human environment” a detailed statement on the environmental impact of the proposed action. If a rule is expected to have significant environmental effects, the agency must prepare an environmental impact statement (EIS), take public comments, publish a final EIS, and publish a record of decision. The environmental impact statement must delineate the direct, indirect, and cumulative effects of the proposed action. Agencies are also required to include in the

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<sup>36</sup> Executive Order 13212, “Actions to Expedite Energy-Related Projects,” 66 *Federal Register* 28357, May 22, 2001.



statement (1) any adverse environmental effects that cannot be avoided should the proposal be implemented, (2) alternatives to the proposed action, (3) the relationship between local short-term uses of the environment and the maintenance and enhancement of long-term productivity, and (4) any irreversible and irretrievable commitments of resources that would be involved if the proposed action should be implemented. If it is unclear whether the rule will have such effects, the agency may first prepare an environmental assessment (EA), which may reveal significant effects (which would then require an EIS) or no significant effects (in which case the agency would issue a “finding of no significant impact,” or FONSI, and proceed with the issuance of the rule). Both the EA and the EIS should discuss the need for the rule, alternative courses of action, and environmental effects, although the EIS process is more complex. If an agency determines that a category of actions will not have “significant” environmental effects, it may publish a categorical exclusion to the analysis requirement in the *Federal Register* and take public comments on the exclusion.<sup>37</sup>

Under Section 309 of the Clean Air Act (42 U.S.C. § 7609), EPA is required to review and publicly comment on the environmental impacts of major federal actions, including actions that are the subject of an EIS. If EPA determines that the action is environmentally unsatisfactory, it is required by Section 309 to refer the matter to the Council on Environmental Quality (CEQ). In accordance with a Memorandum of Agreement between EPA and CEQ, EPA carries out the operational duties associated with the administrative aspects of the EIS filing process.

## **Regulatory Flexibility Act**

The Regulatory Flexibility Act (RFA, 5 U.S.C. §§ 601-612) requires federal agencies to assess the impact of their forthcoming regulations on “small entities,” which the Act defines as including small businesses, small governmental jurisdictions, and certain small not-for-profit organizations. Section 603 of the RFA requires agencies to prepare an “initial regulatory flexibility analysis” (IRFA) before publishing a proposed rule, which is to contain (1) a description of the reasons why the rule is being considered, (2) a statement of the rule’s objectives and legal basis, (3) a description of and, where feasible, an estimate of the number of small entities to which the rule would apply; (4) a description of the projected reporting, recordkeeping, and other compliance requirements, including an estimate of the classes of small entities that will be subject to the rule and the types of professional skills necessary for preparation of any report or records; and (5) an identification of all federal rules that may duplicate, overlap, or conflict with the proposed rule. The IRFA is also to contain “a description of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities,” such as differing compliance or reporting requirements or timetables, simplification of requirements, and exemptions for small entities.

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<sup>37</sup> See <http://ceq.hss.doe.gov/> for more information on NEPA.

When an agency issues a final rule for which a proposed rule is required, the agency is required to prepare a “final regulatory flexibility analyses” (FRFA), which is required to contain (1) a state of the need for and objectives of the rule; (2) a summary of the significant issues raised by the public comments in response to the IRFA, the agency’s assessment, and any changes made pursuant to those comments; (3) a description of and an estimate of the number of small entities to which the rule will apply, or an explanation of why the estimate is not available; (4) a description of the steps the agency has taken to minimize the significant economic impact on small entities, including a “statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected.”<sup>38</sup> In complying with the requirements for an IRFA and a FRFA, agencies are permitted to provide “either a quantifiable or numerical description of the effects of a proposed rule or alternatives to the proposed rule, or more general descriptive statements if quantification is not practicable or reliable.”<sup>39</sup>

However, the agency is not required to prepare an IRFA or a FRFA at all if the rule published without an NPRM, or if the agency certifies that the rule is not expected to have a “significant economic impact on a substantial number of small entities” (SEISNSE)<sup>40</sup> Agencies are required to publish such certifications in the *Federal Register* at the time the proposed and final rules are published, along with a statement providing the factual basis for such certification.<sup>41</sup> Section 612 of the RFA requires the SBA Chief Counsel for Advocacy to monitor agency compliance with the Act and to report at least annually to the President and to the Committees on the Judiciary and Small Business of the Senate and House of Representatives.

Several other statutes, executive orders, and memoranda supplement, but do not alter, the RFA’s requirements, and do not themselves require an analysis. For example, Section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA, P.L. 104-121, 5 U.S.C. § 601 note) requires agencies to develop one or more compliance guides for each final rule or group of related final rules for which the agency is required to prepare a regulatory flexibility analysis under the RFA. Executive Order 13272<sup>42</sup> generally requires federal agencies to issue written procedures and policies to ensure proper consideration during the rulemaking process of the impacts of their draft rules on small entities. The order also requires agencies to notify the SBA Chief Counsel for

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<sup>38</sup> 5 U.S.C. § 604.

<sup>39</sup> 5 U.S.C. § 607.

<sup>40</sup> 5 U.S.C. § 605(b).

<sup>41</sup> The RFA initially did not permit judicial review of agencies’ actions under the act. However, amendments to the act in 1996 as part of the Small Business Regulatory Enforcement Fairness Act (SBREFA, 5 U.S.C. § 601 note) permitted judicial review regarding, among other things, agencies’ regulatory flexibility analyses for final rules and any certifications that their rules will not have a significant impact on small entities. As a result, a small entity that is adversely affected or aggrieved by an agency’s determination that its final rule would not have a significant impact on small entities could seek judicial review of that determination within one year of the date of the final agency action. In granting relief, a court may remand the rule to the agency or defer enforcement against small entities.

<sup>42</sup> Executive Order 13272, “Proper Consideration of Small Entities in Agency Rulemaking,” 67 *Federal Register* 53461, August 16, 2002.

Advocacy of any draft rules that may have a significant economic impact on a substantial number of small entities under the RFA, and to give “every appropriate consideration” to any comments the Chief Counsel provides. Also, a January 18, 2011, presidential memorandum on “Regulatory Flexibility, Small Business, and Job Creation” 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.”<sup>43</sup>

## **Paperwork Reduction Act**

The Paperwork Reduction Act (PRA, 44 U.S.C. §§ 3501-3520) was originally enacted in 1980, but was subsequently amended in 1986 and again in 1995. One of the purposes of the PRA is to minimize paperwork burden for individuals, small businesses, and others resulting from a collection of information by or for the federal government.<sup>44</sup> The PRA requires agencies to justify any covered collection of information from the public by establishing the need and intended use of the information, estimating the burden that the collection will impose on respondents, and showing that the collection is the least burdensome way to gather the information.<sup>45</sup> “Burden” is also broadly defined in the Act to include all of the “time, effort, or financial resources expended by persons to generate, maintain, or provide information to or for a Federal agency,” including any time or other expenditure needed to review instructions, acquire technology, or search data sources.<sup>46</sup> Paperwork burden is most commonly estimated in terms of “burden hours,” which is a function of (1) the frequency of an information collection, (2) the estimated number of respondents, and (3) the amount of time that the agency estimates it takes each respondent to complete the collection. A “collection of information” is defined as “obtaining, causing to be obtained, soliciting, or requiring the disclosure to third parties or the public” of information from 10 or more persons, not including agencies or employees of the federal government. The PRA does not apply to collections of information “during the conduct of a Federal criminal investigation,” or “during the conduct of ... an administrative action or investigation involving an agency against specific individuals or entities.”<sup>47</sup> However, the PRA does apply to “the collection of information during the conduct of general investigations ... undertaken with reference to a category of individuals or entities such as a class of licensees or an entire industry.”<sup>48</sup>

The original PRA established the Office of Information and Regulatory Affairs (OIRA) within OMB to provide central agency leadership and oversight of government-wide efforts to reduce unnecessary paperwork burden and improve the management of

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<sup>43</sup> See <http://www.gpo.gov/fdsys/pkg/DCPD-201100033/pdf/DCPD-201100033.pdf> for a copy of this memorandum.

<sup>44</sup> 44 U.S.C. § 3501(1).

<sup>45</sup> 44 U.S.C. § 3506(c).

<sup>46</sup> 44 U.S.C. § 3502(2).

<sup>47</sup> 44 U.S.C. § 3518(c)(1).

<sup>48</sup> 44 U.S.C. § 3518(c)(2).

information resources. Agencies must receive OIRA-approval (signified by an OMB control number displayed on the information collection) for each collection request before it is implemented, and those approvals must be renewed at least every three years. Failure to obtain OIRA approval for an active collection, or the lapse of that approval, represents a violation of the act, and triggers the PRA's public protection provision. Under that provision, no one can be penalized for failing to comply with a collection of information subject to the Act if the collection does not display a valid OMB control number.<sup>49</sup> OIRA can disapprove any collection of information if it believes the collection is inconsistent with the requirements of the PRA. However, multi-headed independent regulatory agencies can, by majority vote of the leadership, void any OIRA disapproval of a proposed information collection.<sup>50</sup>

## Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act (UMRA, 2 U.S.C. §§ 1532-1538) requires covered agencies (cabinet departments and independent agencies, but not independent regulatory agencies)<sup>51</sup> to, among other things, prepare a written statement containing specific descriptions and estimates for any proposed rule or any final rule for which a proposed rule was published that includes any federal mandate that may result in the expenditure of \$100 million or more (indexed for inflation) in any year by state, local, or tribal governments, in the aggregate, or the private sector. The written statement is to contain (among other things) a “qualitative and quantitative assessment of the anticipated costs and benefits ... as well as the effect of the Federal mandate on health, safety, and the natural environment.” It is also generally required to include estimates of future compliance costs, and any disproportionate budgetary effects on particular regions, governments, or segments of the private sector, and estimates of effects on the national economy, including effects on job creation, productivity, full employment, and international competitiveness. Also, Section 205 of UMRA generally requires agencies preparing a written statement to “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 objectives of the rule,” or explain why the least costly, most cost-effective or least burdensome method of achieving the objectives of the rule was not adopted, or why the provisions are inconsistent with law. However, UMRA's analytical requirements do not apply if the agency issues the final rule without a previous notice of proposed rulemaking, if the rule is not considered a “mandate” (e.g., a

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<sup>49</sup> For an up-to-date inventory of OMB-approved information collections, see <http://www.reginfo.gov/public/do/PRAMain>.

<sup>50</sup> 44 U.S.C. § 3507(f). For more information on the PRA, see U.S. Congressional Research Service, *Paperwork Reduction Act (PRA): OMB and Agency Responsibilities and Burden Estimates*, CRS Report R40636, June 15, 2009, by Curtis W. Copeland and Vanessa K. Burrows, available at <http://graphics8.nytimes.com/packages/pdf/nyregion/2009/records/paperworkreductionreportbycrs.pdf>.

<sup>51</sup> The PRA (44 U.S.C. 3502(5)) defines an independent regulatory agency by listing a number of agencies (e.g., the Board of Governors of the Federal Reserve System, the Consumer Product Safety Commission, the Federal Communications Commission, the Nuclear Regulatory Commission, and the Securities and Exchange Commission) and also saying it includes “any other similar agency designated by statute as a Federal independent regulatory agency or commission.”

condition of federal financial assistance, or a duty arising from participation in a voluntary federal program); if it incorporates requirements specifically set forth in law; and for various other reasons. Section 208 of UMRA requires OMB to submit an annual report to Congress on agencies' compliance with Title II.

### **Privacy Assessments Under the E-Government Act and P.L. 108-447**

Section 208 of the E-Government Act (44 U.S.C.A. §3601 note) requires agencies to conduct a “privacy impact assessment” before initiating a new covered collection of information that uses information technology and contains individually identifying information.<sup>52</sup> These assessments must analyze and describe what information is to be collected (e.g., nature and source); why the information is being collected (e.g., to determine eligibility); the intended use of the information (e.g., to verify existing data); with whom the information will be shared (e.g., another agency for a specified programmatic purpose); what opportunities individuals have to decline to provide information (i.e., where providing information is voluntary) or to consent to particular uses of the information (other than required or authorized uses), and how individuals can grant consent; how the information will be secured (e.g., administrative and technological controls); and whether a system of records is being created under the Privacy Act (5 U.S.C. § 552a).

Also, Section 522(a) of the Consolidated Appropriations Act, 2005 (P.L. 108-447, 5 U.S.C. 552a note) requires each agency to have a chief privacy officer, whose duties include “conducting a privacy impact assessment of proposed rules of the Department on the privacy of information in an identifiable form, including the type of personally identifiable information collected and the number of people affected.”

### **Family Assessments Under Section 654 of P.L. 105-277**

Section 654 of the Treasury and General Government Appropriations Act, 1999 (P.L. 105-277, 5 U.S.C. § 601 note) requires federal agencies (other than GAO) to assess their pending regulations that “may affect family well-being” to determine whether the proposed benefits of the action justify the financial impact on the family. Agencies are also to determine in these “family policymaking assessments” whether the rule would have other types of effects (e.g., “strengthens or erodes the stability or safety of the family and, particularly, the marital commitment;” “strengthens or erodes the authority and rights of parents in the education, nurture, and supervision of their children;” and “increases or decreases disposable income or poverty of families and children”). For each proposed rule that may affect family well-being, agencies are required to submit a written certification to OMB and to Congress that the rule has been assessed in accordance with these requirements, and provide an “adequate rationale” for implementation of each rule that may negatively affect family well-being. Agencies are

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<sup>52</sup> See [http://www.whitehouse.gov/omb/memoranda\\_m03-22](http://www.whitehouse.gov/omb/memoranda_m03-22) for more information on these assessments.

required to conduct such assessments and provide certifications upon request by a Member of Congress. This requirement went into effect in October 1998 when the appropriations Act was signed into law. As noted in a January 1999 memorandum from the Director of OMB,<sup>53</sup> this provision reinstated a requirement that was in Executive Order 12606 until it was revoked in April 1997 by Executive Order 13045.

## **Executive Order 12866**

Section 1(a) of Executive Order (EO) 12866<sup>54</sup> states that covered agencies

should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating. Costs and benefits shall be understood to include both quantifiable measures (to the fullest extent that these can be usefully estimated) and qualitative measures of costs and benefits that are difficult to quantify, but nevertheless essential to consider. Further, in choosing among alternative regulatory approaches, agencies should select those approaches 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.

Section 1(b) of EO 12866 delineates certain “Principles of Regulation” that covered agencies “should adhere to” (to the extent permitted by law and where applicable). For example, the agencies are told that they should:

- design their regulations “in the most cost-effective manner to achieve the regulatory objective. In doing so, each agency shall consider incentives for innovation, consistency, predictability, the costs of enforcement and compliance (to the government, regulated entities, and the public), flexibility, distributive impacts, and equity.”
- assess both the costs and the benefits of their intended regulations and, “recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.”<sup>55</sup>
- tailor their regulations “to impose the least burden on society, including individuals, businesses of differing sizes, and other entities (including small communities and governmental entities), consistent with obtaining the regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations.”

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<sup>53</sup> See <http://www.fws.gov/policy/library/rglew.pdf> for a copy of this memorandum.

<sup>54</sup> Executive Order 12866, “Regulatory Planning and Review,” 58 *Federal Register* 51735, October 4, 1993.

<sup>55</sup> The requirement that agencies adopt regulations only if the benefits “justify” the costs was seen as a somewhat different threshold than the one in Executive Order 12291, which had required agencies to determine that regulatory benefits “outweigh” the costs.

The heart of the analytical requirements are in Section 6(a)(3)(B) of the executive order, which states that, for each “economically significant” regulatory action (e.g., proposed and final rules expected to have an annual impact on the economy of \$100 million or more),<sup>56</sup> covered agencies (cabinet departments and independent agencies, but not independent regulatory agencies) are generally required to provide to the Office of Information and Regulatory Affairs (OIRA) within OMB an assessment, including the underlying analysis, of the benefits and costs anticipated from a regulatory action, and the costs and benefits of “potentially effective and reasonably feasible alternatives to the planned regulation... and an explanation why the planned regulatory action is preferable to the identified potential alternatives.” Assessments of benefits and costs are to include, to the extent feasible, a quantification of those benefits and costs. In emergency situations, or when an agency is required by law to act more quickly than normal review procedures allow, the rulemaking agency is required to comply with the order’s requirements “to the extent practicable.”<sup>57</sup>

### *OMB Circular A-4*

The analytical requirements in EO 12866 are further elaborated in OMB Circular A-4, which says a good analysis contains three basic elements: (1) a statement of the need for the proposed action, (2) an examination of alternative approaches, and (3) an evaluation of the benefits and costs—quantitative and qualitative—of the proposed action and the main alternatives identified by the analysis.

- With regard to need, Circular A-4 states that the agency should describe the statutory or judicial directives that authorize the action, and describe the problem that it intends to address. The underlying problem can involve a market failure (e.g., a monopoly that adversely affects consumers, or inadequate information about a product) or other social purposes (e.g., to combat discrimination). The statement of need should also consider other alternatives to federal regulation, including the option of state or local regulation.
- After determining that federal regulation is needed, Circular A-4 requires the agency to consider a “reasonable number” of alternative regulatory approaches available within the statutory authority provided to the agency. For example, the circular says agencies should consider different compliance dates, enforcement methods, levels of stringency, requirements based on firm size or geographic

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<sup>56</sup> Section 3(f) of EO 12866 defines a “significant” rule as one that satisfies any of four conditions: (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. Rules fitting the first of these conditions are often referred to as “economically significant” regulatory actions.

<sup>57</sup> Section 3(a)(3)(D) of Executive Order 12866.

region; performance standards instead of design standards, market approaches instead of direct controls; and informational measures instead of regulation.

- With regard to analytical approaches, the circular states that agencies should use both cost-benefit analysis and cost-effectiveness analysis. When all benefits and costs can be expressed in monetary units, cost-benefit analysis can clearly indicate which approach is most efficient in terms of net benefits.<sup>58</sup> However, in many (and perhaps most) cases, agencies are not able to express all of the benefits or costs in monetary units. In such cases, Circular A-4 states that cost-benefit analysis “is less useful, and it can even be misleading, because the calculation of net benefits in such cases does not provide a full evaluation of all relevant benefits and costs.”<sup>59</sup> Analysts should therefore attempt to quantify benefits or costs as much as possible (e.g., tons of pollution avoided, or the number of children who will not suffer discrimination), and “exercise professional judgment” in determining whether non-quantified factors are important enough to justify consideration of the regulation.

The circular also requires an “accounting statement” with tables reporting benefit and cost estimates for each major final rule.<sup>60</sup> For rules involving annual economic effects of \$1 billion or more, the circular says agencies should present a “formal quantitative analysis of the relevant uncertainties about benefits and costs,” including estimates of the central tendency (e.g., mean and median), ranges, and other characteristics of the distribution.<sup>61</sup>

### *Supplemental Publications*

On October 28, 2010, OMB published an agency checklist for the regulatory impact analyses required by EO 12866 and OMB Circular A-4.<sup>62</sup> It contains repeated references to provisions in the executive order and the circular, and states that nothing in the checklist “alters, adds to, or reformulates existing requirements in any way.” Among other things, the checklist asks whether the agency’s analysis (1) has a reasonably detailed description of the need for the regulatory action, (2) explains how the action will meet that need, (3) quantifies and monetizes the expected costs and benefits of the action to the extent feasible, (4) explains and supports a reasoned justification that the benefits of the regulatory action justify the costs, (5) assesses the potentially effective and reasonable alternatives to the action (including at least one alternative that is more

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<sup>58</sup> For example, if Option A has expected costs of \$100 million and expected benefits of \$200 million, the net benefits are \$100 million. If Option B has expected costs of \$200 million, and expected benefits of \$400 million, the net benefits are \$200 million. In this scenario, Option B produces the largest net benefits.

<sup>59</sup> OMB Circular A-4, p. 10.

<sup>60</sup> See [http://www.whitehouse.gov/omb/circulars\\_a004\\_a-4](http://www.whitehouse.gov/omb/circulars_a004_a-4) for a copy of Circular A-4.

<sup>61</sup> OMB has also published a checklist to assist agencies in the production of regulatory impact analyses under EO 12866 and Circular A-4. See [http://www.whitehouse.gov/sites/default/files/omb/inforeg/regpol/RIA\\_Checklist.pdf](http://www.whitehouse.gov/sites/default/files/omb/inforeg/regpol/RIA_Checklist.pdf).

<sup>62</sup> See [http://www.whitehouse.gov/sites/default/files/omb/inforeg/regpol/RIA\\_Checklist.pdf](http://www.whitehouse.gov/sites/default/files/omb/inforeg/regpol/RIA_Checklist.pdf) for a copy of the checklist.



stringent and less stringent), and (6) explains why the planned regulatory action is preferable to those alternatives.

On January 18, 2011, President Obama issued Executive Order 13563 on “Improving Regulation and Regulatory Review.”<sup>63</sup> The executive order is described as “supplemental to and reaffirms the principles, structures, and definitions governing contemporary regulatory review that were established in EO 12866 of September 30, 1993.” It reiterates many of the principles in the 1993 executive order (e.g., that benefits should “justify” costs, and that agencies should select the regulatory alternative that maximizes net benefits). The primary new element was a requirement that agencies develop a plan for the retrospective review of their existing regulations to determine if any should be modified, streamlined, expanded, or repealed. On July 11, 2011, President Obama issued Executive Order 13579 requesting, but not requiring, independent regulatory agencies to follow the principles in Executive Order 13563, and to develop plans for the review of their existing rules.<sup>64</sup>

On February 7, 2011, OMB published a document entitled “Regulatory Impact Analysis: Frequently Asked Questions.”<sup>65</sup> Again, OMB said “nothing said here is meant to alter existing requirements in any way.” Among other things, OMB indicated that:

- A rule may be considered “economically significant” if it expected to have \$100 million in costs, benefits, or transfers in any one year, and rules that do not cross that threshold but have adversely affect a small sector of the economy and would threaten to create significant job loss would still be considered “economically significant.”
- Agencies’ regulatory impact analyses should be presented in plain language, and should include a clear executive summary of their central conclusions and an accounting statement with a table summarizing the expected costs, benefits, and transfers.
- When considering regulatory alternatives, agencies should begin by asking whether to regulate at all, and should consider deferring to regulation at the state or local level. If federal regulation is needed, agencies should consider analyzing at least three options: the preferred option, a more stringent option, and a less stringent one. Agencies should also generally include a sensitivity analysis showing how results can vary with changes in assumptions, data, and analytical approaches.

On January 4, 2012, OIRA sent a memorandum to the heads of executive departments and agencies requiring that regulatory preambles for “lengthy or complex” proposed and

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<sup>63</sup> Executive Order 13563, “Improving Regulation and Regulatory Review,” 76 *Federal Register* 3821, January 21, 2011.

<sup>64</sup> Executive Order 13579, “Regulation and Independent Regulatory Agencies,” 76 *Federal Register* 41587, July 14, 2011.

<sup>65</sup> See [http://www.whitehouse.gov/sites/default/files/omb/circulars/a004/a-4\\_FAQ.pdf](http://www.whitehouse.gov/sites/default/files/omb/circulars/a004/a-4_FAQ.pdf) for a copy of this document.

final rules should include “straightforward executive summaries” that describe major provisions and policy choices.<sup>66</sup> A suggested template for these summaries stated that they should generally be three to four double-spaced pages in a Word document, and should state (1) the purpose of the regulatory action (including the need, how the action will meet that need, and a statement of legal authority); (2) a summary of the major provisions of the regulatory action; and (for economically significant rules) (3) a table summarizing the estimated costs and benefits, both quantitative and qualitative.

### **Executive Order 12630**

Executive Order 12630 on “constitutionally protected property rights”<sup>67</sup> states that before undertaking any proposed action regulating private property use for the protection of public health or safety that has “takings implications,” executive departments and agencies must, in internal deliberative documents and submissions to OMB, (1) identify the public health or safety risk created by the private property use; (2) show that the proposed action substantially advances the purpose of protecting public health and safety against that risk; (3) show (to the extent possible) that the restrictions imposed on the private property are not disproportionate to the risk; and (4) estimate (to the extent possible) the potential cost to the government in the event that a court later determines that the action constituted a taking.<sup>68</sup>

### **Executive Order 12898**

Executive Order 12898<sup>69</sup> generally requires executive departments and agencies to “collect, maintain, and analyze information assessing and comparing environmental and human health risks borne by populations identified by race, national origin, or income,” and are to “use this information to determine whether their programs, policies, and activities have disproportionately high and adverse human health or environmental effects on minority populations and low-income populations.” Agencies are instructed to do so “to the extent permitted by existing law,” and “whenever practicable and appropriate.”

### **Executive Order 13045**

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<sup>66</sup> See [http://www.whitehouse.gov/sites/default/files/omb/inforeg/for-agencies/clarifying-regulatory-requirements\\_executive-summaries.pdf](http://www.whitehouse.gov/sites/default/files/omb/inforeg/for-agencies/clarifying-regulatory-requirements_executive-summaries.pdf) for a copy of this memorandum.

<sup>67</sup> Executive Order 12630, “Governmental Actions and Interference with Constitutionally Protected Property Rights,” 53 *Federal Register* 8859, March 18, 1988.

<sup>68</sup> In 2003, GAO reported that few takings implications assessments were being prepared. See GAO-03-1015, at <http://www.gao.gov/assets/240/239832.pdf>. To view a hearing on this issue, see <http://judiciary.house.gov/legacy/89877.PDF>.

<sup>69</sup> Executive Order 12898, “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations,” 59 *Federal Register* 7629, February 11, 1994.

Executive Order 13045<sup>70</sup> generally requires covered agencies (cabinet departments and independent agencies, but not independent regulatory agencies) to provide with any “covered regulatory action” an “evaluation of the environmental health or safety effects of the planned regulation on children” and “an explanation of why the planned regulation is preferable to other potentially feasible alternatives considered by the agency.” A “covered” action is defined as those for which the agency publishes an NPRM, that is considered “economically significant” under EO 12866, and that concerns an environmental health or safety risk that the agency “has reason to believe may disproportionately affect children.” In an “emergency situation,” or when an agency is required to act more quickly than normal, the agency is permitted to satisfy the requirement “to the extent practicable.”

### **Executive Order 13132**

Executive Order 13132 on “federalism”<sup>71</sup> generally prohibits covered agencies (cabinet departments and independent agencies, but not independent regulatory agencies) from issuing any regulation that has federalism implications, is not required by law, and imposes substantial direct compliance costs on state and local governments unless the necessary funds are provided or the agency consults with state and local officials and prepares a “federalism summary impact statement” describing the extent of those consultations, a summary of the nature of the officials’ concerns and the agency’s position supporting the need to issue the regulation, and a statement of the extent to which the concerns have been met. The impact statement is to be provided to the Director of OMB and published in a “separately identified portion of the preamble” to the rule. Rules are considered to have “federalism implications” when they 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.”

### **Executive Order 13175**

Executive Order 13175 on consultation and coordination with Indian tribal governments<sup>72</sup> generally prohibits covered agencies (cabinet departments and independent agencies, but not independent regulatory agencies) from issuing any regulation that has tribal implications, is not required by law, and imposes substantial direct compliance costs on tribal governments unless the necessary funds are provided or the agency consults with tribal officials and prepares a “tribal summary impact statement” describing the extent of those consultations, a summary of the nature of the officials’ concerns and the agency’s position supporting the need to issue the regulation, and a statement of the extent to

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<sup>70</sup> Executive Order 13045, “Protection of Children From Environmental Health Risks and Safety Risks,” 62 *Federal Register* 19883, April 23, 1997.

<sup>71</sup> Executive Order 13132, “Federalism,” 64 *Federal Register* 43255, August 10, 1999.

<sup>72</sup> Executive Order 13175, “Consultation and Coordination with Indian Tribal Governments,” 65 *Federal Register* 67249, November 9, 2000.

which the concerns have been met. The statement is to be provided to the Director of OMB and published in a “separately identified portion of the preamble to the regulation.” Rules are considered to have “tribal implications” when they have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.”

## **Executive Order 13211**

Executive Order 13211<sup>73</sup> generally requires covered agencies (cabinet departments and independent agencies, but not independent regulatory agencies) to prepare a “statement of energy effects” for any rule identified as a “significant energy action.” A “significant energy action” is defined as any rule that is “significant” under EO 12866 and is likely to have a “significant adverse effect on the supply, distribution, or use of energy,” or that is so designated by the OIRA Administrator. The statement of energy effects is described as a “detailed statement” relating to “any adverse effects on energy supply, distribution, or use” should the proposal be implemented, and “reasonable alternatives to the action with adverse energy effects and the expected effects of such alternatives on energy supply, distribution, and use.” The statement is to be submitted to OIRA when the rule is submitted pursuant to EO 12866, and it (or a summary) must be included in the proposed and final rule.

## **Agency- or Issue-Specific Analytical Requirements**

In addition to these crosscutting analytical requirements, a number of agency or issue-specific statutory provisions require certain agencies to conduct some type of analysis when issuing regulations.<sup>74</sup> For example:

- Section 1102(b) of the Social Security Act (42 U.S.C. § 1302(b)) requires the Department of Health and Human Services (HHS) to prepare an initial regulatory impact analysis if a proposed rule issued under certain statutory authorities may have a significant impact on the operations of a substantial number of small rural hospitals. The analysis is required to describe the impact of the proposed rule on such hospitals, and must set forth with respect to small hospitals the matters required to be addressed in an IRFA under the RFA. When HHS publishes the

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<sup>73</sup> Executive Order 13211, “Actions Concerning Regulations That Significant Affect Energy Supply, Distribution, or Use.” 66 *Federal Register* 28355, May 22, 2001.

<sup>74</sup> There are also some agency-specific statutory requirements for some type of analysis, but that are not keyed to the issuance of regulations. For example, Section 321(a) of the Clean Air Act (42 U.S.C. § 7621) requires the EPA administrator to conduct “continuing evaluations of potential loss or shifts of employment which may result from the administration or enforcement of the provision of this chapter and applicable implementation plans, including where appropriate, investigating threatened plant closures or reductions in employment allegedly resulting from such administration or enforcement.”

final version of the rule for which an initial analysis is prepared, the department must prepare a final regulatory impact analysis, which must set forth with respect to small rural hospitals the same issues required to be addressed in a FRFA under the RFA.

- 15 U.S.C. § 2058(f)(2) states that the Consumer Product Safety Commission “shall not promulgate a consumer product safety rule unless it has prepared... a final regulatory analysis of the rule containing the following information: (A) A description of the potential benefits and potential costs of the rule, including costs and benefits that cannot be quantified in monetary terms, and the identification of those likely to receive the benefits and bear the costs. (B) A description of any alternatives to the final rule which were considered by the Commission, together with a summary description of their potential benefits and costs and a brief explanation of the reasons why these alternatives were not chosen. (C) A summary of any significant issues raised by the comments submitted during the public comment period in response to the preliminary regulatory analysis, and a summary of the assessment by the Commission of such issues. The Commission shall publish its final regulatory analysis with the rule.”
- The Department of Energy’s requirements for setting or amending energy efficiency standards for certain types of products are in the Energy Policy and Conservation Act (EPCA, 42 U.S. C. 6295(o)), which says that the standards should “achieve maximum improvement” in energy or water efficiency that the Secretary determines is “technologically feasible and economically justified.” To determine whether a standard is economically justified, the Secretary is required to “determine whether the benefits of the standard exceed its burdens” taking into account such factors as the economic impact on manufacturers and consumers, savings in operating costs, impacts on competition, and the total projected energy or water savings likely to result from the standard.<sup>75</sup>

## Requirements to “Consider” Impacts

Other statutory provisions are less specific, requiring that certain agencies “consider” the impact of their rules on regulated parties or the public. For example:

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<sup>75</sup> 42 U.S.C. § 6295(o)(2) states that in determining whether a standard is economically justified, the Secretary shall consider “(I) the economic impact of the standard on the manufacturers and on the consumers of the products subject to such standard; (II) the savings in operating costs throughout the estimated average life of the covered product in the type (or class) compared to any increase in the price of, or in the initial charges for, or maintenance expenses of, the covered products which are likely to result from the imposition of the standard; (III) the total projected amount of energy, or as applicable, water, savings likely to result directly from the imposition of the standard; (IV) any lessening of the utility or the performance of the covered products likely to result from the imposition of the standard; (V) the impact of any lessening of competition, as determined in writing by the Attorney General, that is likely to result from the imposition of the standard; (VI) the need for national energy and water conservation; and (VII) other factors the Secretary considers relevant.” DOE’s rulemaking procedures for the energy conservation program are delineated in a rule. See U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, “Energy Conservation: Program for Consumer Products: Procedures for Consideration of New or Revised Energy Conservation Standards for Consumer Products,” 61 *Federal Register* 36974, July 15, 1996.

- The National Securities Market Improvement Act (15 U.S.C. § 77b(b)) requires the Securities and Exchange Commission (SEC) to consider whether an action “will promote efficiency, competition, and capital formation” whenever it is “engaged in rulemaking and is required to consider or determine whether an action is necessary or appropriate in the public interest.” Also, Section 23(a)(2) of the Securities Exchange Act of 1934 (15 U.S.C. § 78w(a)(2)) states that the SEC and the Secretary of the Treasury, in making rules and regulations pursuant to any provisions of this chapter, shall consider among other matters the impact any such rule or regulation would have on competition. In addition, Section 3(f) of the Exchange Act (15 U.S.C. § 78c(f)) and Section 2(c) of the Investment Company Act of 1940 (15 U.S.C. § 80a-2(c)) require the Commission to consider “whether the action will promote efficiency, competition, and capital formation.”
- Section 15(a) of the Commodity Exchange Act (7 U.S.C. § 19(a)) requires the Commodity Futures Trading Commission (CFTC) to consider costs and benefits before issuing certain regulations, and states that those costs and benefits “shall be evaluated in light of - (A) considerations of protection of market participants and the public; (B) considerations of the efficiency, competitiveness, and financial integrity of futures markets; (C) considerations of price discovery; (D) considerations of sound risk management practices; and (E) other public interest considerations.”
- In determining the effective date and administrative compliance requirements for new regulations that impose additional reporting, disclosure, or other requirements on insured depository institutions, Section 302 of the Riegle Community Development and Regulatory Improvement Act (12 U.S.C. § 4802(a)) requires federal banking agencies to “consider, consistent with the principles of safety and soundness and the public interest - (1) any administrative burdens that such regulations would place on depository institutions, including small depository institutions and customers of depository institutions; and (2) the benefits of such regulations.”
- In determining the effective date and administrative compliance requirements for new regulations that impose additional reporting, disclosure, or other requirements on insured depository institutions, the Riegle Community Development and Regulatory Improvement Act (12 U.S.C. § 4802(a)) requires federal banking agencies to “consider, consistent with the principles of safety and soundness and the public interest - (1) any administrative burdens that such regulations would place on depository institutions, including small depository institutions and customers of depository institutions; and (2) the benefits of such regulations.” The term “federal banking agencies” is defined in Section 4801 of the Riegle Act (12 U.S.C. § 1813) as the “Office of the Comptroller of the Currency, the Office of Thrift Supervision, the Board of Governors of the Federal Reserve System, and the Federal Deposit Insurance Corporation.”

- Section 1022(b)(2)(A) of the Dodd-Frank Wall Street Reform Act (12 U.S.C. § 5512) establishes certain “standards of rulemaking” for the newly established Consumer Financial Protection Bureau (CFPB). Specifically, it states that the Bureau “shall consider—(i) the potential benefits and costs to consumers and covered persons, including the potential reduction of access by consumers to consumer financial products or services resulting from such rule; and (ii) the impact of proposed rules on covered persons, as described in section 1026, and the impact on consumers in rural areas.”
- Before issuing a consumer product safety rule, 15 U.S.C. § 2058(f)(1) requires the CPSC to “consider, and shall make appropriate findings for inclusion in such rule with respect to - (A) the degree and nature of the risk of injury the rule is designed to eliminate or reduce; (B) the approximate number of consumer products, or types or classes thereof, subject to such rule; (C) the need of the public for the consumer products subject to such rule, and the probable effect of such rule upon the utility, cost, or availability of such products to meet such need; and (D) any means of achieving the objective of the order while minimizing adverse effects on competition or disruption or dislocation of manufacturing and other commercial practices consistent with the public health and safety.”

It is unclear whether a requirement that an agency “consider” costs and benefits constitutes an “analytical” requirement. For example, in light of the requirement in Section 15(a) of the Commodity Exchange Act, the CFTC Office of General Counsel and Office of Chief Economist created a template for a uniform cost-benefit analysis methodology to be used in upcoming proposed rules. That template stated, in part, that Section 15(a) “does not require the Commission to quantify the costs and benefits of a rule or to determine whether the benefits of the order outweigh its costs; rather, it requires that the Commission ‘consider’ the costs and benefits of its actions.”

On the other hand, the courts or others may view these “consider” provisions as requiring some type of detailed cost-benefit analysis. On July 22, 2011, the U.S. Court of Appeals for the District of Columbia Circuit vacated an SEC final rule on proxy access, saying the Commission acted arbitrarily and capriciously for having failed to assess the economic implications of a rule adequately.<sup>76</sup> The Court specifically referenced (on p. 3 of the opinion) the requirements in Section 3(f) of the Exchange Act and Section 2(c) of the Investment Company Act of 1940 that the SEC consider the impact of the rule on efficiency, competition, and capital formation. Although the SEC had prepared a cost-benefit analysis and discussed it in the final rule, the Court said (on p. 7 of the opinion) that the SEC had “inconsistently and opportunistically framed the costs and benefits of the rule; failed adequately to quantify the certain costs or to explain why those costs could not be quantified; neglected to support its predictive judgments; contradicted itself; and failed to respond to substantial problems raised by commenters.” Citing an earlier

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<sup>76</sup> *Business Roundtable v. SEC*, D.C. Cir., No 10-1305, July 22, 2010. To view a copy of this decision, see [http://www.cadc.uscourts.gov/internet/opinions.nsf/89BE4D084BA5EBDA852578D5004FBBBE/\\$file/10-1305-1320103.pdf](http://www.cadc.uscourts.gov/internet/opinions.nsf/89BE4D084BA5EBDA852578D5004FBBBE/$file/10-1305-1320103.pdf).

case,<sup>77</sup> the Court said that the agency has a “statutory obligation to determine as best it can the economic implications of the rule.” Some observers believe that this case has “elevated the importance of economic analysis in rulemaking to implement” the Dodd-Frank Wall Street Reform Act.<sup>78</sup>

## Analytical Requirements Cited in 2010 Major Rules

The agencies issuing the 100 major rules that were published in 2010 cited a variety of analytical requirements in the preambles to their rules. (See **Appendix 2** to this report for a summary of the requirements that were cited in each of the 100 major rules, along with other information.) In many of these cases, however, the agencies indicated that an analysis was not required or was not prepared for the rules. For example:

- The agencies mentioned the Regulatory Flexibility Act’s analysis requirements in 99 of the 100 rules.<sup>79</sup> In 72 of the 99 rules, the agencies indicated that a regulatory flexibility analysis was not required, either because the rules were not expected to have a “significant economic impact on a substantial number of small entities” (SEISNSE, 53 rules),<sup>80</sup> the agency was not required to issue a notice of proposed rulemaking (12 rules),<sup>81</sup> or because the agency continued to rely on an analysis prepared for a similar rule (7 rules). In the remaining 27 rules, the agencies prepared an RFA analysis.
- The agencies mentioned the Paperwork Reduction Act in 96 of the 100 major rules.<sup>82</sup> In 21 of the 96 rules, the agencies said the regulation did not contain a covered collection of information, so the PRA did not apply. In 64 of the remaining 75 rules, the agencies indicated that the PRA did apply, and that they had done some type of analysis of paperwork burden hours or costs. In two rules, the Department of Agriculture cited a statutory exemption from the PRA.<sup>83</sup> In the

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<sup>77</sup> *Chamber of Commerce v. SEC*, 412 F.3d 133, 143 (D.C. Cir. 2005).

<sup>78</sup> See, for example, Yin Wilczek, “D.C. Circuit’s Proxy Access Ruling Raises Importance of Economic Review, Panel Says,” *BNA Daily Report for Executives*, August 2, 2011, p. EE-4; and David S. Hilzenrath, “Wall Street Finds Relief in Court from SEC Rules,” *Washington Post*, August 12, 2011, p. A-10.

<sup>79</sup> The RFA was not mentioned in the March 19 Food and Drug Administration rule restricting the sale and distribution of cigarettes and smokeless tobacco to protect children and adolescents. One agency official said that the reason the RFA was mentioned so frequently was because the agencies know that the SBA Office of Advocacy is reviewing the agencies’ actions regarding the RFA.

<sup>80</sup> Nevertheless, in 11 of these 54 rules, the agencies indicated that they conducted an analysis meeting the requirements of the RFA.

<sup>81</sup> The RFA states (5 U.S.C. § 604(a)) that a final regulatory flexibility analysis is required “When an agency promulgates a final rule under section 553 of this title, after being required by that section or any other law to publish a general notice of proposed rulemaking.”

<sup>82</sup> The four rules that did not mention the PRA were a January 25 DOE rule on the weatherization assistance program; a November 9 rule issued by the Centers for Medicare and Medicaid Services on the Medicare program; a November 9 SEC rule on Regulation SHO; and a December 22 rule issued by Treasury on management of federal agency disbursements.

<sup>83</sup> In these rules, the department cited Section 2904 of the Food, Conservation, and Energy Act of 2008 as providing that any regulations issued under Title II would be issued “without regard to” the PRA.



remaining nine rules, the agencies took various other types of actions (e.g., requested reinstatement of or referred to an earlier collection, or referred to another *Federal Register* notice).

- The agencies mentioned the Unfunded Mandates Reform Act in 77 of the 83 major rules issued by cabinet departments and independent agencies covered by UMRA. (Seventeen rules were issued solely by independent regulatory agencies that are not covered by the act.) However, the agencies prepared a written statement pursuant to Section 202 of UMRA in only 4 of the 77 rules. In the remaining 73 rules, the agencies either referred to another analysis as satisfying the requirements of UMRA (9 rules), or cited one of the many exemptions and exceptions to UMRA coverage, such as no “expenditures” of at least \$100 million in a year (30 rules), no UMRA “mandate” as defined in the Act (16 rules), or no prior notice of proposed rulemaking (9 rules).
- In the 83 rules that were issued at least in part by a cabinet department or independent agency covered by the analytical requirements in most executive orders, the agencies mentioned Executive Order 12866 in all 83 rules. However, in 4 of the 83 rules, the agencies did not indicate that an RIA had been prepared,<sup>84</sup> and in 6 rules on migratory bird hunting, the Fish and Wildlife Service relied on a previously developed RIA. In the remaining 73 rules, the agencies prepared some type of regulatory analysis, and usually provided detailed descriptions of the expected costs, benefits, and transfers in the preambles to the rules.
- The agencies cited Executive Order 13132 in 70 of the 83 covered major rules, but said that 60 of the rules did not require a federalism impact statement because the rule would not have significant federalism implications. The agencies said there were significant federalism implications in the remaining 10 rules, and discussed those impacts in the preambles.

The other crosscutting analytical requirements were mentioned much less frequently in the rule preambles, and those requirements were triggered even less frequently. For example:

- The agencies mentioned NEPA in 25 of the 100 major rules, and concluded that only 2 of the rules required an environmental impact statement. In the remaining 23 rules, the agencies either prepared an environmental assessment but ultimately issued a “finding of no significant impact” (FONSI, 10 rules), referenced an earlier environmental impact statement (6 rules), cited a categorical exemption to NEPA (6 rules), or said a NEPA analysis was not necessary (1 rule).

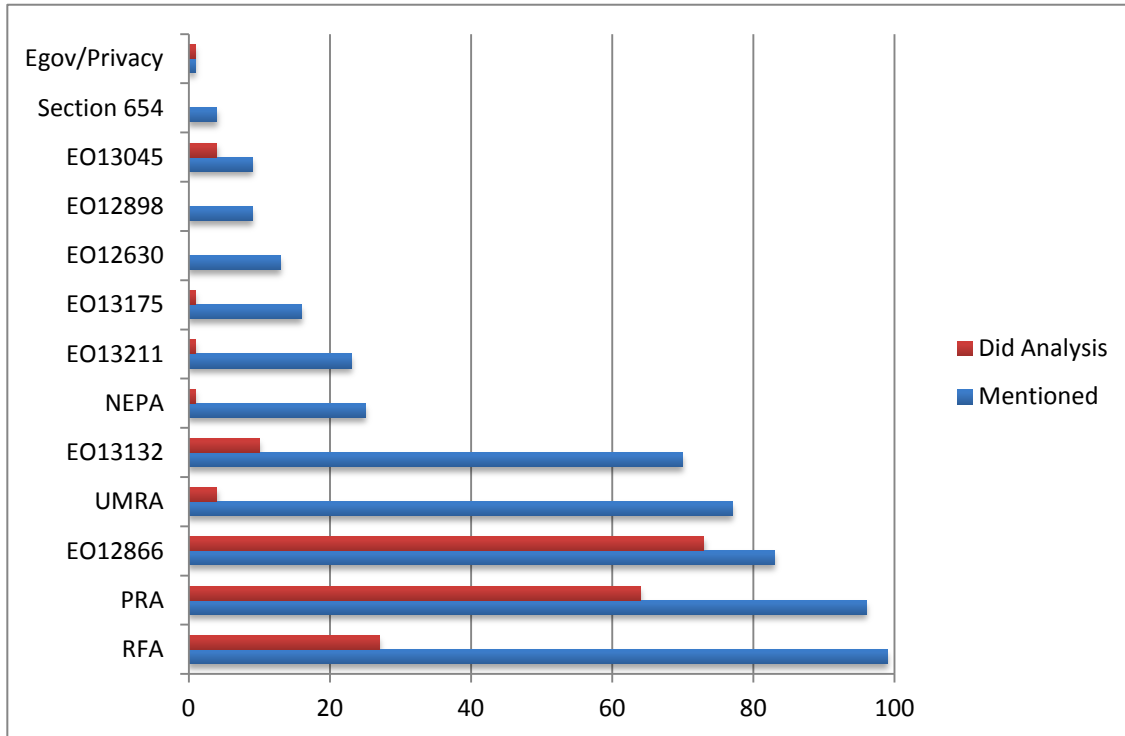
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<sup>84</sup> In one of these rules (a March 19 FDA rule on tobacco products), the agency said OMB did not require a new RIA because the statute required a rule identical to that issued in 1996. In another rule (a May 4 OTS rule on unfair or deceptive practices), the agency said an RIA was not needed because the rule eliminated a provision that an economically significant impact. In two other rules (a January 28 rule on risk-based capital guidelines and a November 16 DOD rule on the homeowner assistance program), the agencies did not indicate that an RIA had been done.

- The agencies mentioned Executive Order 13211 in 23 rules, and concluded that an energy impact analysis was required in only 1 of the rules. The agencies said that the other 22 rules were not “significant energy actions” as defined in the executive order, so no analysis was required.
- Executive Order 13175 was mentioned in 16 of the rules, but only one subpart of one rule triggered the tribal impact analysis. The agencies said that the other 15 rules did not have any tribal implications, so no analysis was required.
- Executive Order 12630 on “takings” was mentioned in 13 rules, and the agencies said that none of the rules triggered the analytical requirements.
- The agencies cited Executive Order 13045 on children and the environment in nine rules, and said four of them triggered the analytical requirement (which was satisfied by another analysis in two instances). In the other five rules, the agencies said the requirements of the executive order did not apply. In three of the five rules (all issued by EPA), the reason cited was because the rule was “based solely on technology performance.”
- Executive Order 12898 on environmental justice was mentioned in nine rules, but the agencies said that none of the rules triggered the analytical requirements.
- Only four rules (all issued by DOE) mentioned the “family assessment” requirement under Section 654 of the Treasury and General Government Appropriations Act of 1999 (P.L. 105-277), but none of the rules triggered the analysis requirement.
- Only one rule mentioned the privacy impact assessments required by the E-Government Act, indicating that the agency had updated a prior assessment, and one other rule mentioned having done a privacy impact assessment under the Section 522 of the 2005 appropriations bill.

**Figure 1** below graphically displays these results.

**Figure I: Some Analytical Requirements Were Rarely Mentioned in Major Rules**



Source: Analysis of preambles of major rules issued during calendar year 2010.

These results are similar to those reported by GAO in 2009. Of 139 major rules and 16 case study rules, the analytical requirements that were most commonly triggered were the PRA, the RFA, and EO 12866 (except for independent regulatory agencies like the SEC, which are not covered by the executive order). Other analytical requirements (e.g., UMRA and EO 13132) were mentioned in more than half of the rules, but the analysis was done only rarely.<sup>85</sup>

### Why Certain Analytical Requirements Were Not Mentioned

<sup>85</sup> U.S. Government Accountability Office, GAO-09-205, p. 25.

When the agencies did not mention a particular analytical requirement, it was usually clear from the context of the rule why it was not mentioned. For example, if a rule was issued by an independent regulatory agency that is not covered by EO 12866 or UMRA, it is understandable that the agency would not mention those requirements. If a rule only made changes in federal banking requirements, it is understandable why the agency would not mention having done an environmental impact statement under NEPA. If a rule has no apparent collection of information from the public, it is understandable why the agency would not mention the PRA.

In other cases, however, it was not clear why the agency did not mention a potentially applicable rulemaking requirement. For example, it was not clear why the Food and Drug Administration's March 19 rule restricting the sale and distribution of cigarettes and smokeless tobacco did not mention the RFA or UMRA, given that both statutes covered the agency, and the rule could conceivably affect small businesses or businesses in general.<sup>86</sup> Even if the agency ultimately concluded that the rule did not trigger the analytical requirements (e.g., because the rule would not have economic effects rising to a SEISNSE, or would not constitute a "mandate" under UMRA), some mention of the statutes would have been appropriate.<sup>87</sup> Several of the agency officials interviewed for this report indicated that the review offices in their departments and agencies encourage the agencies to mention all of the most important analytical requirements, even when an analysis is not required.

## Why Certain Analytical Requirements Were Not Triggered

In many of the rules, the agencies provided lengthy discussions of why certain analytical requirements did not apply. Thus, even though the agencies ultimately concluded that the analytical requirements in a statute or executive order were not applicable, some type of analysis appears to have occurred in order to reach that conclusion. For example:

- In 37 of the 53 rules in which the agencies certified that they would not have a SEISNSE, the agencies provided sometimes-lengthy discussions in the preambles as to why no RFA analysis was required.<sup>88</sup> In 11 other rules, the agencies certified that there was no SEISNSE, but still did an analysis that approximated a final regulatory flexibility analysis. For example, in a December 1 rule on medical loss ratio requirements, HHS said that an RFA analysis was not required for the rule because there had been no notice of proposed rulemaking. Nevertheless, HHS

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<sup>86</sup> See Appendix II of this report to find citations for this and other rules mentioned in the body of the report. The rules in the appendix are organized by date of publication in the *Federal Register*.

<sup>87</sup> An HHS official said during this review that the RFA and UMRA were probably not mentioned because the agency was statutorily required to simply reissue a 1996 rule on this issue, so no RFA or UMRA analysis was believed needed. An FDA official said that the agency probably should have indicated that this was the case in the preamble, as was done for EO 12866.

<sup>88</sup> For example, in a March 31, 2010, rule on "Electronic Prescriptions for Controlled Substances," the Drug Enforcement Administration within the Department of Justice described in detail (at 75 *Federal Register* 16302) the number of small entities affected and the size of those effects, and ultimately concluded that the rule would affect a substantial number of small entities, but would not have a significant economic effect on them.

said it considered the likely impact of the rule on small entities, and discussed the analysis conducted for a related rule, which led to the conclusion that this rule would not have a significant economic impact on a substantial number of small entities.

- Although the agencies prepared a full environmental impact statement under NEPA in only 2 rules, the agencies prepared somewhat less detailed environmental assessments in 10 rules, and referenced an earlier environmental impact statement in 6 other rules. As noted previously, these environmental assessments still discuss the need for the rule, alternative courses of action, and environmental effects.
- In an August 9 rule on “Cranes and Derricks in Construction,” the Occupational Safety and Health Administration (OSHA) within the Department of Labor provided a lengthy discussion of federalism effects, but ultimately decided that a formal federalism impact analysis under EO 13132 was not required.
- In an August 20 rule on emission standards for reciprocating internal combustion engines, EPA concluded that the rule was not a “significant energy action” under EO 13211, and prepared an analysis of energy effects that explained this conclusion.
- In a May 6 rule on the renovation, repair, and painting program, EPA said it assessed the impact of the rule on minority and low-income populations pursuant to EO 12898 as part of the overall economic analysis, but ultimately concluded that the rule would not have adverse effects.

In other cases, however, the agencies did not indicate that any type of analysis preceded the determination that a particular analytical requirement did not apply. The agencies sometimes used the same “boilerplate” language to indicate that the rule would not have a SEISNSE under the RFA, was not a mandate under UMRA, did not contain a covered collection of information under the PRA, or did not have sufficient federalism implications to warrant coverage under EO 13132. For example:

- In DOD’s April 9 rule on the relationship between the TRICARE program and employer-sponsored group health coverage, the department simply said the rule “will not have a significant impact on a substantial number of small entities for purposes of the RFA.” No further explanation was provided. Four other rules (two from DOD, two from CMS) contained similarly brief RFA certification statements.
- In an October 14 rule on oil and gas and sulphur operations in the outer continental shelf, the Bureau of Ocean Energy Management, Regulation and Enforcement within the Department of the Interior said the rule “will impose an unfunded mandate on State, local, or tribal governments or the private sector of more than \$100 million per year,” but then said the rule would not

have a “significant or unique effect” on those entities, and that an UMRA written statement was not required. No further explanation was provided.<sup>89</sup>

- In six rules on migratory bird hunting (August 30, August 31, September 1, September 23, and two on September 24), the Fish and Wildlife Service used the same language to address the requirements in the RFA (citing a 2008 analysis), and to indicate that the requirements of EO 12630, EO 13131, EO 13175, and EO 13211 did not apply.

In some of these cases, given the context of the rulemaking, the reasons for the disqualification were obvious and no lengthy explanation appeared necessary. For example, in DOD’s April 16, 2010, rule on retroactive stop loss special pay compensation, the rule was likely not a “mandate” under UMRA because it simply authorized certain payments to members of the armed forces.

In other cases, however, the reasons why these analytical requirements did not apply were not clear, and additional information beyond the “boilerplate” language would have been helpful to understand why the analytical requirements were not applicable. For example, in a July 16 rule on fee disclosures, the Employee Benefits Security Administration (EBSA) within DOL said the rule would impose paperwork costs of more than \$230 million in the first year of implementation, but later said the rule would not trigger the requirements in Section 202 of UMRA because it did not contain any mandate that could result in expenditures of \$100 million or more in any year.

### **Inconsistency in the Application of the Requirements**

In some of the rules that were issued by multiple agencies, the agencies disagreed as to whether certain types of analyses were required. For example:

- In a July 28 rule on registration of mortgage loan originators, the Office of the Comptroller of the Currency within the Department of the Treasury prepared a final regulatory flexibility analysis under the RFA (reversing a determination in the proposed rule that the rule would not have a SEISNSE after receiving a comment letter from SBA). However, the five other agencies that issued the rule with OCC (the Federal Reserve System, the National Credit Union Administration, the Farm Credit Administration, the Federal Deposit Insurance Corporation, and the Office of Thrift Supervision within the Department of the Treasury) all certified that the rule would not have a SEISNSE. In the same rule, the two issuing agencies that were covered by EO 12866 (OCC and OTS) disagreed as to whether the rule was economically

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<sup>89</sup> Section 203 of UMRA requires a small government plan before an agency establishes requirements that may have a significant or unique effect on small governments. The written statement requirement in Section 202 of UMRA does not require such significant or unique effects. A DOI official said during this review that an analysis was not required for this rule because it was issued without a prior NPRM.

significant under EO 12866. (OCC said it was, but OTS said it was not. Nevertheless, both prepared an RIA.)

- In five separate rules (a February 2 rule under the Mental Health Parity and Addiction Equity Act of 2008, a May 13 rule on coverage of children to age 26, a June 17 rule on grandfathered health plans, a July 19 rule on preventative services, and a July 23 rule on claims and review processes), DOL and HHS said the rules were economically significant under EO 12866, so they prepared detailed assessments of the rules' costs, benefits, and transfers. However, the Department of the Treasury said the five rules were not economically significant, and that such assessments were not required.
- In a May 7 rule on light-duty vehicle greenhouse gas emission standards and corporate average fuel economy that was jointly issued by EPA and the National Highway Traffic Safety Administration (NHTSA), EPA said that the rule had no federalism implications under EO 13132, but NHTSA did not say so, indicating that it was deferring consideration of preemption effects until later. Also, while EPA said the rule had no tribal implications under EO 13175, NHTSA did not mention the executive order. Finally, whereas NHTSA said it complied with EO 12898 by discussing effects on covered populations in the final environmental impact statement, EPA said the executive order did not apply with regard to greenhouse gas emissions, and it was not practical to determine the application with regard to other pollutants.

There also appeared to be some inconsistency across rules within certain agencies regarding when certain analytical requirements were applicable. For example, in a February 9 rule on nitrogen dioxide and a May 7 rule on greenhouse gas emissions and corporate average fuel economy standards, EPA said the rules were subject to EO 13045 because each was an “economically significant regulatory action as defined by Executive Order 12866, and EPA believes that the environmental health or safety risk addressed by this action has a disproportionate effect on children.” However, in a June 3 rule on greenhouse gas emissions and an August 20 rule on reciprocating internal combustion engines, EPA said the rules were not subject to EO 13045 because the agency interprets the executive order as “applying to those regulatory actions that concern health or safety risks, such that the analysis required under section 5-501 of the Order has the potential to influence the regulation.” EPA also said the executive order was not applicable because the rules did not “establish an environmental standard intended to mitigate health or safety risks.”

## **Interviews with Agency Officials**

The agency officials interviewed for this report generally indicated that the previously discussed list of crosscutting analytical requirements reflected the major requirements that they must consider in rulemaking. However, some of the officials suggested some

possible additions. For example, a DOT official said that one could argue the APA's "arbitrary and capricious" standard is essentially an analytical requirement, noting that Justice Antonin Scalia asserted long before he became a judge that agencies would have to do a cost-benefit analysis to show that their rules are "reasonable" under the APA.<sup>90</sup> Similarly, an FCC official said that the APA requires "reasoned decisionmaking," so it may be considered an "analytical requirement." The FCC official also suggested that OMB's 2005 bulletin on peer review might be considered an analytical requirement in that certain scientific and social scientific information would have to be reviewed before it could be used in a rule.<sup>91</sup>

The agency officials often indicated that the analytical requirements that are most commonly applicable to their rules are the RFA, the PRA (when an information collection is involved), and (for cabinet departments and independent agencies) the cost-benefit analysis requirements in EO 12866. On the other hand, several of the officials said that some of the crosscutting analytical requirements are rarely triggered by their agencies' rules. For example,

- An EPA official said that her agency did not issue many rules with "takings" implications under EO 12630, or that required privacy impact statements under the E-Government Act. EPA reportedly has a standard set of statutes and executive orders that they consider and discuss in the preambles of rules signed by the agency's administrator.
- DOI officials said that many of the executive orders that require analysis of effects on such topics as children's health or environmental justice generally do not apply to the department's rules, and therefore can be dealt with through "boilerplate" language.
- A DOE official said that because DOE is setting performance standards in its energy conservation rules (and not establishing traditional "command and control" regulatory requirements), many of the crosscutting analytical requirements do not apply.
- A USDA official noted that the 2008 farm bill explicitly permits the department to issue certain rules without regard to the PRA, and without an NPRM (which, in turn, permits the issuing agencies to avoid the analytical requirements in the RFA and UMRA).<sup>92</sup> He also said that NEPA primarily

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<sup>90</sup> As one author noted, in the courts' application of the "hard look" doctrine under the APA, they "examine the agency's explanatory material to determine whether the agency used the correct analytical methodology..." Thomas O. McGarity, "The Courts and the Ossification of Rulemaking: A Response to Professor Seidenfeld," *Texas Law Review*, volume 75 (1997), p. 527.

<sup>91</sup> Office of Management and Budget, "Final Information Quality Bulletin for Peer Review," 70 *Federal Register* 2664, January 14, 2005, available at [http://www.whitehouse.gov/sites/default/files/omb/assets/omb/fedreg/2005/011405\\_peer.pdf](http://www.whitehouse.gov/sites/default/files/omb/assets/omb/fedreg/2005/011405_peer.pdf).

<sup>92</sup> Section 1601(c)(2) of the 2008 farm bill (H.R. 6124, 110<sup>th</sup> Congress, P.L. 110-246) states that the "promulgation of the regulations and administration of this title [Title I on commodity programs] and the amendments made by this title shall be made without regard to-- (A) chapter 35 of title 44, United States Code (commonly known as the "Paperwork



applies to rules issued by the Forest Service and the Animal and Plant Health Inspection Service (APHIS), and that USDA only rarely issues rules that trigger other analytical requirements (e.g., privacy assessments and family assessments). Finally, he said the reason that UMRA was not mentioned at all in one rule (the “access to pasture” rule) was probably because it was not likely to have a mandate, and that the issuing agency should have briefly indicated that was the case.

- An FDA official said that the agency often does not mention the analytical requirements that are not applicable to its rules, but should probably do so in some way because those requirements “are there for a reason, and we should explain why we did not do an analysis.”

Some of the agencies indicated that although certain rules do “trip the wire” for analysis, the trigger is not due to compliance costs. For example:

- Officials from DOI indicated most of the “major” or “economically significant” rules that the department issues are the migratory bird hunting rules that have at least a \$100 million annual effect on the economy because of consumer spending, not compliance costs. To avoid having to do a full cost-benefit analysis for each rule, DOI relies on a 1982 opinion from OIRA allowing the department to update existing RIAs when new data become available, and to do a “thorough review” of the RIA every five years.<sup>93</sup>
- An HHS official said that most CMS major rules are transfer payments, and the analysis done is more like the type scoring that CBO would do for legislation (i.e., looking at budgetary impacts) than a true cost-benefit analysis. She said these transfer rules often have to be done every year, so if they had to do a full cost-benefit analysis it would not only be uninformative, but could make it difficult for the agency to issue the rules on time.
- A USDA official noted that five of the six major rules issued in 2010 were transfer rules, which require a different type of analysis than rules with \$100 million or more in compliance costs.<sup>94</sup> For transfers, he said, the analysis is usually less rigorous, and is more of an accounting exercise in which the agency simply reports the amount of money being sent out, and whether that is an increase or decrease from previous years. He said USDA typically works

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Reduction Act”); (B) the Statement of Policy of the Secretary of Agriculture effective July 24, 1971 (36 Fed. Reg. 13804), relating to notices of proposed rulemaking and public participation in rulemaking; and (C) the notice and comment provisions of section 553 of title 5, United States Code.” Section 2904(b) of the legislation contains similar language for Title II on conservation programs.

<sup>93</sup> Letter from Christopher C. DeMuth, OIRA Administrator, to G. Ray Arnett, Assistant Secretary for Fish and Wildlife and Parks, Department of the Interior, April 20, 1982, available from the author.

<sup>94</sup> The official said although the APA contains an exemption for matters relating to federal benefits, under the provisions of the “Statement of Policy of the Secretary of Agriculture effective July 24, 1971,” issued by Secretary Hardin in 1971 (36 *Federal Register* 13804 (the “Hardin Memorandum”), the Department normally engages in rulemaking related to federal benefits despite that exemption.

it out in advance with OIRA that the analysis will primarily be an accounting exercise, with a brief qualitative discussion of the benefits. If there are administrative costs in addition to the transfers, then other types of analysis (e.g., PRA or RFA) may be the focus of OIRA's review.

## Agency- or Issue-Specific Analytical Requirements

In addition to the crosscutting analytical requirements, several of the major rules that were issued in 2010 and/or the agency officials that were interviewed for this report mentioned agency- or issue-specific analytical requirements. For example:

- In three of the four DOE major rules, the department indicated that the Energy Policy and Conservation Act (EPCA) was the primary factor in the analysis. As noted previously, EPCA requires that energy conservation standards must be designed to “achieve the maximum improvement in energy efficiency” that “is technologically feasible and economically justified” (42 U.S.C. § 6295(o)(2)(A) and 6316(a)). Also, the standard must “result in significant conservation of energy” (42 U.S.C. § 6295(o)(3)(B) and 6316(a)). A DOE official said that EPCA is “the standard by which our rules are ultimately measured. Therefore, he said, the bulk of the regulatory analysis is done to satisfy EPCA, with the other required analyses “tiered off” the EPCA analysis. For example, in the January 8 rule setting energy conservation standards for commercial clothes washers, more than 50 pages of the preamble were devoted to discussing the analyses done to satisfy EPCA, but only 4 pages were devoted to the various crosscutting analytical requirements (e.g., EO 12866, the RFA, the PRA, and other executive orders).
- An SEC official said there are several provisions in the statutes underlying most of the agency's rules that require certain factors to be considered during their development. For example, Section 202(c)(1) of the Advisers Act (15 U.S.C. § 80b-2(c)) requires SEC to “consider, in addition to the protection of investors, whether the action will promote efficiency, competition, and capital formation.” Also, Section 204 of the Act (15 U.S.C. § 80b-4) states that SEC must consider whether the rule is “necessary or appropriate in the public interest or for the protection of investors.” Section 2(c) of the Investment Company Act (15 U.S.C. § 80a-2(c)) requires the SEC to consider “whether the action will promote efficiency, competition, and capital formation.” Section 3(f) of Exchange Act (15 U.S.C. § 78c(f)) requires SEC to consider effects on efficiency, competition, and capital formation, and Section 23(a)(2) of the Act, requiring consideration of effects on competition. Section 23(a)(2) of the Exchange Act (15 U.S.C. § 78w(a)(2)) requires SEC to consider the impact on competition, and prohibits the Commission from adopting any rule that would impose a competition burden not necessary or appropriate. The SEC official said that these provisions, although

important, are not what drives the agency to do cost-benefit analyses for its rules, and that the agency had done such analyses before these statutes were enacted. He said the analyses are primarily done as a way to ensure that the agency's rules are well considered, not in response to any statutory or executive order requirement.<sup>95</sup>

- A USDA official noted two agency-specific analytical requirements: (1) Section 304 of the Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994 (P.L. 103-354), which requires an analysis of risk and costs/benefits for each rule that is expected to have a \$100 million impact on the economy in 1994 dollars, and whose primary purpose is to regulate issues of human health or safety;<sup>96</sup> and (2) Departmental Regulation 4300-4, which requires a “civil rights impact analysis” for any rule to determine possible adverse impacts on women, minorities, and disabled stakeholders and USDA employees.<sup>97</sup>
- An official at the Department of Commerce said that the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. §§ 1801-1884) contains provisions requiring NOAA to balance conservation and environmental interests with the sustainability of the fishing industry. Therefore, she said the department has to prepare a “kind of indirect cost-benefit analysis” to achieve that balance. In general, she said, the Magnuson-Stevens Act establishes the basis for what NOAA is trying to do, and then the requirements of EO 12866 and the RFA come into play.
- In more than a dozen of its rules, the Department of Health and Human Services cited the previously-mentioned requirement in Section 1102(b) of the Social Security Act that it analyze the effect of its rules on small rural hospitals. An HHS official also said that some statutes contain rule specific analytical requirements.
- One rule issued by the Drug Enforcement Administration within the Department of Justice cited a requirement in OMB's December 2004 E-Authentication Guidance for Federal Agencies (M-04-04) that the agency prepare a risk assessment to determine the level of assurance needed to allow the use of electronic prescriptions for controlled substances.<sup>98</sup>

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<sup>95</sup> These requirements were also mentioned in several of the SEC's major rules. For example, the Section 202(c)(1) and Section 204 requirements were cited in the January 11 rule on custody of funds. The Section 204 requirements were also mentioned in the agency's July 14 rule on political contributions by certain investment advisors. The Section 2(c) requirement was mentioned in the March 4 rule on money market fund reform.

<sup>96</sup> The Commodity Credit Corporation also mentioned this requirement in a June 3, 2010, major rule on the conservation stewardship program,

<sup>97</sup> For more information, see <http://www.ocio.usda.gov/directives/doc/DR4300-004.pdf>. Several of the USDA major rules also mentioned the requirement for a civil rights impact analysis pursuant to this departmental regulation.

<sup>98</sup> This document is available at <http://www.whitehouse.gov/sites/default/files/omb/memoranda/fy04/m04-04.pdf>.

- In an April 1 rule on electronic fund transfers, the Federal Reserve System cited a requirement for an economic impact analysis under Section 904(a)(2) of the Electronic Fund Transfer Act (15 U.S.C. § 1993 et seq.).
- An EPA official noted that the Clean Air Act requires that certain rules have an “ample margin of safety” or meet certain levels of risk (e.g., “protective of human health”). Therefore, she said the agency has to prepare analyses showing that those criteria have been satisfied.
- OSHA said in its August 9 rule on cranes and derricks in construction that the Occupational Safety and Health Act of 1970 requires the agency to demonstrate the “technological and economic feasibility of its rules.”

## Consolidation of Analytical Requirements

The second objective of this report is to examine whether the various crosscutting analytical requirements could or should be consolidated or otherwise changed to make the federal rulemaking process more efficient and effective. This section will first note several factors that must be considered to determine whether the requirements could be combined or consolidated. It will then provide examples from the 2010 major rules of overlapping requirements, and actions the agencies have taken to combine the requirements. Finally, the section will provide information from interviews with agency officials on whether the analytical requirements could or should be combined.

### Factors to Consider When Comparing Analytical Requirements

Comparison of the crosscutting analytical requirements to determine whether they could be combined or consolidated requires consideration of at least three factors: (1) which agencies and rules the different analytical requirements cover, (2) the amount of discretion that agencies have to determine whether the requirements are triggered, and (3) the specific issues that the agencies are required to address in the analyses. The more similar the analytical requirements are in these respects, the easier it is likely to be to consolidate them into a single statute or executive order.

### Agencies and Rules Covered

Some of the analytical requirements (e.g., NEPA, the RFA, the PRA) apply to virtually all executive branch agencies, including independent regulatory agencies like the Federal Reserve and the SEC. However, many other requirements (e.g., UMRA, EO 12866, and EO 13132) only apply to cabinet departments and independent agencies like EPA, and specifically exclude independent regulatory agencies.<sup>99</sup> In fact, only two of the executive

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<sup>99</sup> Independent regulatory agencies may, however, be covered by certain non-analytical requirements in these executive orders (e.g., the requirement in EO 12866 to prepare a regulatory agenda), or may be encouraged to comply with other

orders appear to apply to independent regulatory agencies.<sup>100</sup> Therefore, consolidation of the analytical requirements would require either applying certain requirements to independent regulatory agencies for the first time, or excluding independent regulatory agencies from certain requirements that already cover them.

The analytical requirements differ even more dramatically in terms of the types of rules that are included and excluded from coverage. For example, although both EO 12866 and UMRA apply to the same agencies (cabinet departments and independent agencies, but not independent regulatory agencies), UMRA contains many more exclusions and exceptions than EO 12866, and therefore applies to significantly fewer rules than the executive order. In one notable difference, EO 12866 generally applies to all rules that are expected to have a \$100 million annual “effect on the economy” (which, as noted previously, can include costs, benefits, federal expenditures, user fees, consumer surplus transfers, and other types of effects), and the \$100 million figure is not adjusted for inflation. UMRA, on the other hand, only applies to rules that require an “expenditure” of \$100 million in any year (adjusted for inflation) by the private sector, or by state, local, or tribal governments in the aggregate. Therefore, a rule that is expected to reduce the amount of income received by private sector companies by more than \$200 million (e.g., fishing restrictions, or product importation changes that drive down the cost of domestic products) would be covered by EO 12866, but would not be covered by UMRA because the rule did not require those companies to actually spend any money. In addition to the “expenditures” exclusion, UMRA also excludes final rules that:

- Do not require a notice of proposed rulemaking.<sup>101</sup>
- Incorporate requirements specifically set forth in law.<sup>102</sup>
- Are not “federal mandates,” which is defined in title I of the Act as an “enforceable duty” that is not “a condition of Federal assistance” or “a duty arising from participation in a voluntary Federal program.”<sup>103</sup>
- Enforce the constitutional rights of individuals.
- Enforce rights prohibiting discrimination.<sup>104</sup>

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requirements.

<sup>100</sup> Most of the executive orders define a covered “agency” as “any authority of the United States that is an “agency” under 44 U.S.C. § 3502(1), other than those considered to be independent regulatory agencies, as defined in 44 U.S.C. 3502(5).” However, EO 12630 does not contain this limitation, instead requiring action by “each Executive department and agency.” Similarly, EO 12898 generally requires action by “each Federal agency.”

<sup>101</sup> The agencies cited this exclusion in at least 9 of the 100 major rules published in 2010, and could have cited it in several other rules that were issued without an NPRM. The rules in which this reason was cited included a February 2 rule issued by multiple agencies under the Mental Health Parity and Addiction Equity Act of 2008; and rules issued by multiple agencies on May 13, June 17, June 28, July 19, and July 23 under the Patient Protection and Affordable Care Act.

<sup>102</sup> In a July 28 major rule on registration of mortgage loan originators, the issuing agencies said that the written statement requirements in UMRA did not apply because the rule only incorporated requirements in the underlying statute.

<sup>103</sup> In two rules (a January 19 rule issued by the Federal Emergency Management Agency on special community disaster loans, and a November 8 rule issued by the Federal Highway Administration on the “real-time system management information program”), the agencies said UMRA did not apply because conditions of federal financial assistance are not considered “mandates.” DHS said a September 24 rule on the citizenship and immigration services fee schedule was not covered by UMRA because any mandate arose from a voluntary federal program.

<sup>104</sup> In two rules issued by the Department of Justice on September 15, the department said the rules were not subject to

- Provide for emergency assistance.
- Are necessary for national security or foreign affairs.
- Relate to certain programs under the Social Security Act.

None of these exclusions are in EO 12866. In essence, therefore, the set of rules that are subject to UMRA’s analytical requirements are a subset of the rules that are subject to the analytical requirements in EO 12866. In 1998, GAO reported that 78 of the 110 economically significant final rules issued in the first two years of UMRA’s implementation did not require a written statement for one or more of the above reasons.<sup>105</sup> In 2004, GAO said that federal agencies identified only 9 of the 122 major and/or economically significant rules published in 2001 or 2002 as containing mandates under UMRA.<sup>106</sup> GAO also reported that 65 of the 113 rules that had not triggered UMRA had impacts on nonfederal parties that those affected might perceive as unfunded mandates. In February 2011 congressional testimony, GAO reiterated these conclusions, noting that there are 14 reasons why a rule would not be considered a “mandate” under UMRA.<sup>107</sup>

The other analytical requirements also contain various exclusions and exceptions. For example:

- The RFA’s regulatory flexibility analysis requirements (like the UMRA written statement requirements discussed above) do not apply to final rules that do not require a notice of proposed rulemaking. In at least 12 of the 100 major rules issued in 2010, the agencies said the RFA did not apply because there was no NPRM, and other agencies could have cited this reason in a number of other rules. GAO estimated in 1998 that half of all final rules issued the previous year did not have a prior notice of proposed rulemaking.<sup>108</sup>
- Also, courts have ruled for more than 25 years that agencies need not prepare regulatory flexibility analyses if the effects of a rule on an industry are indirect.<sup>109</sup> For example, in its February 9 major rule establishing

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UMRA because it excludes rules prohibiting discrimination on the basis of handicap or disability.

<sup>105</sup> U.S. General Accounting Office, *Unfunded Mandates: Reform Act Has Had Little Effect on Agencies’ Rulemaking Actions*, GAO/GGD-98-30, February 4, 1998.

<sup>106</sup> U.S. General Accounting Office, *Unfunded Mandates: Analysis of Reform Act Coverage*, GAO-04-637, May 12, 2004.

<sup>107</sup> Testimony of Denise M. Fantone, Director, Strategic Issues, U.S. Government Accountability Office, before the Subcommittee on Technology, Information Policy, Intergovernmental Relations and Procurement Reform, House Committee on Oversight of Government Management, available at <http://www.gao.gov/products/GAO-11-385T>.

<sup>108</sup> U.S. General Accounting Office, *Federal Rulemaking: Agencies Often Published Final Actions Without Proposed Rules*, GAO/GGD-98-126, August 31, 1998.

<sup>109</sup> See, for example, *Mid-Tex Electric Cooperative, Inc. v. FERC*, 773 F.2d 327, 343 (D.C. Cir. 1985). See also *American Trucking Associations, Inc. v. U.S. Environmental Protection Agency*, 175 F.3d 1027 (D.C. Cir. 1999), affirmed in part and reversed in part, *Whitman v. American Trucking Associations*, 532 U.S. 457 (2001), in which the U.S. Court of Appeals for the District of Columbia ruled that EPA had complied with the RFA because the states, not EPA, had the direct authority to impose requirements to control ozone and particulate matter consistent with EPA health standards.

primary national ambient air quality standards (NAAQS) for nitrogen dioxide, EPA said the rule did not require a regulatory flexibility analysis “because NAAQS themselves impose no regulations upon small entities.” (According to the agency’s regulatory impact analysis, implementation of the NAAQS by the states was estimated to cost between \$270 million and \$580 million in the year 2020.)<sup>110</sup>

- The PRA does not apply to rules that do not contain a covered “collection of information.” Of the 100 major rules that were published in calendar year 2010, 25 of the rules did not appear to contain an information collection that triggered an analysis under the PRA.<sup>111</sup> Also, some statutes specifically exclude certain rules from PRA coverage. For example, in two of the major rules published in 2010, the Commodity Credit Corporation within USDA stated that Section 2904 of the Food Conservation, and Energy Act of 2008 provides that any regulation under Title II of the Act would be issued “without regard to” the PRA.<sup>112</sup>
- The analytical requirements in EO 12866 do not apply to rules that are not “economically significant.” Between 1997 and 2010, federal agencies published between 2,900 and 4,500 final rules each year, or an average of about 3,600 rules each year. Of these, between 50 and 100 rules each year were considered “major” under the Congressional Review Act (which is definitionally very similarly to “economically significant” in EO 12866), or about 68 rules each year.<sup>113</sup> Therefore, on average, more than 98% of all final rules were not subject to the analytical requirements of EO 12866 and OMB Circular A-4, even before excluding rules that were issued by independent regulatory agencies or were otherwise exempt from the executive order’s requirements. Also, Section 6(a)(3)(D) of EO 12866 allows agencies to comply with the analytical requirements in the executive order “to the extent

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<sup>110</sup> EPA has taken this position in other rules. For example, when EPA published a final rule establishing national ambient air quality standards (NAAQS) for particulate matter in October 2006, the agency certified the rule as not triggering the RFA “because NAAQS themselves impose no regulations on small entities.” In its cost-benefit analysis for the rule, EPA estimated the cost of installing controls to meet the health standard at \$5.6 billion in 2020. See U.S. Environmental Protection Agency, “National Ambient Air Quality Standards for Particulate Matter; Final Rule,” 71 *Federal Register* 61144, 61217. See also U.S. Environmental Protection Agency, “Primary National Ambient Air Quality Standard for Sulfur Dioxide,” 74 *Federal Register* 64810, at 64865, December 8, 2009; and “National Ambient Air Quality Standards for Carbon Monoxide,” 76 *Federal Register* 8158, at 8195, February 11, 2011.)

<sup>111</sup> In 21 of the rules, the agencies specifically said there were no new collections of information. In four other rules, the agencies did not mention the PRA, which could indicate that there were no covered information collections.

<sup>112</sup> The two rules were issued on June 3 and July 28 on the Conservation Stewardship Program and the Conservation Reserve Program, respectively.

<sup>113</sup> Section 3(f)(1) of the executive order defines an economically significant rule as one that 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.” In its guidance on the CRA, OMB said that the main difference between “economically significant” and “major” rules is that some rules may be captured by the CRA definition that are not considered “economically significant” under EO 12866, “notably those rules that would have a significant adverse effect on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.” See [http://www.whitehouse.gov/sites/default/files/omb/assets/memoranda\\_2010/m99-13.pdf](http://www.whitehouse.gov/sites/default/files/omb/assets/memoranda_2010/m99-13.pdf).

practicable” in “emergency situations or when an agency is obligated by law to act more quickly than normal review procedures allow.” In at least one of the major rules issued in 2010, the issuing agencies invoked this exception and did not indicate whether a regulatory impact analysis was prepared.<sup>114</sup>

## Agency Discretion

Some of the analytical requirements give agencies relatively little discretion to decide whether their rules are covered by the requirement. For example, if a rule requires 10 or more persons outside of the federal government to provide facts or opinions to the agency, a third party, or the public in any form or format in response to identical questions, the agency must comply with the information collection requirements in the PRA. If a rule issued by a cabinet department or independent agency is expected to have a \$100 million annual effect on the economy of any kind, then the rule would generally be covered by the analytical requirements in EO 12866. Even if the agency understates those effects to fall under the \$100 million threshold, OMB may determine that the rule is economically significant for other reasons (e.g., the rule may “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”).<sup>115</sup>

However, other analytical requirements give agencies wide latitude to determine whether their rules are covered, which can lead to inconsistency in the application of those requirements. Perhaps most notable in this regard is the RFA, which allows agencies to avoid conducting an initial or final regulatory flexibility analysis if they certify that their rules will not have a “significant economic impact on a substantial number of small entities.” The RFA does not define the terms “significant economic impact” or “substantial number of small entities,” thereby giving federal agencies substantial discretion regarding when the act’s analytical requirements are initiated. In addition, some agencies do not consider an RFA analysis to be required if the rule is expected to have significant positive effects on small entities.<sup>116</sup>

GAO has examined the implementation of the RFA several times within the past 20 years, and a recurring theme in GAO’s reports is a lack of clarity in the Act and a resulting variability in its implementation. For example, in 1991 GAO reported that each of the four federal agencies that it reviewed had a different interpretation of key RFA

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<sup>114</sup> This was the January 28 rule issued by the Office of the Comptroller of the Currency, the Federal Reserve System, the Federal Deposit Insurance Corporation, and the Office of Thrift Supervision, in which the agencies cited a November 15, 2009, deadline for the rule’s implementation.

<sup>115</sup> Section 6(a)(3)(C) of Executive Order 12866 states that rules may be identified as economically significant by the agency or by the Administrator of OIRA.

<sup>116</sup> See, for example, U.S. Department of Health and Human Services, “Patient Protection and Affordable Care Act; Establishment of Consumer Operated and Oriented Plan (CO-OP) Program,” *76 Federal Register* 43237, July 20, 2011, in which the department said that the Centers for Medicare and Medicaid Services interprets the RFA analysis requirement “as applying only to regulations with negative impacts.” However, the department said it routinely prepares a voluntary analysis when there are significant positive impacts.



provisions.<sup>117</sup> In 1994, GAO again reported that agencies' compliance with the RFA varied widely from one agency to another and that agencies were interpreting the statute differently.<sup>118</sup> In a 1999 report, GAO concluded that agencies had broad discretion to determine what the statute required.<sup>119</sup> In a 2000 report, GAO said that EPA had certified more than 95% of its final rules issued in the late 1990s, and characterized EPA as having a "high threshold" for analysis (albeit within the discretion permitted in the statute).<sup>120</sup> In all of these reports, GAO suggested that Congress consider clarifying the act's requirements and/or give the Small Business Administration (SBA) or some other entity the responsibility to develop criteria for whether and how agencies should conduct RFA analyses.<sup>121</sup> In 2001, GAO testified that the promise of the RFA might never be realized until Congress or some other entity defines what a "significant economic impact" and a "substantial number of small entities" mean in a rulemaking setting.<sup>122</sup> However, other observers have indicated that the definitions of these terms should remain flexible because of significant differences in each agency's operating environment.<sup>123</sup>

Other analytical requirements also give agencies a great deal of discretion to decide whether an analysis is required. For example:

- NEPA requires a detailed statement on the environmental impact of rules that are "major Federal actions significantly affecting the quality of the human environment." As discussed in a Congressional Research Service report, just about every word in the term "major Federal actions significantly affecting the quality of the human environment" has been disputed, scrutinized, and defined by the courts.<sup>124</sup>
- Section 654 of the Treasury and General Government Appropriations Act, 1999 (P.L. 105-277) requires agencies to prepare a family policymaking assessment before issuing any rule that "may affect family well-being." As one observer noted, the determination of whether a family assessment is

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<sup>117</sup> U.S. General Accounting Office, *Regulatory Flexibility Act: Inherent Weaknesses May Limit Its Usefulness for Small Governments*, GAO/HRD-91-16, January 11, 1991.

<sup>118</sup> U.S. General Accounting Office, *Regulatory Flexibility Act: Status of Agencies' Compliance*, GAO/GGD-94-105, April 27, 1994.

<sup>119</sup> U.S. General Accounting Office, *Regulatory Flexibility Act: Agencies' Interpretations of Review Requirements Vary*, GAO/GGD-99-55, April 2, 1999.

<sup>120</sup> U.S. General Accounting Office, *Regulatory Flexibility Act: Implementation in EPA Program Offices and Proposed Lead Rule*, GAO/GGD-00-193, September 20, 2000, p. 31.

<sup>121</sup> Section 612 of the RFA requires the SBA Chief Counsel for Advocacy to "monitor" agencies' compliance with the RFA, but does not require SBA to issue binding rules defining key terms.

<sup>122</sup> U.S. General Accounting Office, *Regulatory Flexibility Act: Key Terms Still Need to Be Clarified*, GAO-01-669T, April 24, 2001.

<sup>123</sup> See, for example, page 17 of the SBA Office of Advocacy's guidance on the implementation of the RFA, available at <http://www.sba.gov/sites/default/files/rfaguide.pdf>, which says "Significance should not be viewed in absolute terms...."

<sup>124</sup> U.S. Congressional Research Service, *Overview of National Environmental Policy Act (NEPA) Requirements*, CRS Report RS20621, by Kristina Alexander, January 11, 2008, available at <http://www.nationalaglawcenter.org/assets/crs/RS20621.pdf>.

required, and determinations within those assessments, “call for extremely subjective judgments on the part of the agency.”<sup>125</sup>

- EO 12630 requires agencies (to the extent permitted by law) to identify the “takings implications” of any proposed regulatory action submitted to OMB, and should identify and discuss “significant” takings implications in notices of proposed rulemakings. Of the 13 major rules published in 2010 that mentioned EO 12630, the agencies indicated that none of them required a takings analysis.
- EO 12898 requires agencies (to the “extent permitted by existing law”, and “whenever practical and appropriate”) to collect, maintain, and analyze information assessing and comparing environmental and human health risks borne by populations identified by race, national origin, or income. Also, “to the extent practical and appropriate,” the agencies are to use this information to determine whether their programs, policies, and activities have “disproportionately high and adverse human health or environmental effects on minority populations and low-income populations.” The executive order does not indicate what constitutes a “disproportionately high” effect. Also, the phrase “whenever practical and appropriate” is repeated 10 times in the executive order. Of the eight rules that mentioned EO 12898, the agencies indicated that none of them triggered the order’s analytical requirements.<sup>126</sup>
- EO 13045 requires agencies (unless prohibited by law) to evaluate the environmental health or safety effects of each rule considered economically significant under EO 12866 that “concern[s] an environmental health risk or safety risk that an agency has reason to believe may disproportionately affect children.” The executive order does not indicate what constitutes a “disproportionate” effect, or even indicate whether the effect must be a negative effect. The analysis is also required “to the extent permitted by law and appropriate, and consistent with the agency’s mission.”
- EO 13132 requires agencies (“to the extent practicable and permitted by law”) to prepare an impact statement for any rule with “federalism implications,” which is defined as a rule with “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.” The term “substantial direct effects” is not defined in the executive order. Of the 69 major rules published in 2010 that mentioned EO

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<sup>125</sup> Lubbers, p. 265.

<sup>126</sup> In the June 3 greenhouse gas “tailoring” rule, EPA said it was “not practicable to identify and address disproportionately high and adverse health or environmental effects on minority populations and low income populations” under EO 12898.

13132, the agencies indicated that 59 of them did not have sufficient federalism implications to warrant an analysis.<sup>127</sup>

- EO 13175 requires agencies (“to the extent practicable and permitted by law”) to prepare a tribal summary impact statement for any rule that has “tribal implications and that preempts tribal law.” “Tribal implications” is defined as including rules 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.” The term “substantial direct effects” is not defined in the executive order. Of the 16 major rules issued in 2010 that mentioned EO 13175, the agencies indicated that 15 of them did not have tribal implications that triggered the analytical requirement.
- EO 13211 requires agencies (to the extent permitted by law) to prepare a statement of energy effects for any rule considered a “significant energy action,” which is defined as any significant regulatory action under EO 12866 that is “likely to have a significant adverse effect on the supply, distribution, or use of energy.”<sup>128</sup> The executive order does not define the term “significant adverse effect.” Of the 23 major rules issued in 2010 that mentioned EO 13211, the agencies indicated that 22 of them were not significant energy actions that required analysis.

Because the analytical requirements differ in the amount of discretion that agencies have regarding whether an analysis is required, reconciliation and consolidation of these requirements would necessitate either more discretion or less discretion than is currently permitted in individual executive orders.

## Nature of the Requirements

Some of the broad themes in the crosscutting analytical requirements are quite similar. As **Table 3** below shows, all four of the analytical requirements that were most commonly cited in the 2010 major rules (the RFA, the PRA, UMRA, and EO 12866) generally require some type of (1) discussion of the need for the regulatory action, including the statutory or legal basis; (2) assessment of costs and/or benefits of the rule; and (3) discussion of alternatives to the regulatory action that could have been selected. Other analytical requirements also often have one or more of these three elements.<sup>129</sup>

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<sup>127</sup> In a January 15 major rule on positive train control systems, the Federal Railroad Administration said the rule would “have no federalism implications, other than the preemption of state laws,” which it said was caused by the underlying statute, not the regulation. Therefore, the agency said no federalism impact statement was required.

<sup>128</sup> The OIRA administrator can also designate a rule as a “significant energy action.”

<sup>129</sup> For example, EO 13132 on federalism requires agencies to “consult with appropriate State and local officials as to the need for national standards and any alternatives that would limit the scope of national standards or otherwise preserve State prerogatives and authority.” The federalism impact statement is to include the “agency’s position supporting the need to issue the regulation.” EO 13211 on energy effects requires agencies to describe “reasonable alternatives to the action with adverse energy effects and the expected effects of such alternatives on energy supply,

**Table 3: Similar Elements in Analyses Pursuant to the RFA, UMRA, the PRA, and EO 12866**

<b>Elements Required in Analysis</b>	<b>RFA</b>	<b>UMRA</b>	<b>PRA</b>	<b>EO 12866</b>
Need/legal basis	IRFA is to include a “description of the reasons why action by the agency is being considered” and “the objectives of, and legal basis for,” the rule; FRFA to include a “statement of the need for, and objectives of, the rule.”	Section 202 written statement is to include an “identification of the provision of Federal law under which the rule is being promulgated.”	<i>Federal Register</i> notice is to include a “brief description of the need” for the information collection, and the submission to OMB is to include the statutory authority for the collection.	Agencies are to provide to OMB a “description of the need for the regulatory action and...how the regulatory action will meet that need”; also an “explanation of the manner in which the regulatory action is consistent with a statutory mandate.”
Assessment of costs and/or benefits of the rule	FRFA is to include a “description of... [the] compliance requirements” including the number and classes of affected small entities and the skills needed.	Written statement is to include a “qualitative and quantitative assessment of the anticipated costs and benefits of the Federal mandate.”	Notice to include an “estimate of the burden that shall result” from the information, and agency review includes a “specific, objectively supported estimate of burden.”	Agencies are to provide an “assessment, including the underlying analysis,” of costs and benefits anticipated from the action, including quantification (if feasible).
Alternatives and reasons for selection	IRFA is to “discuss significant alternatives” to the rule; FRFA to include “steps the agency has taken to minimize” the economic effects of the rule, and explain why other significant alternatives not selected.	Section 205 generally requires written statement to “identify and consider a reasonable number of regulatory alternatives” and to select the least costly, most cost-effective, or least burdensome option (or explain why).	Agencies are to certify to OMB and provide evidence that paperwork burden has been reduced to extent possible (e.g., through consideration of different reporting provisions, exemptions, and simplified provisions).	Economic analysis is to include an “assessment... of costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation.” Agencies are to explain why the planned action is preferable to the alternatives. (In principles, agencies are to select the alternative that maximizes net benefits.)

distribution, and use.”

Other types of information or analysis are stipulated in two or more of the requirements. For example, both UMRA and EO 12866 (including Circular A-4) require a discussion of effects on “health, safety, and the natural environment,” the economy, and future compliance costs.<sup>130</sup> The RFA, UMRA, and the PRA each require a discussion of the public comments received (although only UMRA specifically requires the agency to evaluate those comments).<sup>131</sup>

Also, some of the analytical requirements specifically refer to other requirements. For example, one of the certifications that agencies are required to provide OMB pursuant to the PRA is that the draft information collection

reduces to the extent practicable and appropriate the burden on persons who shall provide information to or for the agency, including with respect to small entities, as defined under section 601(6) of title 5 [the RFA], the use of such techniques as (i) establishing differing compliance or reporting requirements or timetables that take into account the resources available to those who are to respond; (ii) the clarification, consolidation, or simplification of compliance and reporting requirements; or (iii) an exemption from coverage of the collection of information, or any part thereof.<sup>132</sup>

Therefore, the PRA essentially requires agencies to certify that they have taken the types of actions that are required under the RFA. Also, if HHS is required to prepare a regulatory flexibility analysis under the RFA, Section 1102(b) of the Social Security Act states that the RFA analysis “shall specifically address the impact of the rule or regulation on small rural hospitals.”<sup>133</sup>

## *Differences*

However, the origins, objectives, and political constituencies of these crosscutting analytical requirements are often quite different. For example, the primary objective of the regulatory impact analysis requirements in EO 12866 is the maximization of regulatory net benefits.<sup>134</sup> In contrast, the goal of the RFA analysis is to minimize the burden associated with a rule on small businesses and other small entities while still meeting the regulation’s purpose.<sup>135</sup> These two objectives are not necessarily

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<sup>130</sup> Circular A-4 requires the use of discounting to account for future benefits and costs in current dollars.

<sup>131</sup> The RFA requires agencies to summarize the “significant issues raised by the public comments” in the FRFA. UMRA requires the written statement to include a “summary of the comments and concerns” that were presented by state, local, and tribal governments, and “the agency’s evaluation of those comments.” The PRA certification to OMB is to include “public comments received by the agency.”

<sup>132</sup> 5 U.S.C. § 3506(c)(3)(C).

<sup>133</sup> 42 U.S.C. § 1302(b)(3).

<sup>134</sup> In its statement of regulatory philosophy, EO 12866 says that agencies should select regulatory approaches “that maximize net benefits” unless a statute requires another regulatory approach.

<sup>135</sup> Congress said the purpose of the RFA is to establish as a principle of regulatory issuance that “agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational

consistent,<sup>136</sup> so any attempt to combine these analytical requirements into a single statute or executive order would require that these differences be reconciled in some way. Consolidation with other requirements adds another level of complication.<sup>137</sup>

Also, because some of these crosscutting analytical requirements primarily focus on particular issues (e.g., small entities, governmental units, or paperwork issues), it is not surprising that there are differences in the particular elements required in the analyses. For example, only the RFA requires agencies to determine the number and classes of small entities affected, and the skills needed to comply with regulatory requirements. Only UMRA requires an assessment of any “disproportionate budgetary effects,” the extent to which the federal government may pay for costs to state, local, and tribal governments, and the extent to which federal resources are available to pay for the mandate. Only UMRA requires a description of the agency’s consultation with elected representatives of state, local, and tribal governments. Only the PRA specifically requires an estimate of paperwork burden. The PRA also requires a separate submission to and clearance from OIRA (in addition to submissions under EO 12866), and requires a separate notice and comment from the requirements in the APA.

The provisions in some of the other analytical requirements are even more particularized, and therefore more likely to be different from other requirements. For example:

- Only EO 12898 specifically requires agencies to determine whether their rules have “disproportionately high and adverse human health or environmental effects on minority populations and low-income populations.”
- Only EO 13045 specifically requires agencies to evaluate the “environmental health or safety effects of the planned regulation on children.”
- Only EO 13211 requires agencies to prepare a “statement of energy effects” describing adverse effects on energy supply, distribution, or use if the rule is implemented.

Therefore, beyond the three general elements that the primary analytical requirements have in common (statement of need, assessment of costs and benefits, and consideration of alternative approaches), reconciling and combining the other requirements in these statutes and executive orders would either expand the number of issues that are currently being addressed in the analyses, or eliminate certain issues from consideration.

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requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation.”

<sup>136</sup> For example, one regulatory approach could have the least impact on small businesses, and produce net benefits of \$100 million. Another approach could produce net benefits of \$500 million, but could have a much more negative effect on small businesses than the first alternative.

<sup>137</sup> For example, one of the goals of the PRA is to minimize paperwork burden, which may or may not be consistent with the goals of maximizing net benefits or minimizing effects on small entities.

## *Recognition of Overlaps/Duplication in the Analytical Requirements*

Several of the analytical requirements themselves appear to recognize that they may overlap or duplicate other requirements, and specifically allow agencies to combine the requirements as appropriate. For example:

- Subsection 605(a) of the RFA states that “Any Federal agency may perform the analyses required by sections 602, 603, and 604 of this title in conjunction with or as a part of any other agenda or analysis required by any other law if such other analysis satisfies the provisions of such sections.” Also, subsection 605(c) says “In order to avoid duplicative action, an agency may consider a series of closely related rules as one rule for the purposes of sections 602, 603, 604 and 610 of this title.”
- Subsection 202(c) of UMRA states that the written statement required under subsection 202(a) may be prepared “in conjunction with or as a part of any other statement or analysis, provided that the statement or analysis satisfies the provisions of subsection (a).” Similarly, in its discussion of UMRA, OMB Circular A-4 states that the “analytical requirements under Executive Order 12866 are similar to the analytical requirements under this Act, and thus the same analysis may permit you to comply with both analytical requirements.”<sup>138</sup>
- Section 5-503 of EO 13045 states that the required evaluation of environmental health or safety effects on children “may be included as part of any other required analysis.”

However, the other analytical requirements do not contain such statements explicitly permitting one analysis to satisfy multiple requirements.

## **Summary**

Although the crosscutting analytical requirements are similar in some respects, they are also quite different in terms of the agencies and rules they cover, the amount of discretion agencies have to decide whether an analysis is required, and they particular issues that the analyses are required to address. The requirements also differ in terms of the agencies responsible for overseeing or monitoring their implementation. **Table 4** below illustrates some of those differences across the five analytical requirements most commonly cited in the major rules issued during calendar year 2010.

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<sup>138</sup> OMB Circular A-4, available at [http://www.whitehouse.gov/omb/circulars\\_a004\\_a-4](http://www.whitehouse.gov/omb/circulars_a004_a-4).

**Table 4: Crosscutting Regulatory Analysis Requirements Differ in Many Respects**

	<b>NEPA</b>	<b>RFA</b>	<b>PRA</b>	<b>UMRA</b>	<b>EO 12866</b>	<b>EO 13132</b>
Covers independent regulatory agencies	Yes	Yes	Yes	No	No	No
Covers rules without an NPRM	Yes	No	Yes	No	Yes	Yes
Covers rules with indirect effects	Yes	No	Yes	No	Yes	Yes
Uses \$100 million analysis threshold/ indexed for inflation	No	No	No	Yes/Yes	Yes/No	No
Gives agencies broad discretion to determine coverage	Yes	Yes	No	Yes	No	Yes
Overall goal of analysis	Identify effects on environment and alternatives	Minimize effects on small entities	Minimize paperwork burden	Consider impacts on state/local/tribal governments and private sector	Maximize net benefits	Ensure principles of federalism
Specific requirements	EIS must identify direct, indirect, and cumulative environment effects	Identify small entities affected and skills needed to comply	Measure burden in hours to complete paperwork	Identify budget effects, extent of federal payments, and discussions with governments	Determine costs and benefits of rule and major alternative approaches	Describe discussions with state/ local officials and extent concerns met
Oversight agency	EPA and CEQ	SBA Advocacy	OIRA	None	OIRA	OIRA

**Overlaps and Consolidations Cited in 2010 Major Rules**



In many of the 2010 major rules, the agencies indicated that the analytical requirements overlapped or required the same general types of analysis. In many of these cases, the agencies indicated that they had combined the requirements. For example:

- In a January 8 rule on energy conservation standards, DOE said the requirements in the Unfunded Mandates Reform Act “substantially overlap the economic analysis requirements that apply under section 325(o) of EPCA [the Energy Policy and Conservation Act] and Executive Order 12866,” and said that the RIA section of the technical supporting document “responds to those requirements.”<sup>139</sup> DOE also said that it prepared an environmental assessment pursuant to NEPA as part of the technical supporting document.
- In a February 12 rule on the national organic program, the Agricultural Marketing Service noted that the RFA’s requirements overlapped with the RIA prepared under EO 12866, and with the requirements of the PRA.
- In a March 3 rule establishing national emission standards for hazardous air pollutants, EPA said that the economic analysis it used to determine whether the rule would have a SEISNRE under the RFA could be found in the RIA for the rule. EPA also indicated that it prepared the RIA because the rule was economically significant under EO 12866, but summarized the RIA’s findings under the UMRA heading in the rule.
- DOE said that a March 9 rule on energy conservation standards required a written statement under Section 202 of UMRA, but said the technical supporting document, preamble, and regulatory impact analysis for the rule “contain a full discussion of the rule’s costs, benefits, and other effects on the national economy, and therefore satisfy UMRA’s written statement requirement.” Also, the preamble discussion that the department provided under the Energy Policy and Conservation Act was largely repeated and expanded in the section discussing EO 12866.
- EPA indicated in a March 26 rule on changes to the renewable fuel standard program that the discussions of costs and benefits under EO 12866 and UMRA were both “contained in the Regulatory Impact Analysis.”
- In a March 31 rule on electronic prescriptions for controlled substances, the Drug Enforcement Administration said that the economic impact analysis prepared under EO 12866 also included the required analyses under the RFA and UMRA.
- In an April 1 rule issued by the Federal Reserve System on electronic fund transfers, the agency said that the RFA analysis and the section-by-section analysis served as the economic impact analysis pursuant to Section 904(a)(2) of the Electronic Fund Transfer Act (15 U.S.C. § 1993 et seq.).

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<sup>139</sup> 75 FR 1177.

- In several rules issued by the Food and Drug Administration and the Centers for Medicare and Medicaid Services within the Department of Health and Human Services, the agencies indicated that the rules were economically significant under EO 12866 and required an UMRA written statement, but only one economic analysis was discussed in each of the rules.<sup>140</sup>
- In an April 16 rule on energy conservation standards for water heaters, DOE indicated that the technical supporting document contained both the RIA required under EO 12866 and the UMRA written statement.
- In each of the rules that CMS issued, the first sentence under the heading “Regulatory Impact Statement” said that the agency examined the impact of the rule under EO 12866, the RFA, Section 1102(b) of the Social Security Act, UMRA, and EO 13132. CMS also sometimes specifically said that the analysis prepared under EO 12866 satisfied the requirement for an analysis under Section 1102(b) of the Social Security Act.<sup>141</sup>
- In a June 3 rule issued by the Commodity Credit Corporation within USDA, the agency said that although it was not technically required to conduct a risk assessment under Section 304 of the Agriculture Reorganization Act of 1994 (P.L. 103-354), risks were already assessed under the EO 12866 analysis.
- In a June 3 EPA greenhouse gas tailoring rule, EPA said that although an UMRA written statement was not required, the RIA prepared for the rule under EO 12866 met UMRA’s requirement for a cost-benefit analysis.
- In a June 17 rule issued jointly by IRS, EBSA, and HHS, the agencies said that although the RFA did not apply to the rule (because it was issued without an NPRM), they considered the likely impact on small entities in connection with their assessment under EO 12866.
- In a June 22 rule on sulfur dioxide, EPA said that although EO 13045 did apply to the rule, the required analysis of effects on children was already discussed in an earlier integrated science assessment for particulate matter and the risk and exposure assessment.
- In a July 23 rule on internal claims and external review processes, EBSA and HHS said that although the RFA did not apply to the rule (no notice of proposed rulemaking), they considered the impact on small entities “in connection with” their assessment under EO 12866.

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<sup>140</sup> See, for example, the April 14 FDA rule on ozone-depleting substances, and the April 15 CMS rule on changes to the Medicare advantage and Medicare prescription drug benefit programs.

<sup>141</sup> See, for example, the June 2 CMS rule on hospital inpatient prospective payment systems.

- In a July 28 rule on the electronic health record incentive program, CMS said that the rule did not impose any mandates, but said the RIA and the discussion in the preamble “constitutes the analysis required by UMRA.” CMS also said that the RFA analysis satisfied the requirement for analysis of impacts on small hospitals under Section 1102(b) of the Social Security Act.
- OSHA indicated in an August 9 rule on cranes and derricks in construction that the economic analysis that it prepared under EO 12866 also satisfied the requirements for a final regulatory flexibility analysis under the RFA and the written statement requirement in UMRA.
- The cost information provided in August 12 SEC rule on “Amendments to Form ADV” was drawn largely from the information collection analysis prepared pursuant to the Paperwork Reduction Act.
- In an August 16 rule on Medicare inpatient prospective payment systems, CMS did not prepare a separate RFA analysis, indicating that the “analysis discussed throughout the preamble of this final rule constitutes our final regulatory flexibility analysis.” CMS also said that the analysis required under Section 1102 of the Social Security Act “must conform to the provisions of Section 604 of the RFA.”
- In an August 20 rule on emission standards for reciprocating internal combustion engines, EPA certified that the rule would not have a SEISNSE under the RFA, and indicated that a detailed explanation was available in the RIA that had been prepared for the rule under EO 12866.
- In two September 15 rules on nondiscrimination on the basis of disability, the Department of Justice said that chapter seven of the RIA provided information on why the rules would not have a SEISNSE, but added that the advance notices of proposed rulemaking, the notices of proposed rulemaking, the initial and final RIAs, and other documents collectively “include all of the elements” of a final regulatory flexibility analysis required by the RFA.
- In an October 20 rule on fiduciary requirements, the Employee Benefits Security Administration within the Department of Labor said that it had prepared a final regulatory flexibility analysis under the RFA, but that certain required elements of that analysis (statement of need for the rule, legal basis) could be found in the RIA.
- Although the Federal Highway Administration concluded that its November 8 rule on “real-time system management information” did not impose an unfunded mandate and, as a condition of federal financial assistance, was exempt from UMRA, the effects of the rule were already discussed in the regulatory cost analysis available in the docket.

- In a November 24 rule on the “hospital outpatient prospective payment system” and a November 29 rule on “payment policies under the physician fee schedule,” CMS said “the analysis presented throughout the final rule with comment period constitutes our regulatory flexibility analysis.”
- In the “Regulatory Flexibility Act” section of a December 17 rule on patient care payment systems, the Department of Veterans Affairs said the Secretary had determined that the rule would have a SEISNSE, but referred readers to another section entitled “Executive Order 12866 and Regulatory Flexibility Act” for the results of the regulatory flexibility analysis.

## Interviews with Agency Officials

Many of the agencies (e.g., DOE, DOT, DOC, DOI) indicated that they prepare a single economic or regulatory impact analysis, with different chapters or subheadings discussing each of the different requirements (e.g., the RFA or the PRA). Some of the officials said that consolidating the requirements into a single statute or executive order would have little substantive impact on this aspect of their rulemaking procedures. For example:

- A DOE official said that the department prepares a single technical support document (TSD) that primarily focuses on the requirements in EPCA, but that also addresses the crosscutting analytical requirements. He said that by the time the EPCA analysis is completed, they have essentially satisfied all of the other analytical requirements.<sup>142</sup> If the crosscutting requirements were combined, he said the primary benefit would be that they would only have to do one certification that they have satisfied the consolidated requirement instead of the current multiple certifications.
- A DOT official said that the department does one economic analysis that encompasses all of the applicable analytical requirements. Although the documents always have chapters addressing certain requirements (e.g., EO 12866 and the RFA), other chapters are added addressing other relevant requirements (e.g., energy impacts or family impacts), depending on the particular rule.
- DOI officials said that agencies already consolidate the various analytical requirements into one economic analysis, with subparts discussing each of the requirements. Therefore, they said, consolidating all of the requirements into a single statute or executive order probably would not change that

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<sup>142</sup> To view the technical support document for the January 8, 2010, final rule on commercial clothes washers, see [http://www1.eere.energy.gov/buildings/appliance\\_standards/commercial/clothes\\_washers\\_ecs\\_final\\_rule\\_tsd.html](http://www1.eere.energy.gov/buildings/appliance_standards/commercial/clothes_washers_ecs_final_rule_tsd.html). It includes a market and technology assessment, engineering analysis, energy and water use analysis, shipments analysis, national impact analysis, life-cycle cost subgroup analysis, utility impact analysis, employment impact analysis, regulatory impact analysis, and environmental impact analysis.

practice. They also said that OIRA seems to consolidate the requirements in practice. For example, if an agency has described the alternatives that it considered in one place (e.g., for the RFA), OIRA does not require those alternatives to be restated in relation to other requirements.

Other agency officials indicated that they do not prepare a single analytical document, or that at least some of the analyses conducted are very different. For example:

- An FCC official said that the cost-benefit analysis that the agency prepares is not prepared in conjunction with any other analysis, and is reported separately from any RFA or PRA analysis. He said the requirements are sufficiently different in purpose, format, and procedure that they really cannot be combined. For example, the RFA analysis must be published with the proposed or final rule, and the PRA analysis must be submitted to OMB in a separate document from the rule itself.
- An SEC official said that the primary crosscutting analytical requirements that the agency encounters are the RFA and the PRA. Both require reports to, and are subject to oversight by, government agencies (i.e., SBA and OIRA, respectively). Therefore, the SEC tends to do distinct analyses to show SBA that small business interests were considered, and show OIRA that information collection burdens are discussed and analyzed. The official said that the agency had been “experimenting” during the previous year to so with preparing a unified economic analysis that combines the cost-benefit analysis and the statutory requirements. This unified analysis does not, however, include the PRA and RFA requirements, which are discussed separately because their requirements are so different and must be separately submitted to OIRA and SBA.
- DOI officials said that although the department prepares one economic analysis with sections for the different requirements, the PRA analyses are done separately by a different group of people. They said that information collection requirements and procedures are different, and are reviewed differently, even though the burden hour totals may be used in the assessment of regulatory costs.
- An EPA official said that her office oversees the agency’s rulemaking process and the implementation of various analytical requirements (e.g., EO 12866 and UMRA), but that different groups within EPA are responsible for ensuring implementation of the PRA and NEPA.
- Both USDA and HHS officials said that although there is not one “economic analysis” document, their departments always starts with the analysis required by EO 12866 and Circular A-4, with other analyses (e.g., PRA, RFA, UMRA) added as needed. The USDA official said that NEPA is on a different

timing from the rule, and is done by a different group within the department. The HHS official said that the PRA analysis is often done by a separate group, and uses a different metric (burden hours), but is monetized in the EO 12866 analysis. The RFA analysis is different, but uses information from the EO 12866 analysis. She said UMRA is rarely triggered, and even then usually only adds a few sentences to the preamble.

- An FDA official said that types of information required by UMRA are very similar to that required by EO 12866, and that anything in the statute that is not already required by the executive order is “folded in anyway.” He said that FDA should have a separate heading in the preamble for UMRA, but it should simply point the reader to the EO 12866 section.

Some of the agency officials said consolidation of the analytical requirements would have certain advantages. For example:

- DOT official said that if all of the requirements were consolidated into one document, it would be easier for those preparing and reviewing the analyses to know what the agency needed to include.
- Similarly, DOI officials said that putting all of the requirements into one statute or executive order would be “wonderful,” and “would simply things greatly.” Currently, they said, it can be confusing to know whether you have captured all of the relevant requirements. They said it would be “cleaner” and more “logical” if the requirements were consolidated, with one source.
- An FDA official said that although the agency tries to do one analysis that satisfies multiple requirements, consolidation of the requirements would make their jobs easier (doing one analysis rather than multiple analyses that have to be folded together, and making sure that they had “checked every box”), and would likely make it faster for the agencies to issue rules. Hopefully, he said, consolidation would eliminate some of the definitional inconsistencies between the various analytical requirements (e.g., analytical thresholds that are and are not indexed for inflation).

However, even those who supported consolidation of the analytical requirements in theory said that combining the requirements would probably be very difficult to do in practice. For example:

- A DOT official said that combining the requirements would require that they be modified because they often have different goals and use different terms and cutoffs. For example, UMRA requires an analysis for rules with \$100 million in “expenditures” indexed for inflation, while EO 12866 uses \$100 million in “effects on the economy not indexed for inflation. He also said that any consolidated analytical requirement would have to mesh with each agency’s underlying statutory requirements. These underlying statutory

requirements are, he said, “all over the place,” as the requirements were written at different times during the past several decades, and one has to assume that the differences are meaningful (e.g., “issue rules requiring” versus “issue reasonable rules requiring”). He also said that consolidation of crosscutting and agency-specific requirements would inevitably lead to concerns that certain standards were not included (e.g., selection of standards that are “cost beneficial” versus ones that are the “most cost beneficial”). Nevertheless, he believed that some requirements that are vague and therefore difficult for agencies to know what to do (e.g., family impact assessments) could be eliminated.

- An EPA official said that although some of the analytical requirements were similar in some respects, she did not view most of them as duplicative or overlapping. Although her agency prepares a single RIA for each rule, each of the different analytical requirements is discussed separately in the document. She said that different people prepare the analyses, and the analyses use different data sets and contain different requirements and emphases. For example, to satisfy EO 12898 on environmental justice, EPA must attempt to determine how many people live within certain distances from certain facilities – information that would not be gathered to determine overall benefits and costs under EO 12866. Even when the requirements are similar (e.g., the written statement requirement in Section 202 of UMRA and the cost-benefit analysis requirement in EO 12866), there are often differences in definition and analytical thresholds between the requirements that would make consolidation difficult. Even combining requirements that are very similar in the types of information they require would be difficult. For example, combining EO 12866 and UMRA would require reconciling their differences in scope (i.e., either expanding the scope of UMRA to include more rules, or limiting the scope of EO 12866). She also said that consolidating the requirements into a single statute or executive order would likely make it more difficult for interested parties to identify the analysis that they care about (e.g., environmental justice or children). Also, without major changes to the requirements, agencies would likely still have to have separate discussions of those impacts. As a result, the amount of work required would stay about the same, unless certain requirements were eliminated entirely. However, because certain groups only care about certain things, they would likely lobby to keep the requirements, and to keep them distinct.
- An FCC official said that the analytical requirements cover very different things and are differently focused. For example, the PRA is only interested in paperwork burden, while the RFA is interested in all types of burden that are imposed on small businesses and other small entities. Paperwork burden may be part of the small business burden, but may not be all of it. The official also said that if the requirements were consolidated under a single statute or

executive order with OMB in charge of oversight, the rulemaking environment would likely be very different and controversial. For example, if OMB was responsible for the RFA instead of SBA, small businesses would likely feel like they had less of a “voice” in rulemaking, and that their interests were less likely to be advocated by OMB. He also said that, given the current political environment, Congress is unlikely to agree on a statutory consolidation of analytical requirements.

- A Commerce official said that because some agencies are currently exempt from certain requirements, if all of the requirements were put in one place and made universally applicable, then currently exempt agencies would likely object because it would require more analysis. She also said that the various analytical requirements may have different requirements and purposes (e.g., the RFA versus EO 12866), so reconciling those differences and satisfying the different constituencies may be difficult.
- DOI officials said that although some of the requirements may look similar (e.g., the \$100 million threshold), in reality they are often different, which can be confusing. They are also different in purpose, and were developed to serve different interests. And those interests are not likely to be willing to see freestanding requirements eliminated. Also, although some things could be done to make the requirements more similar (e.g., have the \$100 million threshold in EO 12866 indexed for inflation like UMRA, or resolve certain definitional differences), some may not like standardization. For example, if EO 12866 were indexed for inflation, fewer rules would be subject to OIRA review and cost-benefit analysis, which OIRA may not like.
- A USDA official said that while putting all of the analytical requirements into a single statute or executive order might be theoretically possible, it would be difficult to do because they each have different goals, definitions, and thresholds. For example, he said the RFA is more about mitigating the impact of rules on small entities than tallying up costs and benefits. He also said putting all of the requirements into a single document would not likely save much time or money because USDA is already treating them as a unified set of requirements. In some ways, he said, it is easier to think about them as separate requirements.
- An HHS official said that she was not sure what a consolidated statute or executive order would look like, or whether it is even feasible. She said the cost-benefit analysis required by EO 12866 is what drives the HHS work in this area, with other analyses viewed as different from, and supplements to, the EO 12866 cost-benefit analysis. Although the EO 12866 analysis should theoretically include the types of distributive impacts contemplated in other requirements, in reality they are viewed as separate from the analysis of overall costs and benefits. In addition to the technical difficulties associated



with combining different statutes and executive orders, there is also likely to be a political problem associated with eliminating free-standing statutes and folding those requirements into an omnibus statute or executive order. She said that Congress and various interest groups are likely to resist such efforts.

- An FDA official said that consolidation of requirements that have very different purposes (e.g., EO 12866 versus the RFA) would have to ensure that those both objectives are fulfilled – which may be difficult. He also said the various interest groups would probably not be willing to sacrifice free-standing requirements, as they are more interested in pursuing their issue than in making the analysts’ lives easier.

### **Other Changes to Improve Regulatory Analysis**

Three agency officials voluntarily said that changes should be made to the PRA to make it easier for agencies to gather the data needed for regulatory analysis. Currently, they said, if an agency wants to collect information from 10 or more regulated entities to determine the likely effects of forthcoming a rule, the agency would have to obtain public comments and get clearance from OMB under the PRA, which may take a considerable amount of time. Ironically, therefore, to satisfy one analytical requirement (cost-benefit analysis), the agency has to invoke another analytical requirement (the PRA). Some of the agency officials said they might call fewer than 10 affected parties to obtain at least some information, but the accuracy and validity of that information is unclear. One agency official said that the time required to go through that PRA process is a major disincentive to gathering valid information, so the agencies often do analysis “based on assumptions.” She and other officials suggested some type of expedited OMB approval process in such cases, allowing agencies to gather information quickly from 10 or more individuals or organizations when doing so in the context of preparing a regulatory impact analysis.<sup>143</sup>

Several agency officials also supported putting all of the analytical rulemaking requirements in one place so that agencies and the public would know what has to be done. Although some departments and agencies have documents that summarize those and other rulemaking requirements (e.g., USDA’s Departmental Regulation 1512-1), other agencies do not have such documents. Another agency officials also supported putting all of the requirements in one place, and making it clear to agencies that satisfying one requirement can satisfy other requirements. She also said that it would be helpful if Congress and the President would examine the current set of requirements and determine whether they can satisfy any concerns they might have before “piling on” new analytical requirements.

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<sup>143</sup> Federal agencies can obtain generic clearances for certain types of information collections. See [http://www.whitehouse.gov/sites/default/files/omb/assets/inforeg/PRA\\_Gen\\_ICRs\\_5-28-2010.pdf](http://www.whitehouse.gov/sites/default/files/omb/assets/inforeg/PRA_Gen_ICRs_5-28-2010.pdf) for more information. Also, in January 2012, OMB announced a new fast-track process for collection service delivery feedback under the PRA. See <http://www.whitehouse.gov/sites/default/files/omb/assets/inforeg/pr-faqs.pdf> for more information.

One agency official said that it would be helpful if there were some “middle ground” between “no analysis” and a full-blown cost-benefit analysis. He said rules that have a policy impact but are not “economically significant” should be subject to this mid-level type of analysis.<sup>144</sup>

## Analytical Requirements and Ossification

Several previous studies have suggested that the accumulation of analytical requirements (among other things) had “ossified” the rulemaking process, resulting in slower rule issuance and fewer rules overall. For example, Thomas O. McGarity said in 1992 that the informal rulemaking process had become “increasingly rigid and burdensome,” and that the causes of that ossification include the analytical requirements that have been imposed by the courts, Congress, and various Presidents.<sup>145</sup> McGarity’s proposed solutions to this problem included (but were not limited to) amending individual agency statutes to eliminate some of the more burdensome analytical requirements, and reducing or eliminating some of the crosscutting analytical requirements in statutes and executive orders.<sup>146</sup>

However, other studies suggest that analytical and procedural requirements have not slowed rulemaking. For example, Jason Webb Yackee and Susan Webb Yackee examined data from the Unified Agenda of Federal Regulatory and Deregulatory Actions<sup>147</sup> covering rules issued from 1983 to 2006, and reported that agencies appeared “readily able to issue a sizeable number of rules and to do so relatively quickly.”<sup>148</sup> The authors

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<sup>144</sup> Section 6(a)(3)(B) of Executive Order 12866 already requires covered agencies to provide to OIRA an “assessment of the potential costs and benefits” of regulatory actions that are “significant” but not “economically significant.” A full cost-benefit analysis is required only for rules that are considered “economically significant” (e.g., have a \$100 million effect on the economy).

<sup>145</sup> Thomas O. McGarity, “Some Thoughts on ‘Deossifying’ the Rulemaking Process,” *Duke Law Journal*, volume 41 (1992), pp. 1385-1462.

<sup>146</sup> *Ibid.*, pp. 1444-1447. See also Richard Pierce, “Seven Ways to Deossify Agency Rulemaking,” *Administrative Law Review*, volume 47 (1995), pp. 59-95, which evaluates a series of changes in legal doctrines that could deossify rulemaking; and Paul R. Verkuil, “Comment: Rulemaking Ossification—A Modest Proposal,” *Administrative Law Review*, volume 47 (1995), pp. 453-459, which suggested a legislative solution to ossification.

<sup>147</sup> The Unified Agenda is compiled and published twice each year by the Regulatory Information Service Center within the General Services Administration, and provides the public with information about regulations that federal agencies are considering or reviewing. To access the Unified Agenda, see <http://www.reginfo.gov/public/#>.

<sup>148</sup> Jason Webb Yackee and Susan Webb Yackee, “Administrative Procedures and Bureaucratic Performance: Is Federal Rule-making ‘Ossified’?,” *Journal of Public Administration Research and Theory*, volume 20 (2009), pp. 262-282. The authors primarily focused on the amount of time between the issuance of a proposed rule and the issuance of the final rule. The authors recognized that agency rulemaking often begins well in advance of the issuance of the proposed rule, and used the publication of an advance notice of proposed rulemaking as the start of the rulemaking process for a more limited number of rules. They reportedly obtained similar results.

concluded that procedural constraints did not appear to unduly interfere with the ability of federal agencies to act, and may actually speed up the issuance of rules.<sup>149</sup>

## GAO Report

In an April 2009 report, GAO reported that the time needed to develop and finalize 16 case study rules varied considerably, from less than 1 year to about 14 years.<sup>150</sup> The average amount of time was four years. In most of the rules, the majority of the time elapsed before the publication of the proposed rule, although GAO pointed out that it is often difficult to determine when the rulemaking process begins. Factors that GAO said influenced the amount of time needed to issue a rule included (1) the complexity of the issues addressed by the rule; (2) prioritizations set by agency management that can change when new priorities are set (e.g., new congressional mandates); and (3) the amount of internal and external review required at the different phases of the rulemaking process. GAO also said that the agencies “could provide little systematic data on the resources they use, such as staff hours, contract costs, and other expenses, in developing individual rules.”<sup>151</sup>

GAO staff who prepared the report indicated during this study that statutory and executive order analytical requirements, while potentially time consuming, were not the major factor in determining the amount of time that it took for the agencies to issue these rules.<sup>152</sup> When looking at the whole timeline for rulemaking, they said most of the time is taken up with doing the basic science and other preparations for the rule, not the crosscutting analytical requirements. They also said that although agencies often blame certain requirements for slowing down the issuance of a rule (e.g., the analyses required to get OMB clearance under the PRA), it did not seem likely that those requirements were the primary factor in determining how long it took for the agency to issue certain rules.

## A Case Study

An April 2011 study by Public Citizen of one of the 2010 major rules – the August 9 OSHA rule on cranes and derricks – serves as an interesting case study of the extent to which rules are delayed by the analytical requirements, or by other parts of the rulemaking process.<sup>153</sup>

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<sup>149</sup> See also Stephen M. Johnson, “Ossification’s Demise?: An Empirical Analysis of EPA Rulemaking from 2001-2005,” *Environmental Law*, volume 38 (2008), pp. 767-792, who reported that “it did not take EPA much longer to finalize rules subject to the most stringent procedural requirements imposed by the Executive Branch and Congress than it took to finalize rules not subject to those procedures.”

<sup>150</sup> U.S. Government Accountability Office, GAO-09-205, p. 18.

<sup>151</sup> *Ibid.*, p. 6.

<sup>152</sup> Interview with GAO staff, October 26, 2011.

<sup>153</sup> Public Citizen, *Cranes & Derricks: The Prolonged Creation of a Key Public Safety Rule*, April 2011, available at <http://www.citizen.org/documents/CranesAndDerricks.pdf>.

- Public Citizen traced the origins of the rule to 1998, when an advisory committee established a workgroup to recommend changes to an existing rule. The workgroup recommended in 1999 that the agency use negotiated rulemaking to update the rule, but the agency did not announce its intention to follow the workgroup's recommendation until 2002.
- The negotiation committee was not selected until July 2003, and the committee reached consensus and sent a draft standard to OSHA in July 2004.
- At that point, OSHA reportedly began preparing a series of required analyses, including an initial regulatory flexibility analysis under the RFA and an economic analysis under EO 12866. In June 2006, OSHA determined that the rule may have a significant economic impact on a substantial number of small entities, and convened a SBREFA advocacy review panel, which sent OSHA a series of recommendations in October 2006.
- In May 2008, OSHA completed a final economic analysis of the draft proposed rule, and provided OMB with an estimate of its paperwork burden.
- OMB completed its review of the proposed rule in August 2008, and OSHA published the notice of proposed rulemaking in October 2008. It received comments until January 2009.
- In March 2009, OSHA held four days of hearings, and closed the hearing record in June 2009.
- After analyzing and responding to the proposed rule comments and hearing comments, OSHA published the final rule in August 2010.

Therefore, it appears that while the analytical requirements consumed some of the time required to develop the OSHA cranes and derricks rule, a great deal of the 12-year period was taken up by inactivity on the part of the agency and non-analytical procedural actions (e.g., the negotiated rulemaking process, the SBREFA panel, and public hearings). In its discussion of this process, Public Citizen focused on the delays caused by the public participation requirements, not the analytical requirements:

The creation of the cranes and derricks standard clearly illustrates that tremendous redundancy exists in the rulemaking process. Setting aside the rare decision to employ a negotiated rulemaking process, stakeholders in the cranes rule had at least five opportunities to have their voices heard: at the SBREFA stage; to the Office of Management and Budget before it signed off on the proposed rule; during the conventional comment period after the proposed rule was published; during hearings on the proposed rule; and in post-hearing comments and briefs.<sup>154</sup>

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<sup>154</sup> Ibid., p. 10.

## Factors Affecting Ossification

The degree to which analytical rulemaking requirements can significantly increase the amount of time needed to issue a rule appears to be a function of several factors, including (1) whether the rule triggers the requirements, and if so, how many; and (2) whether the requirements can be satisfied simultaneously with other parts of the rulemaking process.

As noted previously in this report, many of the crosscutting analytical requirements do not apply to certain agencies, or cover only certain types of rules or effects. For example, the analytical requirements in EO 12866 do not apply to independent regulatory agencies or any rules that are not “economically significant.” The analytical requirements in the PRA only apply when a rule contains a collection of information. The RFA and UMRA do not apply when an agency issues a final rule without a prior notice of proposed rulemaking. Other requirements provide agencies with substantial discretion as to their application. For example, the RFA allows agencies to avoid analysis if they certify that their rules will not have a “significant” economic impact on a “substantial” number of small entities. EO 13132 only requires an analysis if there are “significant” federalism effects. Also, some requirements are only intended to apply to particular types of rules. For example, NEPA requires an analysis only for “major Federal actions significantly affecting the quality of the human environment.” It is unlikely to be triggered by rules increasing or decreasing federal transfer payments, or by rules establishing banking requirements.

As a result, most of the more than 3,000 final rules that are issued in a typical year do not trigger any of the crosscutting analytical requirements. Even the most significant rules that agencies issue are often not subject to these requirements. For example, only two of the analytical requirements appeared to result in some kind of new analysis for more than half of the 100 major rules that were published in 2010—(1) EO 12866, which appeared to trigger some type of new regulatory impact analysis in 73 rules; and (2) the Paperwork Reduction Act, which appeared to require the issuing agencies to do an analysis of paperwork burden or other compliance costs in 64 rules. In contrast, the agencies prepared a new final regulatory flexibility analysis under the RFA for only 26 of the 100 major rules; prepared a NEPA environmental impact statement or environmental assessment in 12 rules; prepared an EO 13132 federalism impact statement for only 10 rules; and prepared an UMRA Section 202 written statement for only 4 rules.

Even when an analytical requirement is applicable to a rule, at least some of the specific requirements may be satisfied by another analysis. For example, any rule that satisfies the analytical requirements in EO 12866 and Circular A-4 will likely satisfy most if not all of the requirements in Section 202 of UMRA. Estimates of a rule’s paperwork burden that is required under the PRA will be one element of the agency’s estimate of the cost of the rule under EO 12866. As noted earlier in this report, several of the analytical requirements themselves permit agencies to combine the requirements as appropriate.

Also, the agencies frequently indicate that certain requirements overlapped, and that they combined certain requirements.

Nevertheless, some of the analytical requirements are sufficiently different that they cannot be combined with other analyses, and require different procedures. Satisfying these requirements will take time, and are likely to cause some delays in the issuance of a rule.

## Measuring Ossification

To determine empirically whether the crosscutting or other analytical requirements were a significant factor in the length of time it took for agencies to develop and issue the 100 major rules published in 2010, the first step would be to determine the total amount of time it took the agency to issue the rule. Then, one must attempt to determine how much of the overall time was caused by the “analytical requirements.” However, each of these two steps is fraught with difficulties.

To determine how long the overall rulemaking process took, one must determine when the process started for each rule. As GAO pointed out in its 2009 report,<sup>155</sup> though, determining that starting point is often difficult. Many rules are based on statutory authorities that are decades old, and the agencies usually do not indicate in the preambles to their rules when they began development. More commonly, agencies only mention when certain major actions occurred (e.g., publication of an NPRM, or more rarely, an ANPRM), but the lead up to those milestones can take many months or years.

Even if one could determine the rulemaking starting point, and even if one assumes that the ending point is the publication of the final rule,<sup>156</sup> it may be difficult or impossible to determine how much of the overall rulemaking period is a function of the analytical requirements. Agencies typically do not record the amount of time required for analysis, as there is no current business reason to do so. Also, agencies may be preparing the required analyses at the same time as other rulemaking procedures are being carried out (e.g., legal or engineering studies). In such cases, even if the analytical requirements were eliminated entirely, the overall length of time needed to issue the rule could be unchanged.

## Interviews with Agency Officials

Although some of the agency officials interviewed for this report indicated that they data indicating how long it took their agencies to issue final rules, none of the officials had any data showing how much how much of that time was devoted to satisfying the

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<sup>155</sup> GAO-09-205, p. 17.

<sup>156</sup> OMB officials pointed out in the GAO report that a rule that is later subject o a judicial challenge may not have “ended” with the publication of the final rule.

crosscutting analytical requirements. Even the data on the time required to issue rules varied from one agency to the other, with the agencies often using different starting points for their rulemaking process. The officials also frequently pointed out that the analyses needed to satisfy those requirements were occurring at the same time as other rulemaking processes, and that non-analytical steps in the rulemaking process (e.g., public comments, and OMB reviews) were often focused on the regulatory analyses. Therefore, there may be no clear demarcation between the “analytical” and “non-analytical” rulemaking processes.

Some of the agency officials indicated that the crosscutting analytical requirements were a significant factor in how long it took their agencies to issue rules, but recognized that other factors also play a part. For example:

- A DOT official said that EO 12866 was the primary driver behind the economic analyses done for DOT agencies’ rules. He also said that one analysis then in progress had been in development for more than three months, and that if his office determines that the analysis had been done incorrectly, redoing the analysis could add several more months to the process. Just the requirement in Circular A-4 that agencies present a formal uncertainty analysis for rules involving annual economic effects of \$1 billion or more can take weeks. In addition, because of resource constraints, the amount of analysis can not only lengthen the time required to issue rules, but can also reduce the number of rules that an agency can issue. The official also said that the department considers a rule “old and cold” if it takes five years to issue from start to finish. Rules that take that long are often delayed because of intervening court decisions, changes in underlying legislation, or changes in presidential administrations.
- DOI officials said they believe that the analytical requirements are a significant contributor to the length of time it takes the department to issue a rule. They said the primary “drivers” of these analyses are EO 12866 (with OMB Circular A-4) and the RFA. The officials also said that, because the analysis is the primary subject of OIRA’s reviews, those reviews could lead to agencies spending even more time doing the analysis than is absolutely necessary.
- An FDA official said that although the amount of time it takes the agency to issue a rule varies widely, an average rule that took four years from start to finish would spend about a year in the economics office undergoing the various types of analysis required. During this one-year period, however, other rulemaking steps were going on simultaneously. He also said that if the analytical requirements were removed entirely, the average time required to issue the rule might be less than three years, as much of the reviews of the rule within the agency, department, and OIRA are focused on the analysis.

More commonly, however, the agency officials said they did not believe that the crosscutting analytical requirements were the primary factors determining how long it took their agencies to issue their rules. For example:

- A DOE official said that while preparation and revision of regulatory analyses took up a substantial portion of the time needed to issue the department's energy conservation standards (17 months of the 36-month standard timetable to issue such standards), the amount of time required to prepare those analyses was primarily driven by the requirements in EPCA, not the crosscutting analytical requirements. He said that even if all of the crosscutting analytical requirements were taken away, they would still have to do virtually the same amount of analysis to satisfy EPCA. The official said that the amount of analysis is driven somewhat by concerns about judicial review and OIRA review. He also said that rulemaking is also slowed by public participation requirements, and by the number of rules being reviewed by OIRA and the pace of those reviews.
- An EPA official said that much of the time needed to issue a significant EPA rule is taken up doing the basic science underlying the rule; having the rule reviewed by OIRA; public comment periods; and ensuring that the rule meets legal requirements and will not be overturned by the courts. The analytical requirements may play a role in one or more of these elements, but she said it is likely that it would take about the same amount of time to issue an EPA rule even if the analytical requirements were not there – particularly with regard to rules in which EPA is prohibited from considering costs (e.g., the NAAQS).<sup>157</sup> She also pointed out that the PRA usually does not delay the issuance of rules because, although the burden-hour estimates are part of the agency's cost-benefit analysis, the agency often goes through the OIRA review and public comment processes after the rule is written and published. As a result, although the effective date of the information collection element may be delayed, the issuance of the rule itself is not.
- A Commerce official said that although satisfying the analytical requirements for significant rules does take time, most of the time required to issue such rules is taken up with doing the basic science needed to develop regulatory standards, understanding the industry, and achieving consensus among the various parties in the rulemaking. She also said that OIRA reviews and concerns about judicial review could also cause the agencies to take more time and do more analysis than might be otherwise necessary.
- An FCC official said he did not think the RFA affects the amount of time to issue a rule “in the least.” He said the PRA usually does not delay the issuance of rules, but sometimes does delay the effective date of paperwork

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<sup>157</sup> The EPA official said that although courts have ruled that EPA cannot consider costs in setting standards under the Clean Air Act and the Safe Drinking Water Act, the agency does the analysis anyway.



requirements by a few months. However, most of this delay is due to the two-stage notice and comment requirements in the PRA and OMB review, not the paperwork burden analysis per se. He said the primary “drivers” of the length of time it takes FCC to issue a rule are (1) the notice and comment requirements in the APA (allowing adequate comment period), (2) the need to write rules in such a way that they maximize the chances of survival of judicial review, and (3) different FCC priorities that place one regulatory action ahead of another.

- An SEC official said that although the crosscutting analytical requirements clearly have some effect on the amount of time required to issue a rule, he believed that most of the time is driven by the agency’s preparation of the cost-benefit analysis and satisfaction of the requirements in the underlying statutes (e.g., the Advisers Act and the Exchange Act). He said the time required to satisfy the PRA varies considerably, from zero when the rule has no new information collection to a great deal for rules in which the primary burden is associated with an information collection. With regard to the RFA, he said the SEC has an “active community” that ensures that consideration of the effects on small entities is part of the rulemaking from start to finish.
- An HHS official said the time it takes to issue a rule is highly variable (from a few weeks to 20 years), with the amount of time required a function of many different factors (e.g., OMB and departmental review, public participation, and just the time it takes for the agency to understand the underlying problem). She also said that politics can also play a role, with rules taking longer when there is a lack of political will needed to issue a rule, or when other issues become a priority in an administration. The official also said many of the analyses and steps in the rulemaking process are going on simultaneously. Therefore, even if all or most of the crosscutting analytical requirements were removed, the overall amount of time required to issue a rule might be about the same. In fact, she said that without the analytical requirements, she could envision that it would take *more* time for agencies to issue rules, because the agency would know less about them, and would therefore have to spend more time in the review phase debating whether they should be issued.
- A USDA official said the time required to issue the department’s rules varies considerably, with the starting point usually being when the work plan for the rule is filed with the Office of the General Counsel. However, work on the rule sometimes does not begin immediately because of competing agency or departmental priorities. He said the biggest driver for how long it takes USDA to issue a rule is the time it takes for the agency and department to make the policy decisions regarding what the rule should address. If the agency can make those decisions quickly, “the rest follows pretty quickly,”

particularly since many of the different types of analyses can be done simultaneously rather than sequentially.

In some cases, although the analytical requirements themselves were not the cause of delays in rulemaking, they were a contributing factor. For example, an EPA official said that if the agency does not certify that a rule does not have a SEISNSE under the RFA, then they have to convene an advocacy review panel and take input from small entity representatives before issuing an NPRM. She said the conduct of those panels can take six or seven months from start to finish. Therefore, the RFA analysis can trigger a separate but time consuming step in the rulemaking process.

Just the process of determining whether an analysis is required can take substantial time. For example, an EPA official said that the RFA does not really slow down rulemaking if it is clear that the rule will or will not have a SEISNSE. But if EPA is not sure of that effect, the analysis can take substantial amounts of time (e.g., gathering data on the number of small businesses affected and their gross sales).

## **Conclusions/Recommendations**

The primary objectives of this report were to identify the crosscutting analytical requirements that executive branch agencies must comply with in the federal rulemaking process, and to determine whether those requirements could/should be consolidated to make the rulemaking process more efficient and effective. The report also attempted to determine the extent to which those analytical requirements have slowed down (“ossified”) rulemaking.

### **Listing of Analytical Requirements**

Although this report viewed crosscutting analytical requirements somewhat narrowly (i.e., as a subset of all rulemaking requirements), the number of such requirements that agencies must consider when issuing a rule is clearly substantial, covering a wide range of topics and with a variety of underlying objectives. The analytical requirements also vary in terms of what agencies and types of rules are covered, analytical thresholds, definitions, and the types of analyses that are required. Some of the requirements are general in nature, stating that agencies should identify all of the expected costs and benefits of forthcoming regulations. Other requirements are more specific, requiring discussions of environmental impacts, small entity impacts, paperwork burden, and effects on privacy, families, children, property rights, environmental justice, federalism, Indian tribes, and energy.

Although some federal departments and agencies (e.g., DOT and USDA) have developed their own sometimes-lengthy compilations of federal rulemaking requirements (which usually include, but are not limited to, the analytical requirements), there is currently no

authoritative government wide listing of the crosscutting analytical requirements that may apply to agencies' rules. Several of the agency officials interviewed for this report indicated that having a complete, up to date, and authoritative listing of the analytical requirements would make it easier for those preparing and reviewing the analyses to know what issues the agencies need to address in their rules. The lack of such a centralized listing may help explain why many of the analytical requirements (particularly those in the various executive orders) were not even mentioned in many of the major rules issued in 2010. Several of the agency officials indicated that failing to mention certain requirements was an oversight.

OIRA is described in Section 2(b) of EO 12866 as the “repository of expertise concerning regulatory issues, including methodologies and procedures that affect more than one agency.” Therefore, it seems appropriate that OIRA post on its website a list of the crosscutting analytical rulemaking requirements that may apply to the issuance of agency rules. The listing should provide hypertext links to the statutes and executive orders themselves, and could also walk the agencies through the circumstances in which certain analytical requirements apply.<sup>158</sup>

*Recommendation: OIRA should prepare and post on its website a concise listing of the various analytical rulemaking requirements, along with links to the documents themselves.*

## **Transparency and the Applicability of Rulemaking Requirements**

Some of the crosscutting analytical requirements (the RFA, the PRA, UMRA, EO 12866, and EO 13132) were mentioned in most of the major rules published in 2010. However, other requirements were mentioned in a quarter of the rules, or less. Even where the requirements were mentioned, in many cases it was only to say that the analysis was not required – sometimes using standard “boilerplate” explanatory language.

In many cases, given the substance and context of the rule and the nature of the analytical requirements, it is understandable why a particular requirement was not mentioned, or why an analysis was not required. For example, if a rule was issued by an independent regulatory agency that is not covered by EO 12866 or EO 13132, it is understandable (at least to those aware of the scope of the executive orders) why the agency would not mention them in the preamble to the rule. Also, if a rule establishes new disclosure or auditing requirements on the banking industry that will have no effect on the environment, it is understandable why the agency would not mention NEPA, or why a NEPA environmental impact statement would not be required. Even in these situations, though, a brief explanation could help the public understand why certain types of analyses were not performed.

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<sup>158</sup> For example, one section of the “Reg Map” (available at <http://www.reginfo.gov/public/reginfo/Regmap/index.jsp>) walks the reader through a series of basic questions to determine whether particular analytical requirements apply.

Explanations appear to be even more necessary and important for transparency when analytical requirements appear to be applicable, but the rule does not trigger the analysis. Some agencies went to great lengths to demonstrate why certain types of analysis were not required. However, other agencies simply said that certain types of analyses were not required for their rules, with little or no further explanation. The RFA states that when an agency certifies that a rule will not have a SEISNSE, it must include “a statement providing the factual basis for such certification.” Other analytical requirements do not require such explanatory statements.

Some agency officials indicated that requiring agencies to identify in the rule preambles the analytical requirements that are not triggered could be expensive for agencies, since the agencies must pay for each page published in the *Federal Register*. However, the absence of even a brief mention or explanation leaves the public wondering whether the agency even considered the requirement at all.

*Recommendation: Agencies should briefly indicate in the preamble to each rule whether certain analytical requirements are applicable to the rule. For each applicable requirement, when an analysis is not required, agencies should provide at least a brief explanation.*

## Coverage of the Analytical Requirements

Most of the more than 3,000 final rules issued each year are not subject to any analytical requirements, and often for good reason. After all, most final rules are administrative or technical in nature, and relatively uncontroversial, such as FAA airworthiness directives, administrative provisions for grant programs, and catch limitations in certain fishery economic zones. However, as this report points out, even most “major” rules are not covered by many of the analytical requirements. In some cases the lack of coverage is because independent regulatory agencies are not covered by the requirements (e.g., EO 12866 and OMB Circular A-4). In other cases it is because of various exclusions and exceptions written into the requirements (e.g., UMRA), or because of the discretion given to rulemaking agencies to decide whether the analysis is required (e.g., the RFA and various executive orders). GAO and others have reported that the exclusions and exceptions in UMRA, and the amount of discretion that agencies have under the RFA, have prevented those requirements from operating as effectively as they could.

Also, since the issuance of EO 12291 in 1981, executive departments and independent agencies have been required to prepare costs-benefit analyses for “major” or “economically significant” rules that have a \$100 million effect on the economy. However, unlike the \$100 million “expenditure” level in UMRA,<sup>159</sup> the \$100 million “effect” level in EO 12291, and later EO 12866, is not indexed for inflation. As a result, rules with a buying power of \$100 million in 2012 dollars would not have been

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<sup>159</sup> According to the Bureau of Labor Statistics, \$100 million in 1995 has the same buying power as \$148.7 million in 2012 dollars. See [http://www.bls.gov/data/inflation\\_calculator.htm](http://www.bls.gov/data/inflation_calculator.htm).

previously considered “major” or “economically significant. For example, according to the Bureau of Labor Statistics, \$100 million in 2012 dollars has the same buying power as \$40.1 million in 1981 (when EO 12291 was issued), and \$63.7 million in 1993 (when EO 12866 was issued).<sup>160</sup> Conversely, \$100 million in 1981 has the same buying power as \$249.4 million in 2012; \$100 million in 1993 has the same buying power as \$156.9 million in 2012.

Several pieces of legislation were introduced in the first session of the 112<sup>th</sup> Congress that would expand the scope of various analytical requirements. For example, S. 602 would expand the coverage of EO 12866 and generally require all agencies (including independent regulatory agencies) to submit cost-benefit analyses to OIRA for their significant regulatory actions (not just “economically significant” rules). S. 1189 and H.R. 373 would close some of the exemptions currently in UMRA (e.g., the exclusion for rules that are published without an NPRM). S. 474 and H.R. 527 would make several changes to the RFA’s requirements. Other proposed legislation would require certain agencies to do more analyses. For example, H.R. 3309 and S. 1784 would require the FCC, before adopting or amending a rule that may have an economically significant impact, to (1) analyze the specified market failure, actual consumer harm, burden of existing regulation, or failure of public institutions that warrants the rule or amendment; and (2) determine that the benefits justify its costs. In addition to these legislative initiatives, President Obama’s EO 13579 suggested that independent regulatory agencies should comply with certain provisions in EO 13563 (which repeated many of the analytic goals in EO 12866).

*Recommendation: Congress and the President should continue to reconsider the coverage of the crosscutting requirements. That reconsideration should particularly focus on analytical requirements that GAO and others have identified as giving agencies substantial amounts of discretion (e.g., the RFA and various executive orders), and requirements that are written in such a way that they exclude most of the rules that are covered by similar requirements (e.g., UMRA). Also, as part of that reconsideration, and before establishing any new requirements, Congress and the President should index any monetary thresholds for analysis to inflation.*

## **Different Analyses for Different Types of Rules**

In the cabinet departments and independent agencies where the most crosscutting requirements were applicable, the analytical requirement that seemed to drive the analysis most frequently was EO 12866 (and the associated Circular A-4). EO 12866 requires agencies to analyze the costs and benefits of alternative approaches for any rule that is expected to have a \$100 million “effect on the economy” in any year. This approach seems appropriate for rules that are expected to impose substantial compliance costs, or that may result in a “major increase in costs or prices.” However, as this report and the

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<sup>160</sup> See [http://www.bls.gov/data/inflation\\_calculator.htm](http://www.bls.gov/data/inflation_calculator.htm).

associated appendix makes clear, agencies' rules can have a \$100 million "effect on the economy" without imposing any traditional regulatory compliance costs or increasing costs or prices.<sup>161</sup> Nearly half of the "major" rules that were issued in 2010 seemed to be subject to the executive order's analytical requirements for other reasons (e.g., rules increasing or decreasing federal transfer payments, rules triggering consumer spending, or rules setting fee structures that the agencies use to fund certain government services).

Given the different nature of these "major" or "economically significant" rules, and that many of them are simply implementing statutory requirements, it is appropriate to consider whether different types of analyses should be required for different types of rules. The "analysis" that is done for many of the federal transfer rules is more like an accounting exercise, and is unlikely to have an effect on the agency's ultimate decision. Consumer surplus rules and rules that simply establish some type of user fee for government services seem even more different than compliance rules, and are also unlikely to be affected by the analysis. Therefore, it seems reasonable to question whether federal transfer, consumer surplus, and fee structure rules should be subject to the same type of analytical requirements as traditional regulations that impose compliance costs.<sup>162</sup>

Although OMB Circular A-4 mentions transfer payments, and says that they should be addressed in a separate discussion of the regulation's distributional effects, the circular does not clearly describe the type of analysis that should be prepared for rules that are economically significant for this reason. Neither does it describe how agencies should treat other types of "major" or "economically significant" rules (e.g., those setting fee structures, or that trigger consumer spending).

*Recommendation: OMB should amend Circular A-4 to clearly indicate that the analytical requirements should be tailored to the different types of rules. Traditional cost-benefit analysis appears most suited to rules that would impose \$100 million or more in annual compliance costs, or that would result in major increases in costs or prices. Other types of analyses may be more appropriate for rules increasing or decreasing federal transfer payments by at least \$100 million annually. Still other analytical approaches should perhaps be used for rules setting fee structures that are expected to produce \$100 million or more in annual revenues. Finally, consideration should be given to whether rules that are "major" or "economically significant" only because they are expected to stimulate consumer spending (e.g., the DOI migratory bird hunting rules) should be subject to any analytical requirements at all.*

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<sup>161</sup> Not everyone seems to understand this distinction. See, for example, Wayne Crews, "Tyranny of the Unelected; Congress Needs to Get a Handle on Costly Rules," *Washington Times*, October 12, 2010, p. B.1, in which the author states that Congress need not approve all rules, "just the 'major' one costing more than \$100 million annually...." Also, in testimony before the House Judiciary Committee's Subcommittee on the Courts and Commercial and Administrative Law on January 24, 2011, former Representative David McIntosh said that major rules are "those projected to impose cost on the American economy of more than \$100 million each." See <http://judiciary.house.gov/hearings/pdf/McIntosh01242011.pdf>.

<sup>162</sup> However, rules that are expected to result in non-federal annual transfers \$100 million or more from one population group to another (e.g., rules issued on February 2 and May 13 by IRS, EBSA, and CMS pursuant to the health care reform law) may well be affected by the agencies' analyses, and therefore are not considered part of this group.

## Overlapping Analytical Requirements

Each of the crosscutting analytical requirements that were most commonly cited in the 2010 major rules (the RFA, the PRA, UMRA, and EO 12866) share certain themes. Each generally requires some type of (1) discussion of the need for the regulatory action, (2) assessment of costs and/or benefits of the rule, and (3) discussion of the alternatives to the regulatory action that could have been selected. In some cases, the overlaps between the analytical requirements are substantial. For example, any rule that triggers the requirement for an UMRA Section 202 written statement will likely trigger the economic analysis requirements in EO 12866 and Circular A-4. There may also be substantial overlaps between crosscutting and agency or issue-specific analytical requirements. For example, DOE has indicated that the requirements of EO 12866 and UMRA substantially overlap with those in the Energy Policy and Conservation Act. Also, some of the analytical requirements can be integral parts of other requirements. For example, if a rule contains a covered collection of information under the PRA, an agency's estimate of the burden hours and other costs associated with that collection would naturally be part of the agency's overall estimate of regulatory costs under EO 12866.

A review of the 100 major rules published in 2010 indicates that the agencies recognize these overlaps, and that many of the analytical requirements are already being combined in some way. Many of the agency officials interviewed for this report indicated that the agencies often prepare a single analytical document intended to satisfy a range of crosscutting and agency- or issue-specific requirements, sometimes with separate chapters for particular types of studies. Therefore, in practice, the agencies already appear to be consolidating some of the analytical requirements.

Some of the crosscutting analytical requirements (e.g., the RFA, UMRA, and EO 13045) explicitly permit agencies to satisfy them as part of, or in conjunction with, some other analysis. However, other analytical requirements do not contain such statements. To ensure that agencies know that they need not duplicate their efforts, each of the analytical requirements could be amended to make this point clear. However, amending each of the statutes and executive orders would likely be very difficult. Another approach could be for OMB or OIRA to issue a document (or amend an existing document, like OMB Circular A-4, or the February 7, 2011, "Regulatory Impact Analysis: Frequently Asked Questions") clearly stating that any analysis can be used to satisfy more than one analytical requirement.

*Recommendation: Either as part of a reconsideration of OMB Circular A-4 or elsewhere, OMB or OIRA should notify agencies that a single analysis can be used to satisfy more than one analytical requirement. Agencies need not prepare separate analyses for each analytical requirement.*

## Consolidation of Analytical Requirements

Although many agencies appear to be consolidating some of the crosscutting analytical requirements in practice, consolidation of the requirements themselves into a single statute or executive order is likely to be difficult, if not impossible, for a variety of reasons. As noted earlier in this report and illustrated in **Table 4**, the requirements vary substantially in terms of the agencies and rules that they cover, their goals and specific requirements, and even the agencies responsible for their oversight. Some of the requirements apply to virtually every executive branch agency, while others specifically exclude independent regulatory agencies. Some of the requirements apply to most major rules, while others exclude most such rules. Specifically, some cover rules that are issued without an NPRM, and others do not. Some use a fixed dollar threshold (\$100 million) to determine coverage, but others do not. Even in the two analytical requirements that use a \$100 million analytical threshold, there are major differences. In UMRA, the analytical trigger is \$100 million in “expenditures,” and the figure is indexed for inflation. In EO 12866, one of the triggers (but not the only trigger) is \$100 million in economic “effect,” and that threshold is not indexed for inflation. Some of the requirements give agencies little or no discretion to decide whether an analysis is required, while others allow agencies wide latitude to decide whether the effects of the rule are “significant” or “substantial” enough to merit analysis. In determining whether the analytical requirements are triggered or as part of the analysis itself, some provisions require the agencies to consider indirect effects, while others do not. Combining requirements with such dissimilar coverages and terms would require that these differences be reconciled in some way, either by expanding the scope of one or limiting the scope of the other.

For example, although EO 12866 and UMRA cover the same agencies and require similar types of analysis, agencies prepared a regulatory analysis pursuant to the executive order in 73 of the 83 covered major rules issued in 2010; in contrast, the agencies prepared an analysis pursuant to Section 202 of UMRA in only four rules. If the analytical requirements in EO 12866 and UMRA were combined into a single statute or executive order, the coverage of EO 12866 would need to be limited to match UMRA, the coverage of UMRA would need to be expanded to match EO 12866, or some compromise position between the two extremes would have to be reached.

Consolidation of the RFA and EO 12866 could be even more difficult. First, the RFA covers virtually every executive branch agency, while EO 12866 excludes independent regulatory agencies. Consolidation would either require a limitation of the RFA’s coverage, or an expansion of the agencies covered by EO 12866. Those who favor keeping independent regulatory agencies at arms length from presidential control are likely to resist having those agencies prepare cost-benefit analyses that are overseen by OIRA, the President’s agent. Also, the RFA gives agencies substantial discretion to determine whether their rules have a “significant” economic impact on a “substantial” number of small entities, and therefore whether an analysis is required. EO 12866 gives agencies much less discretion; any rule that is expected to have an annual “effect on the economy” of \$100 million or more is required to have an RIA, and OIRA may require agencies to prepare an analysis for rules below that threshold. Consolidation of the RFA



and EO 12866 would require that these major differences in scope and agency discretion be reconciled in some way.

The analytical requirements are also very different in terms of their origins and objectives. For example, while the overall goal of the analytical requirements in EO 12866 is the maximization of regulatory net benefits, the goal of the RFA analysis is to minimize impacts on small entities (while still meeting the purpose of the rule) – goals that may or may not be consistent. Also, meshing these analytical requirements with the statutory authorities underlying agency rules and the implicit or explicit analytical requirements therein might be even more difficult. (Therefore, EO 12866 and the other executive orders often say that their analytical requirements are to be met “to the extent permitted by law.”)

An even larger barrier to consolidation of the various analytical requirements may be the interested parties that advocated for the creation of certain requirements, and who are likely to view with suspicion any effort to combine them with other requirements. For example, the small business community, SBA’s Office of Advocacy, and the House and Senate Small Business Committees are likely to resist any effort to fold regulatory flexibility analyses under the RFA into a general analytical requirement. State and local government representatives are likely to oppose consolidation of unfunded mandate and federalism analyses into a broader analytical requirement. Other groups that are primarily interested in particular issues (e.g., the effect of rules on children, minorities, or energy supplies) may also resist merging these stand-alone analyses into a single, omnibus study.

Also, consolidation of the requirements without narrowing their applicability or the nature of the analyses would not likely save the rulemaking agencies much time or money. Many agencies already view the requirements as a set of interrelated but sequentially discussed analyses, which is unlikely to change if the requirements are housed in a single statute or executive order. The manner in which the analytical requirements are consolidated (i.e., via statute or executive order) is also likely to be important. Unless specifically excluded, statutory requirements may be considered subject to enforcement by the courts through judicial review. Executive order requirements, on the other hand, are generally considered management requirements, and are usually enforceable only by the executive. Placing the current executive order analytical requirements into a statute could open new avenues for judicial challenge, which could make the rulemaking process slower and more adversarial.

If any of the crosscutting analytical requirements were to be consolidated, the most likely candidates would be the various executive order requirements that have been established over the past 25 years on such topics as constitutionally protected property rights (EO 12630), environmental justice (EO 12898), children and the environment (EO 13045), federalism (EO 13132), and energy effects (EO 13211). Rather than having to enact legislation, the President could simply issue a new executive order combining all or some of the analytical requirements into a single executive order, or explicitly folding these considerations into the economic analysis required by EO 12866. (EO 12866 and

Circular A-4 already call for agencies to consider the “distributional effects” of their forthcoming rules.) The President could also make clear that these consolidated requirements are not subject to judicial review. Nevertheless, consolidation of these executive orders would require reconciling many of the differences in scope that were previously described. For example, while EO 12630 and EO 12898 arguably include independent regulatory agencies, the other executive orders clearly do not. EO 13045 excludes rules for which the agency does not publish an NPRM; the other executive orders do not contain this restriction. EO 13211 only applies to rules that are considered “significant” under EO 12866; the other executive orders apply to all rules issued by covered agencies. Also, as noted previously, certain interest groups may resist elimination of freestanding analytical requirements into a single omnibus requirement.

As noted at the beginning of this report, in 1993, ACUS recommended that Congress “reconsider the need for continuing statutory analytical requirements that necessitate broadly applicable analyses or action to address narrowly-focused issues.” However, since many of the crosscutting requirements are currently in executive orders, ACUS may want to consider making the same type of recommendation to the President.

*Recommendation: The President should review the current set of executive order analytical requirements and determine whether some or all of them could be consolidated into a single executive order.*

## **Analytical Requirements and Ossification**

Satisfying the crosscutting analytical requirements, or even just determining that a particular type of analysis is not required, can clearly take agencies substantial amounts of staff time and resources. The agency officials interviewed for this report said the time required to issue rules varied substantially, and some said they had data on how long the overall process took (although the starting point for the process was not always clear or uniform). However, none of the officials said their agencies had data showing how much of the time needed to issue a rule was a function of the crosscutting analytical requirements. They often indicated that the amount of time needed to issue a rule was driven by a variety of factors, such as gathering data to understanding the industry that is being regulated, obtaining basic scientific information, balancing competing interests, obtaining political support to go forward with the rule, allowing the public to participate in the rulemaking process, and having the draft rule reviewed within the department or agency and by OIRA – often pursuant to what were identified as non-analytical requirements at the beginning of this report (e.g., the Administrative Procedure Act, or the review provisions in EO 12866).

In many ways, the dividing line between the analytical requirements and the non-analytical rulemaking requirements is not well defined. For example, in some rules, many of the comments provided during the notice and comment process, and OIRA’s reviews of draft rules, are about the regulatory analyses that the agencies conducted.

Also, concerns about OIRA review under EO 12866 and judicial review under the APA's "arbitrary and capricious" standard may well cause agencies to do more than the minimal amount of analysis that is required. In some agencies, the analyses that are conducted are primarily driven not by the crosscutting analytical requirements, but by the statutes underlying the rules (e.g., EPCA within DOE). In other agencies (e.g., EPA, OSHA, and the new CFPB), if the agency concludes that a rule has a "significant" economic impact on a "substantial" number of small entities under the RFA, the agency must hold an advocacy review panel and prepare a compliance guide – steps that, while not analytical themselves, are triggered by an analysis and can cause significant delays. Finally, many of the agency officials indicated that the analyses required by the various statutes and executive orders are being conducted at the same time as other steps in the rulemaking process (e.g., engineering studies and legal reviews). Therefore, while the analytical requirements might add to the number of "person days" required to issue a rule, the actual number of elapsed days may increase only slightly, or not at all.

It should be recognized that not everyone views "ossification" negatively. Some consider the additional time required to do analyses a good thing, as they believe the rulemaking process should be as slow and deliberative as necessary to produce sound decisions. Because agencies have no data showing that the analytical requirements themselves add significant amounts of time to the rulemaking process, and because the analyses can often be done simultaneous with other rulemaking steps, this report makes no recommendations in this area.

# Appendix 1: Why Rules Were Considered “Major”

As noted in the body of this report, the Congressional Review Act (CRA) defines a “major rule” as

any rule that the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget finds has resulted in or is likely to result in—(A) an annual effect on the economy of \$100,000,000 or more; (B) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (C) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. The term does not include any rule promulgated under the Telecommunications Act of 1996 and the amendments made by that Act.<sup>163</sup>

Some observers have indicated that all major rules have \$100 million dollars or more in annual compliance costs. For example, Wayne Crews of the Competitive Enterprise Institute said major rules “are the ones costing \$100 million annually.”<sup>164</sup> Also, an editorial in the *Las Vegas Review-Journal* (“Too Many Rules,” January 24, 2011, p. B9) stated that the REINS Act (H.R. 10 in the 112<sup>th</sup> Congress) requires an up-or-down vote on “regulations likely to cost \$100 million or more.” In fact, however, many rules are considered “major” because of an annual “effect on the economy” that is unrelated to compliance costs (e.g., increases or decreases in federal transfer payments, changes in consumer spending, or changes in fees for government services). Also, where compliance costs are a factor in why rules are considered “major,” more often than not the rules are expected to have benefits that exceed those costs.

This appendix, drawn from a report prepared by the Congressional Research Service (CRS),<sup>165</sup> discusses why the 100 major rules issued in calendar year 2010 appeared to be considered “major,” and provides examples of transfer rules (increasing and decreasing federal transfer payments, and non-federal transfers; consumer surplus rules and rules establishing fees; rules considered major because of costs, benefits, or both; and rules that appeared to be major because of major increases in costs or prices.

## Transfer Rules

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<sup>163</sup> 5 U.S.C. § 804(2).

<sup>164</sup> Wayne Crews, “Tyranny of the Unelected; Congress Needs to Get a Handle on Costly Rules,” *Washington Times*, October 12, 2010, p. B.1.

<sup>165</sup> U.S. Congressional Research Service, *REINS Act: Number and Type of “Major” Rules in Calendar Year 2010*, by Curtis W. Copeland and Maeve P. Carey, April 2011.

Several rules that involved transfers of funds from one party to another were considered “major” because the amount of federal transfer payments were increasing or decreasing, or because the rules involved non-federal transfers.

### *Increasing Federal Transfer Payments*

In 23 of the rules, the federal transfer payments appeared to be increasing. For example:

- A January 25, 2010, DOE rule on “Weatherization Assistance Program for Low-Income Persons” reduced the procedural burdens on evaluating applications from buildings that are part of HUD assisted and public housing programs, the Federal Low Income Housing Tax Credit Program, and the USDA Rural Development Program. DOE indicated that the \$5 billion in grants provided under this program by the American Recovery and Reinvestment Act of 2009 (P.L. 111-5) made the rule a major rule, and “constitute transfer payments, meaning that they do not represent a change in the total resources available to society.”<sup>166</sup>
- A January 29, 2010, USDA Food and Nutrition Service rule established new eligibility and certification requirements for the receipt of food stamps. USDA said that it expects this rule to simplify program administration, allow states greater flexibility, and provide enhanced access to eligible populations. The agency estimated that the total transfer costs to the government of this rule would be \$2.669 billion in FY2010 and \$13.541 billion during the five-year period from FY2010 through FY2014.<sup>167</sup>
- A March 12, 2010, rule issued by the Office of Innovation and Improvement within ED established priorities, requirements, definitions, and selection criteria under the Investing in Innovation Fund, which provides funding support to local educational agencies (LEAs) and nonprofit organizations in a partnership with one or more LEAs or a consortium of schools with a record of improving student achievement and attainment. ED estimated that the final rule would result in associated “annual monetized transfers” of \$643 million per year from the federal government to LEAs and nonprofit organizations.<sup>168</sup>

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<sup>166</sup> U.S. Department of Energy, “Weatherization Assistance Program for Low-Income Persons,” *75 Federal Register* 3847, January 25, 2010. DOE stated (p. 3854) that the \$5 billion in grants for the weatherization program “at a level greater than \$100 million makes this rulemaking economically significant under [Executive Order 12866].” As noted later in this report, the definition a “major rule” in the CRA is slightly broader than the definition of “economically significant” in the executive order. DOE also indicated (on p. 3856) that the rule was “major” under the CRA.

<sup>167</sup> U.S. Department of Agriculture, Food and Nutrition Service, “Food Stamp Program: Eligibility and Certification Provisions of the Farm Security and Rural Investment Act of 2002; Final Rule,” *75 Federal Register* 4911, January 29, 2010.

<sup>168</sup> U.S. Department of Education, Office of Innovation and Improvement, “Investing in Innovation Fund; Final Rule and Notice,” *75 Federal Register* 12003, March 12, 2010.

- An April 16, 2010, DOD rule provided for retroactive stop loss special pay to members of the military service as authorized and appropriated in the Supplemental Appropriations Act, 2009 (Section 310 of P.L. 111-32). Although DOD did not provide a cost-benefit analysis with the final rule, in the preamble to the rule the department stated that the rule would have a \$100 million annual impact on the economy in that the “Supplemental Appropriations Act, 2009 appropriated \$534,400,000 to the Department of Defense, to remain available for obligation until expended.”<sup>169</sup>
- A July 22, 2010, rule issued by the Centers for Medicare and Medicaid Services (CMS) within HHS announced the annual update to the hospice wage index for FY2011 and continued the phase out of the wage index budget neutrality adjustment factor. As a result, CMS estimated that total federal hospice payments would increase by \$220 million in FY2010.<sup>170</sup>
- A July 30, 2010, rule issued by the Office of Consumer Information and Insurance Oversight (OCIIO) within HHS implemented Section 1101 of the Patient Protection and Affordable Care Act of 2010 (PPACA, P.L. 111-148, March 23, 2010), which required HHS to establish, either directly or through contracts with states or nonprofit entities, a temporary high-risk health insurance pool program to provide affordable health insurance coverage to uninsured individuals with pre-existing conditions. OCIIO estimated that the annual reporting and recordkeeping costs would be less than \$2 million, but said that \$5 billion in federal funds would be transferred from the Secretary to contractors to aid in administering the program from July 1, 2010, to December 31, 2013.<sup>171</sup>
- An August 31, 2010, DVA rule amended the department’s adjudication regulations to implement the decision of the Secretary of Veterans Affairs that there is a positive association between exposure to certain herbicides and the subsequent development of hairy cell leukemia and other chronic B-cell leukemias, Parkinson’s disease, and ischemic heart disease. DVA estimated that the total cost for this rulemaking (primarily retroactive and ongoing benefits payments) to be \$13.6 billion during FY2010, \$25.3 billion for 5 years, and \$42.2 billion over 10 years.<sup>172</sup>

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<sup>169</sup> U.S. Department of Defense, Office of the Secretary, “Retroactive Stop Loss Special Pay Compensation,” 75 *Federal Register* 19878, April 16, 2010. For more information on the stop loss special pay program, see [http://www.defense.gov/home/features/2010/0710\\_stoploss/](http://www.defense.gov/home/features/2010/0710_stoploss/).

<sup>170</sup> U.S. Department of Health and Human Services, “Medicare Program; Hospice Wage Index for Fiscal Year 2011; Notice,” 75 *Federal Register* 42943, July 22, 2010.

<sup>171</sup> U.S. Department of Health and Human Services, Office of Consumer Information and Insurance Oversight, “Pre-Existing Condition Insurance Plan Program,” 75 *Federal Register* 45013, July 30, 2010.

<sup>172</sup> U.S. Department of Veterans Affairs, “Diseases Associated With Exposure to Certain Herbicide Agents (Hairy Cell Leukemia and Other Chronic B-Cell Leukemias, Parkinson’s Disease and Ischemic Heart Disease),” 75 *Federal Register* 53202, August 31, 2010.

- An October 25, 2010, rule issued by the Farm Service Agency (FSA) within USDA provided emergency assistance to reestablish the purchasing of rice, cotton, soybeans, and sweet potatoes in specified counties for which a disaster designation was issued based on excessive moisture and related conditions for the 2009 crop year. The rule specified the eligibility requirements, payment calculations, and application procedures for the Crop Assistance Program. FSA estimated that the total cost to the government for the program would be between \$137 million and \$543 million, depending on how many producers in disaster counties applied for payments.<sup>173</sup>

One other rule appeared to be “major” because federal loans were expected to be converted into transfer payments (which CRS considered to be a transfer increase). On January 19, 2010, the Federal Emergency Management Agency (FEMA) within DHS published a rule that amended the agency’s Special Community Disaster Loan (CDL) Program regulations to establish procedures and requirements for Special CDL cancellations. The loan cancellations were authorized by Section 4502(a) of the U.S. Troop Readiness, Veterans’ Care, Katrina Recovery, and Iraq Accountability Appropriations Act, 2007 (P.L. 110-28). The Special CDL Program and the cancellation provisions applied to communities in the Gulf Coast region who received Special CDLs following Hurricanes Katrina and Rita. FEMA estimated that up to \$1.3 billion in loans, interest, and costs could be forgiven under this effort.<sup>174</sup>

### *Decreased Federal Transfers*

Nine other rules appeared to be “major” at least in part because they were decreasing the amount of federal transfers provided.<sup>175</sup> For example:

- An August 12, 2010, CMS rule implemented a new prospective payment system for Medicare outpatient end-stage renal disease dialysis facilities, in compliance with the Medicare Improvements for Patients and Providers Act of 2008 (P.L. 110-275). The rule also replaced the previous payment system and the methodologies for the reimbursement of separately billable outpatient end-stage renal disease services. CMS estimated that there would be an approximately \$200 million decrease in payments to all end-stage renal disease facilities for renal dialysis during calendar year 2011,

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<sup>173</sup> U.S. Department of Agriculture, Farm Service Agency, “Crop Assistance Program,” 75 *Federal Register* 65423, October 25, 2010.

<sup>174</sup> U.S. Department of Homeland Security, Federal Emergency Management Agency, “Special Community Disaster Loans Program,” 75 *Federal Register* 2800, January 19, 2010. FEMA stated (p. 2815) that although “the impact of the rule could be spread over multiple years as applications are received, processed, and loans cancelled, the total economic effects of a specific loan cancellation would occur once, rather than annually.”

<sup>175</sup> Seven of these rules appeared to be “major” only because of decreased transfers, and two other rules involved decreased transfers and one other category of explanation.

compared to what the payments would have been that year in the absence of this rule.<sup>176</sup>

- An August 16, 2010, CMS rule revised the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals to implement changes arising from the agency's continuing experience with these systems, and to implement certain statutory provisions. The rule also described the changes to the amounts and factors used to determine the rates for Medicare acute care hospital inpatient services for operating costs and capital-related costs, and updated the rate-of-increase limits for certain hospitals excluded from the IPPS that are paid on a reasonable cost basis subject to these limits. In addition, the rule updated the payment policy and the annual payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs) and set forth the changes to the payment rates, factors, and other payment rate policies under the LTCH PPS. CMS estimated that the final applicable percentage increase to the IPPS rates required by the statute, in conjunction with other final payment changes in the rule, would result in a \$440 million decrease in FY2011 operating payments and an estimated \$21 million decrease in FY2011 capital payments.<sup>177</sup>
- An October 15, 2010, DOD rule implemented Section 703 of the National Defense Authorization Act for Fiscal Year 2008, which stated that, with respect to any prescription filled on or after the date of enactment, the TRICARE Retail Pharmacy Program shall be treated as an element of DOD for purposes of procurement of drugs by federal agencies under 38 U.S.C. § 8126, to the extent necessary to ensure pharmaceuticals paid for by DOD that are provided by network retail pharmacies to TRICARE beneficiaries are subject to Federal Ceiling Prices (FCPs). Section 8126 established FCPs for covered drugs (requiring a minimum 24% discount) procured by DOD and three other agencies from manufacturers. DOD estimated that the rule would result in cost reductions from applying FCPs to the TRICARE Retail Pharmacy Network in FY2010 through FY2015 of between \$375 million and \$560 million for Defense Health Program spending, and between \$474 million and \$707 million for Medicare-Eligible Retiree Health Care Fund spending.<sup>178</sup>

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<sup>176</sup> U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, "Medicare Program; End-Stage Renal Disease Prospective Payment System; Final Rule and Proposed Rule," *75 Federal Register* 49029, August 25, 2010.

<sup>177</sup> U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, "Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System Changes and FY2011 Rates; Provider Agreements and Supplier Approvals; and Hospital Conditions of Participation for Rehabilitation and Respiratory Care Services; Medicaid Program: Accreditation for Providers of Inpatient Psychiatric Services," *75 Federal Register* 50041, August 16, 2010.

<sup>178</sup> U.S. Department of Defense, Office of the Secretary, "Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)/TRICARE: Inclusion of TRICARE Retail Pharmacy Program in Federal Procurement of Pharmaceuticals," *75 Federal Register* 63383, October 15, 2010.



## *Non-federal Transfers*

Five rules appeared to be “major” not because of increases or decreases in the transfer of federal funds, but because they were (at least in part) expected to result in annual transfers of \$100 million or more from one population group to another.<sup>179</sup> Four of the rules were jointly issued by the Internal Revenue Service (IRS) within the Department of the Treasury, the Employee Benefits Security Administration (EBSA) within the Department of Labor, and CMS within the Department of Health and Human Services. For example:

- A February 2, 2010, rule required parity between mental health or substance use disorder benefits and medical/surgical benefits with respect to financial requirements and treatment limitations under group health plans and health insurance coverage offered in connection with a group health plan. The rule replaced regulations implementing the Mental Health Parity Act of 1996, and made conforming changes to reflect modifications to the act. The agencies said that the rule was considered “major” because total health care premiums were expected to rise 0.4%, and that increase was considered a transfer from those individuals not using mental health and substance use disorder benefits to those who do. The agencies estimated that those undiscounted transfers to be about \$25.6 billion during the next 10 years.<sup>180</sup>
- A May 13, 2010, rule implemented the requirements for group health plans and health insurance issuers in the group and individual markets under provisions of the Patient Protection and Affordable Care Act regarding dependent coverage of children who have not reached age 26. Specifically, a plan or issuer that makes available dependent coverage of children was required to make such coverage available for children until attainment of 26 years of age. The agencies estimated the 2011 to 2013 transfers associated with this rule at between \$3.5 and \$6.9 billion, with the funds moving from individuals with family health insurance coverage who do not have dependents aged 19-25 to those individuals with family health insurance coverage that do have such dependents.<sup>181</sup>

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<sup>179</sup> Four of these rules appeared to be “major” only because of non-federal transfers, and one other rule also involved another category of explanation.

<sup>180</sup> U.S. Department of the Treasury, Internal Revenue Service; Department of Labor, Employee Benefits Security Administration; Department of Health and Human Services, Centers for Medicare and Medicaid Services, “Interim Final Rules Under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008,” 75 *Federal Register* 5409, February 2, 2010. Discounted benefits or costs are sometimes referred to as “discounted present values,” or simply “present values,” and are used when the costs and the benefits of rules are expected to occur at different times. OMB Circular A-4 recommends that agencies use both a 7% and a 3% discount rate. The annual undiscounted transfer estimates ranged from \$2.36 billion to \$2.81 billion per year.

<sup>181</sup> U.S. Department of the Treasury, Internal Revenue Service; Department of Labor, Employee Benefits Security Administration; Department of Health and Human Services, Centers for Medicare and Medicaid Services, “Group Health Plans and Health Insurance Issuers Relating to Dependent Coverage of Children to Age 26 Under the Patient Protection and Affordable Care Act,” 75 *Federal Register* 27121, May 13, 2010.

One other rule issued by the Commodity Credit Corporation within USDA also appeared to be a major rule because of these kinds of non-federal transfers.<sup>182</sup>

### **“Consumer Surplus” Rules and Rules Establishing Fees**

Six of the 100 major final rules published in 2010 appeared to be “major” because they were expected to trigger a certain type of economic activity by the public (termed a “consumer surplus”).<sup>183</sup> All six of these rules were issued by DOI’s Fish and Wildlife Service (FWS), and established hunting seasons and bag limits for certain types of migratory birds. For example, a September 23, 2010, FWS rule prescribed final late-season frameworks from which the states could select season dates, limits, and other options for the 2010-2011 migratory bird hunting seasons.<sup>184</sup> FWS estimated that the rule would result in a consumer surplus of between \$205 million and \$270 million. The other five FWS rules had similar consumer surplus estimates.

Four other rules appeared to be considered “major” because they established fee structures that were intended to fund certain government operations. For example:

- A June 16, 2010, NRC rule amended the licensing, inspection, and annual fees charged to the agency’s applicants and licensees. NRC said it viewed these amendments as necessary to implement the Omnibus Budget Reconciliation Act of 1990, as amended (42 U.S.C. § 2214), which the agency said generally requires the NRC to recover through fees approximately 90% of its budget authority in FY2010. NRC determined that its required fee recovery amount for FY2010 was approximately \$912.2 million and that, after accounting for billing adjustments, the total amount to be billed as fees was approximately \$911.1 million.<sup>185</sup>
- A June 28, 2010, Department of State rule adjusted the Schedule of Fees for Consular Services based on an independent cost of service study’s findings that the United States was not fully covering its costs for providing these services under the previous fee structure. The department said that its primary objective was to ensure that fees for consular services reflected the costs to the United States of providing the services to the extent possible. Among other things, the rule increased the Passport Book Application

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<sup>182</sup> U.S. Department of Agriculture, Commodity Credit Corporation, “Conservation Reserve Program,” *75 Federal Register* 44067, July 28, 2010. According to the GAO major rule report, certain provisions in the rule would “largely substitute one [conservation reserve program] participant for another, or one practice for another, leading in a shift in costs and benefits to different participants and practices, but little net cost or benefit for the [commodity reserve program] as a whole.”

<sup>183</sup> In this case, the consumer surplus is an estimate of the amount individuals are willing to pay to hunt waterfowl and other types of migratory birds.

<sup>184</sup> U.S. Department of the Interior, Fish and Wildlife Department, “Migratory Bird Hunting; Final Frameworks for Late-Season Migratory Bird Hunting Regulations,” *75 Federal Register* 58249, September 23, 2010.

<sup>185</sup> U.S. Nuclear Regulatory Commission, “Revision of Fee Schedules; Fee Recovery for FY 2010,” *75 Federal Register* 34219, June 16, 2010

Services fee (for applicants age 16 and older) from \$55 to \$70, which was expected to produce additional fees of about \$138 million. An increase in the Passport Book Security Surcharge from \$20 to \$40 was expected to generate additional fees of nearly \$239 million.<sup>186</sup>

- A September 24, 2010, DHS rule adjusted the fee schedule for the U.S. Citizenship and Immigration Services to fully recover costs and maintain adequate service. DHS said that the rule would provide it with an average of \$209 million in FY2010 and FY2011 annual fee revenue over the fee revenue that would have been collected under the previous fee structure. DHS said that the increased revenue would be used to fund the full cost of processing immigration benefit applications and associated support benefits, providing similar benefits to asylum and refugee applicants, and providing similar benefits to others at no charge.<sup>187</sup>

### **Costs, Benefits, or Both**

As the above discussion illustrates, final rules can be considered “major” for a variety of reasons unrelated to traditional notions of regulatory costs or benefits. Nevertheless, 39 of the 100 major rules that were published in 2010 appeared to be “major” in part because they were expected to result in at least \$100 million in annual compliance costs, \$100 million in annual benefits, or both.<sup>188</sup> (Thirty of the rules were expected to have regulatory costs of at least \$100 million, and 29 rules were expected to have regulatory benefits of at least \$100 million.) In 20 of the 39 rules, estimated costs and benefits were both expected to exceed \$100 million. In the 19 other major rules, the agencies did not provide a monetary estimate of either annual costs or benefits, or those estimates were less than \$100 million.

In almost all of the rules in which both benefits and costs were estimated and monetized, the agencies’ average or central estimates of regulatory benefits were larger than their average or central estimates of compliance costs. However, in some of these cases, the ranges of estimated benefits and costs overlapped, or could overlap. Therefore, while these rules appeared likely to produce net benefits, it is theoretically possible that the costs of the rules could exceed the benefits (assuming the agencies’ estimates of the range of costs and benefits are accurate). For example:

- A February 9, 2010, rule issued by EPA revised the primary nitrogen dioxide national ambient air quality standards. The rule established a new 1-hour standard at a level of 100 parts per billion, and established requirements for

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<sup>186</sup> U.S. Department of State, “Schedule of Fees for Consular Services, Department of State and Overseas Embassies and Consulates,” *75 Federal Register* 36522, June 28, 2010.

<sup>187</sup> U.S. Department of Homeland Security, U.S. Citizenship and Immigration Services, “U.S. Citizenship and Immigration Services Fee Schedule,” *75 Federal Register* 58961, September 24, 2010.

<sup>188</sup> Thirty-seven of the rules appeared to be “major” only because of such costs and/or benefits, and two other rules also involved one other category of explanation.

a nitrogen dioxide monitoring network that will include monitors at locations where maximum nitrogen dioxide concentrations are expected. EPA estimated that the cost of the rule in the year 2020 would be between \$270 million and \$510 million (in 2006 dollars), and the estimated benefits that year would be between \$120 million and \$580 million (in 2006 dollars). Therefore, EPA said the rule could result in either positive or negative net benefits.<sup>189</sup>

- A March 3, 2010, EPA rule promulgated national emission standards for hazardous air pollutants for certain existing stationary compression ignition reciprocating internal combustion engines. The rule also promulgated national air standards for hazardous air pollutants for certain existing non-emergency stationary compression ignition engines. EPA estimated the total national capital cost for the final rule to be \$744 million, with a total national annual cost of \$373 million in 2013. EPA estimated the monetized benefits of the rule to be between \$850 million and \$2.3 billion in 2013. Therefore, if \$478 million or more of the expected capital costs occur in 2013, the total estimated costs of the rule in that year would exceed the lowest estimated benefits.<sup>190</sup>
- A May 28, 2010, rule issued by the Federal Aviation Administration (FAA) within DOT amended the agency's regulations by adding equipment requirements and performance standards for Automatic Dependent Surveillance-Broadcast (ADS-B) Out avionics on aircraft operating in Classes A, B, and C airspace, as well as certain other specified classes of airspace within the U.S. National Airspace System. FAA said that the rule facilitated the use of ADS-B for aircraft surveillance by FAA and DOD air traffic controllers to safely and efficiently accommodate aircraft operations and the expected increase in demand for air transportation. The agency estimated that the undiscounted quantified benefits of the final rule ranged from \$6.8 billion to \$8.5 billion, and estimated the undiscounted incremental costs at between \$3.3 billion and \$7.0 billion.<sup>191</sup> Therefore, although average expected benefits substantially exceeded average expected costs, the highest estimate of cost (\$7.0 billion) was slightly higher than the lowest estimate of benefits (\$6.8 billion).

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<sup>189</sup> U.S. Environmental Protection Agency, "Primary National Ambient Air Quality Standards for Nitrogen Dioxide," 75 *Federal Register* 6473, February 9, 2010. Although EPA prepared a cost-benefit analysis for the rule, EPA said that the Clean Air Act and judicial decisions "make clear that the economic and technical feasibility of attaining ambient standards are not to be considered in setting or revising [national ambient air quality standards]."

<sup>190</sup> U.S. Environmental Protection Agency, "National Emission Standards for Hazardous Air Pollutants for Reciprocating Internal Combustion Engines," 75 *Federal Register* 9647, March 3, 2010.

<sup>191</sup> U.S. Department of Transportation, Federal Aviation Administration, "Automatic Dependent Surveillance—Broadcast (ADS-B) Out Performance Requirements To Support Air Traffic Control (ATC) Service," 75 *Federal Register* 30159, May 28, 2010.

- A September 15, 2010, rule issued by the Civil Rights Division within DOJ revised the regulation that implements Title II of the Americans with Disabilities Act (ADA), relating to nondiscrimination on the basis of disability in state and local government services. The department reportedly issued this rule in order to adopt enforceable accessibility standards under the ADA that are consistent with the minimum guidelines and requirements issued by the Architectural and Transportation Barriers Compliance Board (Access Board), and to update or amend certain provisions of the Title II regulation so that they comport with the department's legal and practical experiences in enforcing the ADA since 1991. DOJ's estimate of compliance costs ranged from \$12.8 billion to \$25.8 billion, and the estimate of benefits ranged from \$22.0 billion to \$66.2 billion. Therefore, although average expected benefits substantially exceeded average expected costs, the highest estimate of cost (\$25.8 billion) was higher than the lowest estimate of benefits (\$22.0 billion).<sup>192</sup>

### *Net Benefits*

In 14 of the 20 rules with estimated annual regulatory costs and benefits of at least \$100 million, the agencies' *lowest* estimates of regulatory benefits were larger than the *highest* estimated compliance costs. Therefore, assuming that the agencies' estimates of the range of costs and benefits were correct, the rules should produce positive net benefits. For example:

- A March 9, 2010, DOE rule established energy conservation standards for small electric motors. The department estimated that the annualized costs of this rule would be about \$264 million per year. DOE estimated a range of possible values for the total monetary benefits of this final rule from \$867.5 million to about \$1.36 billion.<sup>193</sup>
- A March 19, 2010, rule issued by the Food and Drug Administration (FDA) within HHS was identical to the provisions of the final rule on cigarettes and smokeless tobacco published by FDA in 1996, with certain required exceptions. The rule prohibited the sale of cigarettes and smokeless tobacco to individuals under the age of 18 and imposed specific marketing, labeling, and advertising requirements. Although FDA did not include a cost-benefit analysis in the 2010 rule, in the 1996 rule, the agency said that the rule could prevent 60,000 early deaths. The monetary value of these and other health benefits was estimated to be between \$9.2 billion and \$43 billion per year. FDA estimated the rule's overall compliance costs at from \$174 million to

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<sup>192</sup> U.S. Department of Justice, Civil Rights Division, "Nondiscrimination on the Basis of Disability in State and Local Government Services," 75 *Federal Register* 56163, September 15, 2010.

<sup>193</sup> U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, "Energy Conservation Program: Energy Conservation Standards for Small Electric Motors," 75 *Federal Register* 10873, March 9, 2010.

\$187 million in one-time costs, and from \$149 million to \$185 million in annual operating costs.<sup>194</sup> Therefore, even if the highest estimated one-time costs occurred in the same year as the highest estimated annual operating costs, the total would still be less than the lowest estimated benefits for that year.

- An April 5, 2010, rule issued by the Federal Motor Carrier Safety Administration (FMCSA) within DOT incorporated new performance standards for electronic on-board recorders (EOBRs) installed in commercial motor vehicles manufactured on or after June 4, 2012. The rule also made motor carriers that have demonstrated serious noncompliance with hours-of-service rules subject to mandatory installation of EOBRs meeting the new performance standards. FMCSA said that the costs of the final rule on an annualized basis over a 10-year period would be \$139 million. FMCSA determined the benefits of the final rule to be \$182 million annually, which included safety benefits of electronic on-board recorder use by estimating reductions in hours of service violations and resulting reductions in fatigue-related crashes.<sup>195</sup>
- An April 16, 2010, DOE rule amended the existing energy conservation standards for residential water heaters (other than tabletop and electric instantaneous models), gas-fired direct heating equipment, and gas-fired pool heaters. DOE determined that the annualized monetized benefits of the rule would be between \$1.67 billion per year and \$2.02 billion per year, with costs estimated to be between \$1.25 billion per year and \$1.28 billion per year.<sup>196</sup>
- An August 9, 2010, rule issued by the Occupational Safety and Health Administration (OSHA) within DOL revised the agency's "Cranes and Derricks Standard" and related sections of the "Construction Standard" to update and specify industry work practices necessary to protect employees during the use of cranes and derricks in construction. This rule also addressed advances in the designs of cranes and derricks, related hazards, and the qualifications of employees needed to operate them safely. OSHA estimated that the total annualized costs of the rule would be \$154.1 million. OSHA estimated that the annual benefits included injuries prevented (175), fatalities prevented (22), and property damage from tipovers prevented (\$7 million), for total monetized benefits of \$209.3 million.<sup>197</sup>

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<sup>194</sup> U.S. Department of Health and Human Services, Food and Drug Administration, "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents," 61 *Federal Register* 44569, March 19, 2010.

<sup>195</sup> Department of Transportation, Federal Motor Carrier Safety Administration, "Electronic On-Board Recorders for Hours-of-Service Compliance," 75 *Federal Register* 17207, April 5, 2010.

<sup>196</sup> Department of Energy, "Energy Conservation Program: Energy Conservation Standards for Residential Water Heaters, Direct Heating Equipment, and Pool Heaters," 75 *Federal Register* 20112, April 16, 2010.

<sup>197</sup> U.S. Department of Labor, Occupational Safety and Health Administration, "Cranes and Derricks in Construction,"

## *Net Costs*

In only one of the major rules did the agency indicate that the rule would likely result in net costs (i.e., that the highest estimate of benefits was less than the lowest estimate of costs). On January 15, 2010, the Federal Railroad Administration (FRA) within DOT issued a rule on “Positive Train Control Systems” that were required on certain passenger and freight rail lines by the Rail Safety Improvement Act of 2008 (P.L. 110-432, 122 Stat. 4854, October 16, 2008).<sup>198</sup> Congress enacted the statutory requirement in the wake of several serious rail accidents involving dozens of fatalities and hundreds of injuries. FRA estimated that the rule would reduce deaths and injuries from this type of accident by more than 50%, and estimated the monetized benefits of the rule at between \$440 million and \$674 million. However, the agency estimated the 20-year costs at between \$9.5 billion and \$13.2 billion—about 20 times greater than the estimated benefits. FRA noted this imbalance in the rule, but said it was “constrained by the requirements of [the Rail Safety Improvement Act of 2008], which do not provide latitude for implementing [positive train controls] differently.”<sup>199</sup> In August 2011, though, DOT announced that it was considering modifying or removing certain provisions in the rule, which were expected to result in savings of between \$443 million and \$1.04 billion over 20 years.<sup>200</sup>

## *Monetized Costs but Non-monetized Benefits*

In several other rules, the agencies estimated the annual compliance costs at \$100 million or more, but provided only qualitative descriptions of expected regulatory benefits. Nevertheless, the agencies indicated in many of these rules that the value of the expected benefits, if monetized, would exceed or “justify” the costs. For example, see the following:

- A January 11, 2010, rule issued by the Securities and Exchange Commission (SEC) amended the custody and recordkeeping rules under the Investment Advisers Act of 1940 and related forms by providing additional safeguards when a registered adviser has custody of client funds or securities. The SEC estimated the aggregate compliance costs at more than \$126 million; it said the non-monetized benefits would be “substantial,” and would include increasing investors’ confidence when obtaining advisory services from

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75 *Federal Register* 47905, August 9, 2010.

<sup>198</sup> U.S. Department of Transportation, Federal Railroad Administration, “Positive Train Control Systems,” 75 *Federal Register* 2598, January 15, 2010. “Positive train control systems” refers to technology that can prevent accidents such as train-to-train collisions and train movements through a switch left in the wrong position. DOT subsequently announced that it had reviewed the rule pursuant to Executive Order 13563, and was planning to revise it to lower implementation costs by hundreds of millions of dollars. See <http://regs.dot.gov/docs/RRR-Planfinal-8-20.pdf> for a copy of DOT’s review plan.

<sup>199</sup> U.S. Department of Transportation, Federal Railroad Administration, “Positive Train Control Systems,” 75 *Federal Register* 2598, January 15, 2010, p. 2685.

<sup>200</sup> This review was done as part of DOT’s response to EO 13563. See <http://regs.dot.gov/docs/RRR-Planfinal-8-20.pdf> for a copy of DOT’s review plan.

registered investment advisers, which could lead to more efficient allocation of investor assets and an increase in the availability of capital.<sup>201</sup>

- An April 14, 2010, FDA rule amended the agency’s regulations on the use of ozone-depleting substances in self-pressurized containers to remove the essential-use designations for certain substances used in oral pressurized metered-dose inhalers. As a result, the agency estimated that private, third-party, and public expenditures on inhaled medicines would increase by roughly \$90 million to \$280 million per year. FDA characterized the benefits as “environmental and public health improvements from protecting stratospheric ozone by reducing chlorofluorocarbons emissions” and “expectations of increased return on investments in environmentally friendly technology.”<sup>202</sup>
- An October 29, 2010, ED rule amended the agency’s regulations under certain programs (e.g., the Federal Family Education Loan Program, the William D. Ford Federal Direct Loan Program, and the Federal Pell Grant Program) to improve the integrity in these programs. The department indicated that annual paperwork-related costs could exceed \$100 million,<sup>203</sup> but provided only qualitative descriptions of the expected benefits (e.g., “updated administrative structures for federal student aid programs,” and “enhanced reliability and security of ability-to-benefit tests”). Nevertheless, ED stated in the rule that it believed “that the benefits of these regulations for students, consumers, and taxpayers justify the burdens of institutional compliance.”<sup>204</sup>

## Major Increase in Costs or Prices

Seventeen of the 100 major rules published in calendar year 2010 appeared to be “major” at least in part because they were expected to result in “major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.”<sup>205</sup> CRS included rules in this category (instead of the earlier category of rules with a \$100 million annual “effect on the economy”) if those costs were either not monetized, or if they were estimated to be less than \$100 million in any year. For example:

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<sup>201</sup> U.S. Securities and Exchange Commission, “Custody of Funds or Securities of Clients by Investment Advisers,” 75 *Federal Register*, 1455, January 11, 2010.

<sup>202</sup> U.S. Department of Health and Human Services, Food and Drug Administration, “Use of Ozone-Depleting Substances; Removal of Essential-Use Designation (Flunisolide, etc.),” 75 *Federal Register* 19213, April 14, 2010.

<sup>203</sup> The agency indicated that the rule could add more than 5 million hours of annual paperwork burden. Using OMB’s estimate of the cost of completing this paperwork of \$30 per hour, compliance costs would exceed \$100 million.

<sup>204</sup> U.S. Department of Education, Office of Postsecondary Education, “Program Integrity Issues,” 75 *Federal Register* 66831, October 29, 2010.

<sup>205</sup> Sixteen of the rules only had this effect, and one rule also appeared to be major for another reason.



- A February 17, 2010, rule issued by the Agricultural Marketing Service (AMS) within USDA amended livestock and related provisions of the national organic program's regulations. The rule generally requires that producers maintain ruminant slaughter stock on pasture for each day that the finishing period corresponds with the grazing season for the geographical location. AMS did not monetize the benefits or the costs of the rule, but said that the benefits of the rule include uniformity in application to the livestock regulations especially as they relate to the pasturing of ruminants, which should result in a near elimination of violations of the pasture regulations. The agency said that the costs of the rule include an increase in the cost of production for producers who currently do not pasture their ruminant animals and those producers who do not manage their pastures at a sufficient level to provide at least 30% dry matter intake. AMS also said there may be an increase in consumer prices, but did not estimate the size of those increases.<sup>206</sup>
- A July 14, 2010, SEC rule addressed "pay to play" practices in investment advising, and prohibited an investment adviser from providing advisory services for compensation to a government client for two years after the adviser or certain of its executives or employees make a contribution to certain elected officials or candidates. The rule also prohibited an adviser from providing payment to any third party for a solicitation of advisory business from any government entity on behalf of such adviser, unless such third parties are registered broker-dealers or registered investment advisers. The SEC said that advisers with government clients would incur costs to monitor contributions and establish compliance procedures, and estimated initial compliance costs of approximately \$2,352 per smaller firm, \$29,407 per medium firm, and \$58,813 per larger firm. The commission also estimated that the rule would impose annual, ongoing compliance expenses of approximately \$2,940 per smaller firm, \$117,625 per medium firm, and \$235,250 per larger firm. In addition, the commission estimated that advisers would incur an aggregate cost of approximately \$200,246 per year and the non-labor costs of \$20,080,000. The SEC did not monetize the expected benefits of the rule, but said it should (among other things) help minimize or eliminate manipulation of the market for advisory services to state and local governments.<sup>207</sup>
- A July 16, 2010, rule issued by the Employee Benefits Security Administration (EBSA) within DOL required that certain service providers to employee pension benefit plans disclose information to assist plan fiduciaries in assessing the reasonableness of contracts or arrangements,

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<sup>206</sup> Department of Agriculture, Agricultural Marketing Service, "National Organic Program; Access to Pasture (Livestock)," *75 Federal Register* 7154, February 17, 2010.

<sup>207</sup> Securities and Exchange Commission, "Political Contributions by Certain Investment Advisers," *75 Federal Register* 41018, July 14, 2010.

including the reasonableness of the service providers' compensation and potential conflicts of interest that may affect the service providers' performance. EBSA did not quantify the expected benefits of the rule, but said that mandatory proactive disclosure would reduce sponsor information costs, discourage harmful conflicts of interest, and enhance service value. EBSA estimated that the annual cost of this rule from 2011 to 2020 would be between \$54.3 million and \$58.7 million.<sup>208</sup>

- A July 28, 2010, rule issued by the Office of the Comptroller of the Currency within the Department of the Treasury and other agencies implemented provisions of the Secure and Fair Enforcement for Mortgage Licensing Act of 2008 (P.L. 110-289). The final rule required mortgage loan originators employed by national banks to register with the Nationwide Mortgage Licensing System and Registry and maintain their registration. Mortgage loan originators were also required to obtain a unique identifier through the registry that will remain with that originator, regardless of changes in employment. In addition, the rule required mortgage loan originators and national banks to provide these unique identifiers to consumers in certain circumstances, and requires national banks to adopt and follow written procedures to assure compliance with the registration requirements. Although the agencies indicated that these requirements would impose certain regulatory costs, they did not provide monetized estimates of those costs in the rule.<sup>209</sup>

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<sup>208</sup> Department of Labor, Employee Benefits Security Administration, "Reasonable Contract or Arrangement Under Section 408(b)(2)- Fee Disclosure," *75 Federal Register* 41600, July 16, 2010.

<sup>209</sup> U.S. Department of the Treasury, Comptroller of the Currency and Office of Thrift Supervision; Federal Reserve System; Federal Deposit Insurance Corporation; Farm Credit Administration; and National Credit Union Administration, "Registration of Mortgage Loan Originators," *75 Federal Register* 44655, July 28, 2010.