FEDERAL RULEMAKING

Agencies Could Take Additional Steps to Respond to Public Comments
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What GAO Found

Agencies did not publish a notice of proposed rulemaking (NPRM), enabling the public to comment on a proposed rule, for about 35 percent of major rules and about 44 percent of nonmajor rules published during 2003 through 2010. A major rule has significant economic impact and may, for example, have an annual effect on the economy of $100 million or more. Agencies published a total of 568 major rules from 2003 through 2010. Agencies also published about 30,000 nonmajor rules during this period, which have less economic significance and can involve routine administrative issues.

Agencies frequently cited the “good cause” exception and other statutory exceptions for publishing final rules without an NPRM. Agencies in GAO’s sample used the “good cause” exception for 77 percent of major rules and 61 percent of nonmajor rules published without an NPRM. Agencies may use the good cause exception when they find that notice and comment procedures are “impracticable, unnecessary, or contrary to the public interest.” In practice, agencies may find an NPRM “impracticable” when the rule must be issued by a statutory deadline, “unnecessary” when the rule pertains to technical corrections, and “contrary to the public interest” in an emergency situation. To a lesser extent, agencies also used other statutory exceptions to issue a rule without an NPRM.

For example, in 84 of the 123 major rules that GAO analyzed, agencies described circumstances in which a statute: (1) either required or authorized them to issue the rule without an NPRM, (2) prescribed the content of the rule, or (3) set a deadline for a rule or program which the agency stated did not allow sufficient time to issue an NPRM.

GAO found that agencies, though not required, often requested comments on major final rules issued without an NPRM, but they did not always respond to the comments received. Agencies may solicit comments through the Federal Register when publishing a final rule without an NPRM, but the public does not have an opportunity to comment before the rule’s issuance, nor is the agency obligated to respond to comments it has received. For example, agencies requested comments on 77 of the 123 major rules issued without an NPRM in GAO’s sample. The agencies did not issue a follow-up rule or respond to comments on 26 of these 77 rules. This is a missed opportunity, because GAO found that when agencies did respond to public comments they often made changes to improve the rules. In addition, each of these 26 rules is economically significant and some of these rules have an impact of a billion dollars a year or more. These rules also cover important issues ranging from national health care policies to manufacturing incentive programs. For example, in one of the 26 rules, an agency defined a pre-existing condition to implement the Patient Protection and Affordable Care Act and sought public comment. The agency received 4,627 comments, but has not published a response to them. When agencies do not respond to comments requested, the public does not know whether the agency considered their comments, or if it intends to change the rule. As the courts have recognized, the opportunity to comment is meaningless unless the agency responds to significant points raised by the public.
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Abbreviations

ACUS  Administrative Conference of the United States
APA  Administrative Procedure Act
CRA  Congressional Review Act
DHS  Department of Homeland Security
DOD  Department of Defense
DOL  Department of Labor
DOT  Department of Transportation
EPA  Environmental Protection Agency
GPO  Government Printing Office
HHS  Department of Health and Human Services
NPRM  notice of proposed rulemaking
OIRA  Office of Information and Regulatory Affairs
OMB  Office of Management and Budget
RFA  Regulatory Flexibility Act
UMRA  Unfunded Mandates Reform Act
USDA  Department of Agriculture

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Agencies publish on average 3,000 to 4,000 final regulations each year to achieve goals such as ensuring the safety of food and products, controlling environmental pollution, and providing oversight of financial institutions and markets. Regulation is one of the primary tools federal agencies use to implement and enforce U.S. laws. Agencies also use regulations to implement programs that provide federal assistance, grants, and other subsidies. The total costs of these regulations are estimated to be in the hundreds of billions of dollars, and the estimated benefits are even higher. Given the significant costs and benefits of regulations, Congress and the President have focused considerable attention on the rulemaking process, especially in recent years, and lawmakers continue to consider legislative proposals to amend the process.

The basic process by which agencies develop and issue regulations is spelled out in the Administrative Procedure Act (APA). APA generally requires agencies to (1) publish a notice of proposed rulemaking (NPRM

\footnote{5 U.S.C. §§ 551–570a.}
in the *Federal Register*; (2) allow interested persons an opportunity to comment on the rulemaking process by providing “written data, views, or arguments;” (3) issue a final rule accompanied by a statement of its basis and purpose (including the agency’s response to comments received on the NPRM); and (4) publish the final rule at least 30 days before it becomes effective. This process, referred to as notice-and-comment rulemaking, gives the public an opportunity to provide information to agencies on the potential effects of a rule or to suggest alternatives for agencies to consider. The benefits of public participation in notice-and-comment rulemaking have been cited by the courts and others to include: generating higher quality rules; ensuring the fair treatment of persons affected by the rules, since all parties potentially affected have a chance to participate; and promoting the political accountability of the agency by giving affected parties the ability to comment at an early stage and having a public record of the agency’s response to those comments.

Prior notice and public comment is not always required, however. Congress sometimes enacts laws that direct an agency to issue rules without notice and comment. In addition, APA recognizes that there are circumstances, such as responding to an emergency situation like a natural disaster, when providing for notice and comment might not be appropriate before issuing a final rule, because expediting the rulemaking process is important to the efficiency and effectiveness of agencies’ activities. Therefore, APA allows agencies to issue final rules without the use of an NPRM in certain cases, including when the agency determines for “good cause” that notice and comment procedures are “impracticable, unnecessary, or contrary to the public interest.” Agencies often invoke “good cause,” for example, when Congress prescribes the content of a rule by law, such that prior notice and public comment could not influence the agency’s action and would serve no useful function.

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In order to retain the benefits of public participation that may be lost when issuing rules without an NPRM, agencies sometimes solicit public comments on such rules, though not required to do so. If an agency solicits comments in these cases, the public’s opportunity to comment does not occur in advance of the rule’s issuance or, in some cases, the effective date for complying with the rule’s provisions. One common type of rule often issued without an NPRM is the interim final rule, which generally is effective immediately but provides an opportunity for public comment after the rule’s issuance. Also, while agencies are required to respond to comments received on rules issued with an NPRM when those rules are finalized, they have no obligation to respond to comments received on final rules issued without an NPRM.5

In 1998, we examined agencies’ publication of rules without an NPRM. We found that 18 percent (11 of the 61) of the final major rules6 and an estimated 51 percent of all rules published during 1997 had been issued without an NPRM, often because agencies invoked the good cause exception.7

You asked us to provide information on the frequency, reasons, and potential effects of issuing final rules without an NPRM, and whether these have changed over time. This report addresses the following objectives for final rules published during calendar years 2003 through 2010:

1. Identify how often agencies issued final rules, including interim rules, without an NPRM, whether this changed over time, and which agencies most often issued such rules.


6A major rule is one that, among other things, has resulted in or is likely to result in an annual effect on the economy of $100 million or more. See infra note 20 and accompanying text.

7We are 95 percent confident that the estimated percent of all rules published in 1997 without an NPRM was between 44 and 58 percent. GAO, Federal Rulemaking: Agencies Often Published Final Actions without Proposed Rules, GAO/GGD-98-126 (Washington, D.C.: Aug. 31, 1998).
2. Identify which exceptions to the requirement for an NPRM agencies used when issuing such rules.

3. Assess whether agencies, when issuing final major rules without an NPRM (a) provided information on the rule’s economic effects, (b) solicited public comments, and (c) responded to public comments.

To address each of these objectives, we used the Government Printing Office’s (GPO) Federal Digital System database on the Federal Register to compile a list of final rules issued during calendar years 2003 through 2010 from which we drew a sample for our analysis.\(^8\) We selected a generalizable stratified random sample of 1,338 final rules published during the 8-year period. Our sample included all major rules (those that have a significant economic effect) issued during calendar years 2007 through 2010, a random sample of major rules published from 2003 through 2006, and a random sample of nonmajor rules published from 2003 through 2010. The sample contained rules by 52 different agencies, including every cabinet-level agency issuing regulations and every agency that published a major rule during the 8-year period.

We supplemented information from GPO’s Federal Register database with information from our database on rules submitted to us under the Congressional Review Act (CRA).\(^9\) We tested the reliability of the databases used to generate our list of all final rules by reviewing related documentation, interviewing knowledgeable agency officials, testing for missing data, and tracing a sample of entries to source documents. We concluded that the data were sufficiently reliable for our purposes.

To address the first two objectives, we reviewed the published text of all final rules in our sample to determine if they had been issued in whole or in part without an NPRM (referred to in this report simply as rules without an NPRM) and to identify which exceptions agencies cited when issuing those rules. To address our third objective we focused primarily on whether agencies issuing major rules without an NPRM: (1) provided information on the economic effects of the rules, (2) solicited public

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\(^8\)Our analyses of major rules include final regulatory actions published in both the Rules and Regulations and the Notices sections of the Federal Register. For simplicity, we use the term “final rules” to apply to all final regulatory actions throughout this report.

\(^9\)CRA requires agencies to submit rules to both Houses of Congress and the U.S. Comptroller General before the rules can become effective. 5 U.S.C. § 801(a)(1)(A).
comments, and (3) had responded to comments received on major rules without an NPRM by June 30, 2012.

We completed additional content analyses of the 123 major rules without an NPRM that we identified in our sample to obtain more detailed information on the reasons behind agencies’ use of exceptions to an NPRM, how agencies described the economic effects of rules, and whether they solicited and responded to public comments. These 123 rules included all major rules without an NPRM from 2007 through 2010 and a sample of major rules from 2003 through 2006. Results of these content analyses are not generalizable to the entire population of rules; they only represent the facts and circumstances of the specific rules we reviewed.

We also met with officials from the Office of Management and Budget (OMB) and the Administrative Conference of the United States (ACUS) who are knowledgeable about federal regulatory and administrative law procedures. We reviewed ACUS recommendations and OMB guidance to executive agencies on the regulatory process. We did not assess the agencies’ decisions regarding claims of good cause and other exceptions or their determinations regarding the effects of their rules. Instead, we are providing information about what the agencies published in the Federal Register as the basis for their findings. Detailed information on our scope and methodology is included in Appendix I.

We conducted this performance audit from June 2011 to December 2012 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

\[10\text{ACUS is an independent agency in the executive branch, established as an advisory agency in administrative law and procedure. ACUS has broad authority to conduct studies and make recommendations for improving the efficiency, adequacy, and fairness of the procedures agencies use in carrying out administrative programs.}\]
APA outlines the process for informal rulemaking, commonly referred to as notice-and-comment rulemaking.\textsuperscript{11} APA includes six broad categorical exceptions to this process, including, for example, rules dealing with agency organization and procedure (see sidebar).\textsuperscript{12}

In addition, as noted earlier, APA provides that an agency may forego notice and comment when it finds “good cause” that notice and public comment are “impractical, unnecessary, or contrary to the public interest.”\textsuperscript{13} In the 1946 Senate Judiciary Committee Report on APA, the Senate Judiciary Committee described the grounds for a good cause exception to include both situations where an agency’s mission would be hampered by notice and comment and where public comment would serve no useful purpose.\textsuperscript{14} In creating these exceptions, the drafters of APA sought to balance the need for public input with competing societal interests favoring the efficient and expeditious conduct of certain government affairs.\textsuperscript{15} When using the good cause exception, APA requires an agency to include in the issued rule a brief statement of its reasons for finding good cause.\textsuperscript{16} Over the years courts have ruled on agencies’ uses of these exceptions, based on the specific facts and

\begin{table}[h]
\centering
\begin{tabular}{|l|}
\hline
1. Exceptions under APA: \\
\hline
\begin{itemize}
\item good cause exception \\
\item broad categorical exceptions \\
\hline
\end{itemize} \\
\hline
\begin{itemize}
\item military or foreign affairs function of the United States \\
\item matter relating to agency management or personnel \\
\item matter relating to public property, loans, grants, benefits, or contracts \\
\item interpretative rules \\
\item general statements of policy \\
\item rules of agency organization, procedure, or practice \\
\end{itemize} \\
\hline
2. Other statutory exceptions \\
\hline
\end{tabular}
\end{table}

\textsuperscript{11}5 U.S.C. § 553. APA also includes provisions on formal rulemaking (“on the record rulemaking”), which apply when rules are “required by statute to be determined on the record after opportunity for an agency hearing.” 5 U.S.C. § 554(a).

\textsuperscript{12}5 U.S.C. §§ 553(a) and (b).

\textsuperscript{13}5 U.S.C. § 553(b)(B). Agencies may also find “good cause” to exempt a rule from APA’s requirement for a 30-day delay of effective date. 5 U.S.C. § 553(d)(3). However, agencies’ use of that good cause exception was not within the scope of this review.

\textsuperscript{14}Administrative Procedure Act: Legislative History, S. Doc. No. 79-248, at 200 (1946).

\textsuperscript{15}Jeffrey S. Lubbers, A Guide to Federal Agency Rulemaking, 5th edition (2012), 53. See also U.S. Dep’t of Labor v. Kast Metals Corp., 744 F.2d 1145, 1153 (5th Cir. 1984) (noting “tension” between agency efficiency and public input). In American Hospital Ass’n v. Bowen, 834 F.2d 1037, 1045 (D.C. Cir. 1987), the D.C. Circuit stated that “[t]he reading of the § 553 exemptions that seems most consonant with Congress’ purposes in adopting the APA is to construe them as an attempt to preserve agency flexibility in dealing with limited situations where substantive rights are not at stake.”

\textsuperscript{16}5 U.S.C. § 553(b)(B). When agencies invoke any other exception to the notice and comment requirement, they are not similarly required to cite the exception or explain their reasoning.
circumstances presented in the rules. In other cases, statutes, such as the 2008 Farm Bill, have authorized or required agencies to issue rules without notice and comment. When agencies invoke any of these exceptions they are not required to request comments from the public or conduct certain regulatory analyses.

CRA, which applies to all agencies, distinguishes between two types of rules, major and nonmajor. CRA defines a “major” rule as one that, among other things, has resulted in or is likely to result in an annual effect on the economy of $100 million or more. Throughout this report, we present results using the CRA distinction between major and nonmajor rules. The Office of Information and Regulatory Affairs (OIRA) within OMB is responsible for determining whether a rule is major.

OIRA also is responsible for providing meaningful guidance and oversight so that each agency’s regulations are consistent with applicable law, the President’s priorities, and the principles set forth in executive orders, and that decisions made by one agency do not conflict with the policies or actions taken or planned by another agency. Under Executive Order 12866 (reaffirmed by Executive Order 13563), OIRA reviews significant proposed and final rules from agencies, other than independent regulatory agencies, before they are published in the Federal Register. OIRA also provides guidance to agencies on regulatory requirements. For

17Courts have authority to review agencies’ decisions to exempt a rule from notice and comment under any one of these exemptions, including good cause. 5 U.S.C. §§ 701-706. See Clipper Cruise Line, Inc. v. United States, 855 F. Supp. 1 (D.D.C. 1994). For examples of differing outcomes when a court reviews an agency’s decision to use “good cause,” compare United States v. Dean, 604 F.3d 1275 (11th Cir. 2010) with United States v. Utesch, 596 F.3d 302 (6th Cir. 2010).


19CRA was designed to give Congress an opportunity to review a rule before it takes effect and to disapprove any rule to which Congress objects through the passage of a joint resolution with presentment to the President. 5 U.S.C. § 801(a)(1)(A).


21Id.

22“Independent regulatory agencies” refers to the boards and commissions identified as such in the Paperwork Reduction Act, for example, the Securities and Exchange Commission. 44 U.S.C. § 3502(5).
example, on August 15, 2011, OIRA issued a primer instructing agencies how best to conduct a regulatory impact analysis. In addition to OIRA’s previously mentioned responsibilities, according to Executive Order 12866, OIRA is to be the “repository of expertise concerning regulatory issues.” Executive Order 12866, other executive orders, and OIRA guidance have all reiterated the importance of public participation and regulatory analysis in rulemaking.

During calendar years 2003 through 2010, agencies published 568 major rules and about 30,000 nonmajor rules. As shown in figure 1, agencies published about 35 percent of major rules and about 44 percent of nonmajor rules without an NPRM during those years.\(^{23}\)

\(^{23}\)Sample estimates based on our review of 1,338 final rules are subject to sampling error and are presented along with their 95 percent confidence intervals, if applicable.
Figure 1: Percentages of Major and Nonmajor Rules That Were Published Without an NPRM from 2003 to 2010

<table>
<thead>
<tr>
<th>Major rules</th>
<th>Nonmajor rules</th>
</tr>
</thead>
<tbody>
<tr>
<td>65% (±7)</td>
<td>56% (±4)</td>
</tr>
<tr>
<td>35% (±7)</td>
<td>44% (±4)</td>
</tr>
</tbody>
</table>

Source: GAO.

Note: Margins of error for the percentage estimates are shown in parenthesis. For example, an estimated 56 percent of nonmajor rules were published without an NPRM, and we are 95 percent confident that the actual value is within plus or minus 4 percentage points of this estimate.

Agencies published 568 major rules during calendar years 2003 through 2010. All of the variance in this estimate for major rules is attributable to the sample of major rules reviewed for the period 2003 through 2006. We reviewed 100 percent of major rules issued from 2007 on, so results for those years have no variance.

Agencies published about 30,000 nonmajor rules during calendar years 2003 through 2010.

Examples of major rules without an NPRM include a May 2010 Department of the Treasury final rule prohibiting certain consumer credit practices, for which the agency invoked the good cause exception, and a September 2008 Department of Health and Human Services (HHS) notice that announced Medicare cost-sharing amounts, for which the agency cited an exception in the Social Security Act and good cause. Examples of nonmajor rules without an NPRM appeared to involve routine, administrative, or technical issues.

Similar examples of nonmajor rules without an NPRM that we identified during this review included a January 2007 Department of Homeland Security (DHS) temporary final rule changing drawbridge operation hours for certain bridges in Florida, and a July 2009 Federal Election Commission rule allowing a committee that is being audited by the Commission to have a hearing prior to the Commission’s adoption of a final audit report.25

As illustrated in figure 2, the percentage of nonmajor final rules without an NPRM was very consistent across the 8-year period we reviewed; varying only slightly among individual years, but the percentage of major rules without an NPRM was less consistent. In particular, from 2008 to 2009, the percentage of major rules without an NPRM increased from 26 percent to 40 percent. Agencies issued the largest numbers of major rules without an NPRM in 2009 and 2010 (34 in each year), though the percentage was higher in 2009 than in 2010. (See app. II for more detailed results of the analyses we conducted during this review, including numbers, percentages, and confidence intervals.)

Figure 2: Frequency of Final Rules Issued without an NPRM from 2003 to 2010 Was Less Consistent for Major Rules than for Nonmajor Rules

<table>
<thead>
<tr>
<th>Major rules without an NPRM(^a)</th>
<th>Nonmajor rules without an NPRM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percentage</td>
<td>Percentage</td>
</tr>
<tr>
<td>60</td>
<td>60</td>
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<tr>
<td>50</td>
<td>50</td>
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<tr>
<td>40</td>
<td>40</td>
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<td>30</td>
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<td>20</td>
<td>20</td>
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<td>10</td>
<td>10</td>
</tr>
<tr>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

2003-2006 2007 2008 2009 2010

Years

Upper bound of 95% confidence interval
Major rules without an NPRM
Lower bound of 95% confidence interval
Nonmajor rules without an NPRM

Source: GAO.

Note: Percentages shown are estimates subject to sampling error. The 95 percent confidence intervals for each of these estimates are displayed as error bars in the figure.

\(^a\)Data points for major rules published from 2007 through 2010 are based on reviewing 100 percent of the population, so have no variance. Our supplemental review of all major rules published in 2011 found that agencies issued 28 percent of those rules without an NPRM.

Two agencies, HHS and the Department of Agriculture (USDA), published 62 (plus or minus 11) percent of major rules in our sample without an NPRM, as shown in figure 3.\(^{26}\) Other agencies accounted for much lower

\(^{26}\)Within HHS, the majority of these rules were published by the Centers for Medicare and Medicaid Services. Within USDA, the majority of these rules were published by the Commodity Credit Corporation or the Farm Service Agency.
percentages of the total, all 7 percent or less. The Environmental Protection Agency (EPA) issued 30 major rules from 2003 through 2010, but none of these were issued without an NPRM. Our supplemental analysis of major rules in 2011 identified one case in which EPA waived an NPRM for one part of a rule in response to a court decision (claiming good cause because it had no discretion based on its obligation to comply with the court’s decision). 76 Fed. Reg. 48,208 (Aug. 8, 2011).
Agencies published 568 major rules during calendar years 2003 through 2010. All of the variance in this estimate for major rules is attributable to the sample of major rules reviewed for the period 2003 through 2006. We reviewed 100 percent of major rules issued from 2007 on, so results for those years have no variance.

Agencies published about 30,000 nonmajor rules during calendar years 2003 through 2010.

The agencies that published rules in our sample used interim rulemaking for a substantial portion of final major rules without an NPRM. As noted earlier, an interim rule becomes effective without an NPRM, but the public generally may provide comments after the rule’s issuance. Across the 8-year time period, agencies issued 47 percent of all major final rules and 8 percent of all nonmajor rules without an NPRM as interim rules. The percentage of major rules without an NPRM that used interim rulemaking increased from 2007 through 2010 but was more variable for nonmajor rules (see fig. 4). Appendix III provides more information on the frequency of agencies’ use of interim rulemaking in general.

Figure 4: Agencies Used Interim Rulemaking More Often for Major Rules without an NPRM than for Nonmajor Rules without an NPRM from 2003 to 2010

<table>
<thead>
<tr>
<th>Major interim rules</th>
<th>Nonmajor interim rules</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percentage</td>
<td>Percentage</td>
</tr>
<tr>
<td>60</td>
<td>60</td>
</tr>
<tr>
<td>48</td>
<td>48</td>
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<td>36</td>
<td>36</td>
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<td>24</td>
<td>24</td>
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<tr>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Source: GAO
Note: Percentages shown are estimates subject to sampling error. The 95 percent confidence intervals for each of these estimates are displayed as error bars in the above figure.

aData points for major interim rules published from 2007 through 2010 are based on reviewing 100 percent of the population, so have no variance. Our supplemental review of all major rules published in 2011 found that 50 percent of the rules without an NPRM were interim rules.

bOur sample estimates for this time period were not sufficiently reliable at a 95 percent confidence level.

Across the 554 rules in our sample without an NPRM, agencies used 109 distinct terms, many of which had only slight wording variations within a broad category, to identify the rulemaking action. The majority of these terms were variations of five broad categories: final rules, interim rules, temporary rules, direct final rules, and notices. In practice, however, there may be little distinction between interim rules and certain other rules without an NPRM that were described using different terminology. For example, a “final rule, request for comments” and an “interim rule with request for comments” both provide an opportunity for the public to comment only after the rule has been published; these rules are in essence the same type of rule. As a result of the inconsistent terminology, it would be difficult for Congress to enact legislation on, or for the public to easily identify, rules without an NPRM based on what agencies call those rules. For example, in legislation to revise rulemaking procedures being considered by the 112th Congress, certain provisions would apply when agencies, for good cause, issue “interim rules.” If the intent is to address all rules using the good cause exception, this proposed legislation would not achieve that goal since our analysis showed that not all rules for which agencies claimed good cause were called “interim rules.” To facilitate public participation in the rulemaking process, OMB officials told us that they are working with the Office of the Federal Register to standardize terminology for agencies to use when publishing rules in the Federal Register.

The agencies that published rules in our sample claimed the good cause exception in 77 (plus or minus 11) percent of major rules and 61 (plus or minus 10) percent of nonmajor rules without an NPRM, as shown in figure 5 below.

**Figure 5: Agencies Cited the Good Cause Exception for Most Final Rules without an NPRM from 2003 to 2010**

The agencies most often invoked the good cause exception were:

<table>
<thead>
<tr>
<th>Good Cause Exception Commonly Used</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>APA good cause</td>
<td>Major: 20% Nonmajor: 60%</td>
</tr>
<tr>
<td>Other specific statutory exceptions</td>
<td>Major: 20% Nonmajor: 40%</td>
</tr>
<tr>
<td>APA broad categorical</td>
<td>Major: 10% Nonmajor: 30%</td>
</tr>
<tr>
<td>Other reason</td>
<td>Major: 5% Nonmajor: 10%</td>
</tr>
</tbody>
</table>

Source: GAO.

Note: Agencies can cite more than one exception for a given rule.
As discussed previously, there are three general reasons under APA why an agency could invoke the good cause exception—impracticable, unnecessary, or contrary to the public interest. Agencies tend not to precisely distinguish among these reasons, although in practice, for example, “impracticable” is used by agencies for rules subject to statutory deadlines or time constraints; “contrary to the public interest” is used when there are emergencies or threats to public safety; and “unnecessary” is used for technical corrections, or for rules where comments are unlikely to yield change, such as a rule pursuant to a statute that prescribed the content of the rule.\(^2\) Examples of these situations and the grounds cited include:

- **Impracticable.** The Department of Education issued a 2009 interim final rule without an NPRM to implement statutory provisions enacted in 2008 related to certain education grants.\(^3\) The statutory provisions impacted grant eligibility. The department reported it did not have time to complete notice-and-comment procedures before the regulation’s effective date of July 1, 2009, which was established by statute.

- **Unnecessary.** EPA published a 2010 final rule without an NPRM to update and correct the addresses for submitting information to the EPA’s Region IX office and certain state and local agency offices.\(^4\)

- **Contrary to the public interest.** The Department of the Interior published a 2010 interim final rule without an NPRM to implement measures to improve the safety of offshore oil and gas drilling in

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\(^2\) An example of a rule where a statute prescribed the rule’s content was a final action making annual rate increases under Medicare, “Medicare Program; Medicare Part B Monthly Actuarial Rates, Premium Rate, and Annual Deductible Beginning January 1, 2011,” 75 Fed. Reg. 68,790 (Nov. 9, 2010).

\(^3\) 74 Fed. Reg. 20,210 (May 1, 2009).

\(^4\) 75 Fed. Reg. 69,348 (Nov. 12, 2010).
federal waters. The department published this rule in light of the Deepwater Horizon oil spill in the Gulf of Mexico on April 20, 2010.

For the rules in our sample, agencies most often said that issuing an NPRM would be contrary to the public interest, but they also frequently cited multiple grounds for invoking the good cause exception (see table 1). They cited multiple reasons more often for major rules than for nonmajor rules—63 (plus or minus 14) percent of major rules and 44 (plus or minus) percent of the nonmajor rules.

<table>
<thead>
<tr>
<th>General reason for citing good cause</th>
<th>Major rules without an NPRM that cited the reason (percentage)</th>
<th>Nonmajor rules without an NPRM that cited the reason (percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contrary to the public interest</td>
<td>68 (±14)</td>
<td>58 (±8)</td>
</tr>
<tr>
<td>Impracticable</td>
<td>55 (±14)</td>
<td>50 (±8)</td>
</tr>
<tr>
<td>Unnecessary</td>
<td>49 (±14)</td>
<td>39 (±8)</td>
</tr>
</tbody>
</table>

Source: GAO.

*Percentages sum to more than 100 percent because agencies sometimes cited more than one reason for a given rule.

Ninety-two of the 123 major rules without an NPRM in our sample invoked the good cause exception. In examining these 92 rules we identified five primary categories of explanations (more than one category sometimes applies to a given rule):

- a law imposed a deadline either requiring the agency to issue a rule or requiring a program to be implemented by a date that agencies claimed would provide insufficient time to provide prior notice and comment—36 rules;
- a law prescribed the content of the rule issued—31 rules;
- the agency said it was responding to an emergency—19 rules;

• the rule implemented technical changes—5 rules; and

• all other explanations (for example, an agency issued a final rule without an NPRM in response to a court decision)—14 rules.

Agencies’ Use of Exceptions in Statutes Other than APA

After good cause, agencies most often cited specific exceptions in statutes other than APA. Such exceptions were cited in 9 (plus or minus 4) percent of nonmajor rules and in 34 (plus or minus 13) percent of all major rules without an NPRM. More specifically, in 38 of the 123 major rules in our sample, we identified 18 different statutory authorities that either required or authorized agencies to issue rules without notice and comment. For example, the 2008 Farm Bill required the issuance of final rules to implement provisions of the law without prior notice and comment. HHS, the Department of Labor (DOL), and the Department of the Treasury issued several joint rules to implement provisions in the Patient Protection and Affordable Care Act as interim rules. In another type of example, a provision of the Social Security Act provides an exception to notice-and-comment rulemaking when a statute establishes a specific deadline for implementation of a rule and the deadline is less than 150 days after its enactment. This provision allowed HHS to issue several Medicare rules without an NPRM because the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 required some rules to be issued within shorter time frames than 150 days. Table 2 provides additional information on all of the statutory exceptions that agencies cited for major rules in our sample.

Table 2: Specific Statutory Exceptions Cited by Agencies in Major Rules without an NPRM from 2003 to 2010

<table>
<thead>
<tr>
<th>Statute or combination of statutes</th>
<th>Whether statute required or authorized issuance of final rule without an NPRM</th>
<th>Number of major rules that cited the exception</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2010</td>
<td>Required</td>
<td>1</td>
</tr>
<tr>
<td>American Jobs Creation Act of 2004</td>
<td>Required</td>
<td>1</td>
</tr>
<tr>
<td>Consolidated Security, Disaster Assistance, and Continuing Appropriations Act of 2009</td>
<td>Required</td>
<td>1</td>
</tr>
<tr>
<td>Consumer Assistance to Recycle and Save Act of 2009</td>
<td>Required</td>
<td>1</td>
</tr>
<tr>
<td>Deficit Reduction Act of 2005</td>
<td>Authorized</td>
<td>1</td>
</tr>
<tr>
<td>Emergency Supplemental Appropriations Act for Defense, the Global War on Terror, and Hurricane Recovery, 2006</td>
<td>Required</td>
<td>1</td>
</tr>
<tr>
<td>Energy Employees Occupational Illness Compensation Program Act of 2000</td>
<td>Authorized</td>
<td>1</td>
</tr>
</tbody>
</table>
### Statute or combination of statutes

<table>
<thead>
<tr>
<th>Statute or combination of statutes</th>
<th>Whether statute required or authorized issuance of final rule without an NPRM</th>
<th>Number of major rules that cited the exception</th>
</tr>
</thead>
<tbody>
<tr>
<td>Family Smoking Prevention and Tobacco Control Act</td>
<td>Required</td>
<td>1</td>
</tr>
<tr>
<td>Farm Security and Rural Investment Act of 2002 (2002 Farm Bill)</td>
<td>Required</td>
<td>2</td>
</tr>
<tr>
<td>Food, Conservation and Energy Act of 2008 (2008 Farm Bill)</td>
<td>Required</td>
<td>12</td>
</tr>
<tr>
<td>Homeland Security Appropriations Act of 2007</td>
<td>Required</td>
<td>1</td>
</tr>
<tr>
<td>Implementing Recommendations of the 9/11 Commission Act of 2007</td>
<td>Authorized</td>
<td>1</td>
</tr>
<tr>
<td>Social Security Act, Section 1871(b)(1)(B)</td>
<td>Authorized</td>
<td>4</td>
</tr>
<tr>
<td>Sudan Accountability and Divestment Act of 2007 (Amendment to the Federal Acquisition Regulation)</td>
<td>Authorized</td>
<td>1</td>
</tr>
<tr>
<td>U.S. Troop Readiness, Veterans’ Care, Katrina Recovery, and Iraq Accountability Appropriations Act, 2007</td>
<td>Required</td>
<td>2</td>
</tr>
</tbody>
</table>

Source: GAO.

*a* If a statutory provision requires an agency to issue a final rule without an NPRM, the agency must do so. If a statutory provision authorizes issuance of a final rule without an NPRM, an agency may choose to do so at its discretion.

*b* This provision authorizes an interim final rule to be issued “if a statute establishes a specific deadline for the implementation of a provision and the deadline is less than 150 days after the date of enactment of the statute.” These rules were issued as interim rules based on various statutes, including for example, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, and the American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, 123 Stat. 115.

*c* Six of the rules were issued jointly by the Department of the Treasury, DOL, and HHS. All three of these statutory authorities include the following: “Consistent with section 104 of the Health Care Portability and Accountability Act of 1996, … [t]he Secretary may promulgate any interim final rules as the Secretary deems are appropriate.” One of the rules was issued by HHS alone.

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### Agencies’ Use of APA’s Broad Categorical Exceptions

As mentioned earlier, in addition to the good cause exception, APA includes six broad categorical exceptions to notice-and-comment rulemaking. Agencies that published rules in our sample invoked these broad categorical exceptions infrequently. They did so in 11 (plus or minus 5) percent of nonmajor rules (most often for rules of agency organization, procedure, or practice), and in 8 (plus or minus 11) percent of major rules (most often citing the exception for rules on public property, loans, grants, benefits, or contracts). These exceptions were cited in 8 of the 123 major rules without an NPRM in our sample. The following are examples of rules in which agencies cited the six APA categorical exceptions:
• Military and foreign affairs—cited by a Department of Commerce 2007 final rule that made several corrections to the Export Administration Regulations regarding Libya and terrorist-supporting countries.\(^{33}\)

• Agency management or personnel—cited by a General Services Administration 2005 rule regarding the Federal Travel Regulation to clarify various provisions on temporary duty travel.\(^{34}\)

• Public property, loans, grants, benefits, or contracts—cited by the Board of Directors of the HOPE for Homeowners Program in a rule establishing a temporary Federal Housing Administration program providing mortgage insurance for refinanced loans made to avoid foreclosure.\(^{35}\)

• Interpretative rules—cited by a DOL 2008 rule revising regulations implementing the nondiscrimination and affirmative action provisions of the Vietnam Era Veterans’ Readjustment Assistance Act of 1974, as amended.\(^{36}\) According to DOL, it published this rule to codify its interpretation of a mandatory job listing requirement.

• General statements of policy—cited by an HHS 2010 rule revising standard federal rates and the extension of wage indexes under the Patient Protection and Affordable Care Act for Medicare payments in conformance with congressional policy.\(^{37}\)

• Agency organization, procedure, or practice—cited by a DOL 2007 rule amending Occupational Safety and Health Administration procedures for handling retaliation complaints.\(^{38}\)

In sum, our review of reasons agencies gave for issuing major rules in our sample without an NPRM showed that they cited grounds relating to


\(^{34}\)70 Fed. Reg. 28,459 (May 18, 2005).

\(^{35}\)Although published directly by the Board, this is a program under HUD. 73 Fed. Reg. 58,418 (Oct. 6, 2008).


\(^{37}\)75 Fed. Reg. 31,118 (June 2, 2010).

When Agencies Publish Major Rules without an NPRM, They Often Provide Information on Economic Effects and Request Comments, But Do Not Always Respond to Comments

Agencies Provided Information on Economic Effects of Most Major Rules without an NPRM

Of the 123 major rules without an NPRM that we reviewed, 113 provided some estimates of economic effects, such as on the potential costs or benefits. Agencies do this because Executive Order 12866 directs non-independent regulatory agencies to assess economic effects, including costs and benefits for all significant rules, whether or not those rules are

39For example, of the 34 major rules issued without an NPRM in 2009, 13 cited statutes that required or authorized agencies to issue final rules without an NPRM, 10 were rules where the underlying statutes prescribed the content of the rules, and 10 were rules responding to statutes that contained deadlines. Sometimes agencies cited more than one reason. Of the 13 rules that cited specific statutory exceptions, 9 cited the 2008 Farm Bill.
issued with an NPRM.\textsuperscript{40} However, according to OMB officials, the requirements of the Executive Order apply only “as practicable.” Of the remaining 10 of the 123 rules that we sampled, 5 provided some economic information but did not include estimates of the costs or benefits, and 5 were issued by independent agencies which are not required to comply with the Executive Order.

Costs and benefits include both quantifiable measures as well as qualitative effects that may be difficult to quantify. The information provided on costs and benefits in the 123 rules we reviewed varied, and included both quantitative and qualitative information. Agencies gave quantitative measures of effects for 104 rules,\textsuperscript{41} and qualitative information on effects for 44 rules included in our sample.\textsuperscript{42} Appendix IV provides summary information about each of the 123 major rules without an NPRM, including the potential benefits, costs, and other economic effects identified by the agencies.\textsuperscript{43}

Some rules involve monetary payments, known as “transfer payments.” These include, for example, payments from the government to the public in the form of federal grants, loans, disaster assistance, agricultural subsidies, or reimbursements for health care costs. Eighty-six of the 123 major rules without an NPRM that we reviewed involved transfer

\textsuperscript{40}Executive Order 12866 defines significant regulatory actions as those that are likely to result in a rule that may: (1) have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866.

\textsuperscript{41}Agencies quantified costs for 50 rules, benefits in 10, and transfers in 86.

\textsuperscript{42}An example of a qualitative effect is an October 2009 Securities and Exchange Commission rule that identified the qualitative benefit to regulated entities of having more time to prepare for compliance with new regulations because the agency delayed their effective date. 74 Fed. Reg. 53,628 (Oct. 19, 2009).

\textsuperscript{43}The information in Appendix IV is generally based on GAO's major rule reports to Congress under CRA.
payments in whole or in part. In these cases, agencies typically reported only the estimated budgetary impacts of transfer payments.\textsuperscript{44}

Additionally, rules that have a significant effect on the economy, whether or not issued with an NPRM, are subject to review by OIRA. Agencies must submit detailed economic analyses of the costs and benefits of all reasonably feasible regulatory alternatives to OIRA for review. For 55 of the 123 major rules we examined, the rule stated that the agency had considered regulatory alternatives.\textsuperscript{45} For example, in a June 2010 rule on the Conservation Stewardship Program, USDA identified and provided analyses on five policy options, as well as the option of no program.\textsuperscript{46} Of the 123 major rules we examined, all but 10 were subject to OIRA review. The 10 rules not subject to OIRA review were issued by independent regulatory agencies.\textsuperscript{47}

The Regulatory Flexibility Act of 1980 (RFA) and the Unfunded Mandates Reform Act of 1995 (UMRA) also impose separate economic analysis requirements for certain rules. RFA requires agencies to assess the impact of their rules on “small entities,” such as small businesses.\textsuperscript{48} UMRA requires agencies to prepare an assessment of the anticipated costs and benefits of any rule that may result in the expenditure of $100 million or more in any 1 year by state, local, or tribal governments in the aggregate or by the private sector.\textsuperscript{49} These requirements do not apply when agencies issue a rule without an NPRM, but we observed that agencies discussed RFA in 119, and UMRA in 96, of the 123 major rules we analyzed. This is consistent with our findings for RFA in 1998. See...

\textsuperscript{44}In some rules implementing budgetary transfers, the agency might have stated that the amount of the transfer was a “cost” to the federal government and a “benefit” to beneficiaries (such as states or providers of medical services), but if the agency characterized all such effects as transfers, we counted them only as transfers.

\textsuperscript{45}Agencies may have considered alternatives but did not summarize their findings in the published final rules, so there may be other rules among the 123 for which agencies considered regulatory alternatives.

\textsuperscript{46}75 Fed. Reg. 31,610 (June 3, 2010).

\textsuperscript{47}Statutes sometimes direct independent regulatory agencies to analyze certain economic effects of their rules, such as effects on competition within a regulated industry.

\textsuperscript{48}Small entities are defined as including small businesses, small governmental jurisdictions, and certain small not-for-profit organizations. 5 U.S.C. §§ 601, 603.

\textsuperscript{49}2 U.S.C. §§ 1531–1535.
Although Not Required, Agencies Often Requested Comments on Major Final Rules Issued without an NPRM, but Did Not Always Respond to Comments Received

Of the 123 major rules without an NPRM in our sample, we found that agencies requested comments for 77 rules where they had discretion over at least part of the regulation’s content. Agencies sometimes solicit public comments through the Federal Register on such rules, though not required to do so. If an agency solicits comments in these cases, the public’s opportunity to comment does not occur in advance of the rule’s issuance or, in some cases, the effective date for complying with the rule’s provisions. Major rules in which the agency has some discretion may benefit from consideration of public comments, because the public could add value by identifying issues, information, and analyses that the agency might not have initially considered. However, agencies were not obligated to respond to comments received on these rules, a key difference from comments received on proposed rules when those rules are finalized. In 26 of the 77 rules without an NPRM in our sample where the agency had discretion, the agency did not publish a follow-up rule or respond to any comments received (see figure 6).

 Agencies requested comments in 34 percent (plus or minus 6) percent of nonmajor rules without an NPRM. However, for these rules, the lack of prior notice and an opportunity to comment appears to have had little effect. As noted earlier, many nonmajor rules without an NPRM involved routine administrative or technical issues that public comments were unlikely to affect. For other nonmajor rules without an NPRM, agencies sometimes used alternative procedures to provide advance notice or obtain comments. Moreover, for nonmajor “interim rules” in our sample that were subsequently finalized, agencies reported receiving comments on about half of the rules and made changes to about 24 percent.
Typically, agency responses to comments received from the public are published in the Federal Register when a follow-up rule is issued. We analyzed each of these 77 major rules to determine whether, by the end of June 2012, agencies had published a follow-up rule in the Federal Register and, if so, whether the agencies reported receiving comments and making changes to the original rules.51 In 26 of these 77 rules, there

51We did not limit our search to final rules; we also searched for responses in subsequent proposed rules and notices.
was no follow-up rule. We examined publicly available information and found that the public submitted comments for at least 15 of these 26 rules but the agencies did not respond to them. Each of these 26 rules has significant economic effects, with some of these rules having an impact of a billion dollars a year or more. These rules also cover important issues ranging from national health care policies to manufacturing incentive programs. For example, in one of the 26 rules, an agency defined a pre-existing condition to implement the Patient Protection and Affordable Care Act, and sought public comment. The agency received 4,627 comments, but has not published a response to them. When agencies do not publish their response to any comments received, the public record is incomplete. The public does not know whether the agency considered the comments, accepted or rejected the views or evidence presented, or if the agency intends to finalize and potentially change the rule. As the courts have recognized, the opportunity to comment is meaningless unless the agency responds to significant points raised by the public.

We found that when agencies did respond to public comments they often made changes to the rules. In the 51 major rules without NPRMs in our sample for which the agencies had discretion and requested comments, the agencies did issue a follow-up rule, and our analysis of those cases illustrates the potential benefits of follow-up efforts. The agencies reported receiving public comments on all but 3 of these 51 major rules, which indicates that the public usually takes advantage of the opportunity to comment on rules without an NPRM following publication. In addition, we found that agencies made changes to the text of 31 of the 51 rules, most often in response to public comments. For example, DHS finalized a

52 In 2003, the federal government launched the regulations.gov web site to enable citizens to search, view, and comment on regulations issued. Comments may have been received for more than these 15 rules, since certain agencies may not have transferred all dockets or comments received to the regulations.gov system.

53 Agency officials explained, however, that 4,100 of these comments were on a single aspect of the rule and that public comments informed subsequent program guidance.


55 However, in some cases, agencies might not have received comments until after the original rules had taken legal effect.
In response to public comments, the agency removed two provisions of the original interim rule regarding air cargo screening requirements. These changes reduced the costs of the rule. In a similar example, in June 2011, the Department of the Treasury, DOL, and HHS followed up on a jointly-issued July 2010 rule on group health plans and health insurance issuers. The agencies stated that the amendments in the subsequent rule were being made in response to public comments received on the prior rule and that the primary effect of the amendments was to reduce the costs of compliance.

Over the years, the Administrative Conference of the United States (ACUS), an advisory agency in administrative law and procedure, has also highlighted the potential benefits of following up on final rules issued without an NPRM. In particular, to ensure public participation and limit undesirable effects regarding final rules issued without notice and comment, ACUS recommended that agencies request comments whenever they invoke the “impracticable” or “contrary to the public interest” reasons under the good cause exemption and publish a responsive statement on significant and relevant issues raised by such comments. ACUS noted that in such cases public comments could provide both useful information to the agency and enhanced public acceptance of the rule. Although this recommendation has not been implemented, ACUS continues to support it in an effort to improve transparency and public participation in rulemaking.

Agencies issue thousands of final rules each year that affect many aspects of citizens’ lives. The rulemaking procedures that agencies follow balance the public’s right to be involved in the rulemaking process against agencies’ need to carry out their missions in an efficient and effective manner. When rulemaking is expedited, there is a trade-off between

Conflicts and Trade-offs

Conclusions

5674 Fed. Reg. 47,672 (Sept. 16, 2009). In this case, DHS was specifically required by law to issue an interim rule and then finalize the rule within a specified time frame.


58ACUS Recommendation 95-4, Procedures for Noncontroversial and Expedited Rulemaking, 60 Fed. Reg. 43,108 (Aug. 18, 1995). ACUS also suggested that agencies use such follow-up procedures for other rules issued initially without notice and comment, such as interpretative or procedural rules.
obtaining the benefits of advanced notice and comment and the goal of issuing the rule quickly. The consequences of such trade-offs could be most significant for major rules issued without an NPRM, given their substantial annual effects on society.

Agencies often lessened this trade-off by requesting public comments on rules issued without an NPRM for which they had some discretion. This is a positive practice that promotes the benefits of public participation. However, if agencies and the public are to fully benefit from the process of public comments, what matters is not simply providing an opportunity for comment but also public understanding of whether comments were considered. For more than a third of the major rules published without an NPRM between 2003 and 2010 where agencies had discretion and requested comments, the agencies did not respond to comments received. Some of these rules related to significant national issues such as health care. When agencies solicit but leave unclear whether comments were considered, the public record is incomplete. Though such follow-up is not required, agencies may be missing an opportunity to fully obtain for themselves, and provide to the public, the benefits of public participation. Further, agencies may create the perception that they are making final decisions about the substance of major rules without considering data, views, or arguments submitted in public comments. The benefit of follow-up efforts is demonstrated by our finding that, when agencies did issue follow-up rules, they often made substantive changes to the original rules, usually in response to public comments.

<table>
<thead>
<tr>
<th>Recommendation for Executive Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>To better balance the benefits of expedited rulemaking procedures with the benefits of public comments that are typically part of regular notice-and-comment rulemakings, and improve the quality and transparency of rulemaking records, we recommend that the Director of OMB, in consultation with the Chairman of ACUS, issue guidance to encourage agencies to respond to comments on final major rules, for which the agency has discretion, that are issued without a prior notice of proposed rulemaking.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Agency Comments and Our Evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>We provided a draft of this report to the Director of OMB and the Chairman of ACUS for their review and comment. We received written comments on the draft report from OMB, which are reprinted in Appendix V. OMB also provided a technical comment which we incorporated as appropriate. ACUS provided technical comments, which we also incorporated as appropriate.</td>
</tr>
</tbody>
</table>
OMB disagreed with our recommendation to issue guidance to encourage agencies to respond to comments on final major rules, for which the agency has discretion, that are issued without a prior notice of prior rulemaking. OMB stated that it does not believe it is necessary to issue guidance on this topic at this time. In its response, OMB reiterated the value of public participation during the rulemaking process and noted that it routinely encourages agencies to establish procedures to consider public comments received on interim final rules. However, OMB believes that the timing and extent of an agency’s responses is a discretionary matter that an agency must consider in the context of the nature and substance of the particular rulemaking, as well as the particular agency’s resource constraints and competing priorities. OMB further stated that this case-specific approach is generally appropriate—especially given the often unique circumstances faced by agencies issuing rules without a prior notice of proposed rulemaking—and that it is not aware of compelling evidence that a more general, undiscriminating policy, set out in guidance, would offer substantial benefits.

We continue to believe that enhanced guidance would improve the quality and transparency of rulemaking procedures. We recognize the fact that OMB encourages agencies to establish procedures to consider public comments but believe that OMB needs to go further to encourage all agencies to respond to public comments on the record. We believe that there is compelling evidence that such guidance would offer substantial benefits. ACUS identified this as an issue of concern in 1995, and our current review confirmed that agencies still do not always follow up on rules issued without an NPRM. For more than a third of the major rules published without an NPRM between 2003 and 2010 where agencies had discretion and requested comments, we found that the agencies did not respond to comments received. As our evidence demonstrated, some of these rules had economic impacts in the billions of dollars, attracted over 4,000 comments, and addressed significant national issues, such as health care. When it is unclear whether agencies considered comments, rulemaking is less transparent to the public, and, as courts have recognized, the opportunity to comment is meaningless unless the agency responds to significant points raised by the public. Further, we disagree with OMB’s characterization of the scope of our recommendation. We are not suggesting an undiscriminating policy, instead we are recommending that OMB work with ACUS to develop appropriate guidance. Such guidance could maintain the flexibility for agencies that OMB believes is necessary. Also, following up on rules issued without an NPRM is not necessarily resource intensive. For
example, an agency could simply post a summary response to public comments on regulations.gov.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the Director of OMB, the appropriate congressional committees, and other interested parties. In addition, the report will be available at no charge on GAO’s website at http://www.gao.gov.

If you or your staff has any questions concerning this report, please contact Melissa Emrey-Arras at (617) 788-0534 or emreyarrasm@gao.gov, or Robert Cramer at (202) 512-7227 or cramerr@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. Key contributors are listed in Appendix VI.

Sincerely yours,

Melissa Emrey-Arras
Acting Director
Strategic Issues

Robert J. Cramer
Managing Associate General Counsel
Office of General Counsel
Appendix I: Scope and Methodology

For final rules published during calendar years 2003 through 2010, the objectives of this report were to:

1. Identify how often agencies issued final rules, including interim rules, without a notice of proposed rulemaking (NPRM), whether this changed over time, and which agencies most often issued such rules.

2. Identify which exceptions agencies used when issuing final rules without an NPRM.

3. Assess whether agencies, when issuing final major rules without an NPRM (a) provided information on the rule’s economic effects, (b) solicited public comments, and (c) responded to public comments.

To address each of these objectives, we selected and reviewed a representative sample of final regulatory actions published during calendar years 2003 through 2010 to estimate the prevalence of certain characteristics in this population. We used the Government Printing Office’s (GPO) Federal Digital System database on the Federal Register to compile a list of 30,583 final regulatory actions published in the Rules and Regulations section during those years. We defined our units of analysis as “actions” rather than “final rules,” because not all of the individual documents published in the Rules and Regulations section of the Federal Register are rules (e.g., some extended comment periods or made editorial corrections). Further, one published action may include multiple rules, and there is no way to determine the total number of rules published short of reviewing each action. However, for simplicity of presentation, we use the term “final rules” instead of “final regulatory actions” throughout this report. We supplemented information from GPO’s Federal Register database with information from our database on rules published short of reviewing each action.

1Published by the Office of the Federal Register, National Archives and Records Administration, the Federal Register is the official daily publication for rules, proposed rules, and notices of federal agencies and organizations, as well as executive orders and other presidential documents. The Rules and Regulations section contains final rules and regulations—those regulatory documents having general applicability and legal effect.

2This is consistent with our approach in GAO/GGD-98-126.

3For example, in November 2010, the Department of Health and Human Services’ Centers for Medicare & Medicaid Services included one final rule with comment period, two final rules, and one interim final rule with comment period in the same action (75 Fed. Reg. 71,800, Nov. 24, 2010).
submitted to us under the CRA.\textsuperscript{4} We tested the reliability of the databases used to generate our list of all final rules by reviewing related documentation, interviewing knowledgeable agency officials, testing for missing data, and tracing a sample of entries to source documents. We concluded that the data were sufficiently reliable for our purposes.

From this population of 30,583 final rules published in the Rules and Regulations section from 2003 through 2010, we selected a generalizable stratified sample of 1,311 final rules. To ensure that we reviewed the rules expected to have the most significant effects, we selected all major rules, as identified under the CRA for calendar years 2007 through 2010.\textsuperscript{5} The remaining rules during this period were stratified and sampled by year (2007 through 2010) and by whether they contained the term “interim” in the text of the \textit{Federal Register} action.\textsuperscript{6} We also included rules for calendar years 2003-2006 in our sample. For this period, we grouped the rules into three additional strata: major rules, “interim” rules, and other rules. Table 3 summarizes the population and sample size by stratum.

\begin{table}[ht]
\centering
\begin{tabular}{lcccc}
\hline
Rule stratum & Population\textsuperscript{a} & Sample\textsuperscript{a} & Total & In scope & Out of scope\textsuperscript{b} \\
\hline
2007-2010 major rules & 313 & 313 & 313 & 0 \\
2010 other (excluding interim) & 2,889 & 144 & 144 & 0 \\
2010 interim\textsuperscript{c} & 594 & 51 & 48 & 3 \\
\hline
\end{tabular}
\caption{Disposition of Sample of Rules Published in Rules and Regulations Section of the \textit{Federal Register}, 2003 to 2010}
\end{table}

\textsuperscript{4}CRA requires agencies to submit rules to both Houses of Congress and the Comptroller General before the rules can become effective. 5 U.S.C. § 801(a)(1)(A).

\textsuperscript{5}As defined by CRA, a major rule is a rule that the Administrator of the Office of Information and Regulatory Affairs finds has resulted in or is likely to result in (1) an annual effect on the economy of $100 million or more, (2) a major increase in costs or prices, or (3) significant adverse effects on competition, employment, investment, productivity, or innovation. CRA requires GAO to prepare a report to Congress on each major rule. 5 U.S.C. § 804(2).

\textsuperscript{6}Our preliminary research showed that we could not identify rules that were related to an interim rulemaking based on rules’ titles or on how agencies named the actions. We stratified on whether the word “interim” occurred in the text of the action to increase the chance of capturing interim rules in our sample.
Appendix I: Scope and Methodology

<table>
<thead>
<tr>
<th>Rule stratum</th>
<th>Population</th>
<th>Total selected</th>
<th>In scope</th>
<th>Out of scope</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009 other (excluding interim)</td>
<td>2,801</td>
<td>144</td>
<td>140</td>
<td>4</td>
</tr>
<tr>
<td>2009 interim</td>
<td>579</td>
<td>50</td>
<td>45</td>
<td>5</td>
</tr>
<tr>
<td>2008 other (excluding interim)</td>
<td>3,136</td>
<td>147</td>
<td>146</td>
<td>1</td>
</tr>
<tr>
<td>2008 interim</td>
<td>593</td>
<td>50</td>
<td>48</td>
<td>2</td>
</tr>
<tr>
<td>2007 other (excluding interim)</td>
<td>2,971</td>
<td>146</td>
<td>140</td>
<td>6</td>
</tr>
<tr>
<td>2007 interim</td>
<td>569</td>
<td>48</td>
<td>48</td>
<td>0</td>
</tr>
<tr>
<td>2003-2006 major</td>
<td>207</td>
<td>27</td>
<td>27</td>
<td>0</td>
</tr>
<tr>
<td>2003-2006 other (excluding interim)</td>
<td>13,135</td>
<td>157</td>
<td>155</td>
<td>2</td>
</tr>
<tr>
<td>2003-2006 interim</td>
<td>2,796</td>
<td>34</td>
<td>33</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>30,583</td>
<td>1,311</td>
<td>1,287</td>
<td>24</td>
</tr>
</tbody>
</table>

Source: GAO.

The population total excludes 48 major rules and the sample total excludes 27 major rules that agencies published in the Notices section of the Federal Register.

Rules that were outside of the scope of this review included those for which informal rulemaking procedures under the Administrative Procedure Act did not apply, such as when an agency used formal rulemaking procedures or when the published action was not a rule of general applicability. Based on the 24 sample cases in this category, we estimate a total population of 587 such actions published in the Rules and Regulations section of the Federal Register over the 8-year period, with a 95 percent confidence interval lower bound estimate of 315 actions and an upper bound estimate of 994 actions.

The “interim” strata was composed of rules whose text included the term interim. Not all of these were interim rules.

Based on this sample, we are able to estimate characteristics of the population of all final rules published in the Rules and Regulations section of the Federal Register. To ensure that all the rules expected to have the most significant effects were reviewed, we also included an additional 27 major rules that were not published in the Rules and Regulations section, but instead were published as Notices (bringing the total number of rules we reviewed to 1,338). For this report, when we present estimates for all major rules, we are projecting to the major rules published in both the Rules and Regulations section and those published in Notices. All other estimates presented in this report are estimates of the population of rules published in the Rules and Regulations section for 2003 through 2010.

To supplement our review for changes over time, we also conducted a limited analysis of all 80 major rules published during calendar year 2011.
Our sample contained rules by 52 different agencies, including every cabinet-level agency issuing regulations and every agency that published a major rule during the 8-year period.

Because this is a probability sample, our sample is only one of a large number of samples that we might have drawn. Since each sample could have provided different estimates, we express our confidence in the precision of our particular sample’s results as a 95 percent confidence interval (for example, plus or minus 7 percentage points). This is the interval that would contain the actual population value for 95 percent of the samples we could have drawn.

We reviewed the published text of all selected final rules to determine if they had been published in whole or in part without NPRMs (referred to in the rest of this report simply as rules without NPRMs). Our analysis included rules where only a part of the rule was issued without an NPRM to ensure that our results reflected all instances when agencies cited an exception to notice and comment. To address our third objective we focused primarily on whether agencies issuing major rules without an NPRM: (a) provided information on the economic effects of the rules, (b) solicited public comments when issuing final rules without an NPRM, and (c) responded to comments received on major rules without an NPRM by June 30, 2012. We used standardized data collection instruments and applied criteria from the Administrative Procedure Act, Regulatory Flexibility Act, Unfunded Mandates Act, and Executive Order 12866 to collect and analyze information to address each key question. If the final rule in our sample was not itself a rule, but was related to a rulemaking (e.g., if it extended a comment period) we used the underlying rule to address our questions if sufficient information was provided to identify the underlying rule. In addition to using our sample to generate estimates for the entire population on these objectives, we also did additional content analyses of the major rules without NPRMs in our sample to help address the objectives. Unlike the generalizable results from our reviews of the broader sample of rules, the results of these content analyses are not generalizable to the entire population. They only represent the facts and circumstances of the specific rules we reviewed. We also met with officials from the Office of Management and Budget (OMB) and Administrative Conference of the United States (ACUS) who are knowledgeable about federal regulatory and administrative law procedures.

We did not assess the agencies’ decisions regarding claims of good cause and other exceptions or their determinations regarding the effects
of their rules; instead, we are providing information about what the agencies published in the *Federal Register* as the basis for their findings. Further, we limited our analysis to only what agencies specifically stated in *Federal Register* notices. For example, we counted a particular exception only if the agency specifically cited it or quoted from part of APA’s description. We did not assume that an agency meant to claim a particular exemption based on the general content of the rule. Therefore, our results may understate the frequency with which APA’s good cause and categorical exceptions applied.

We conducted this performance audit from June 2011 to December 2012 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.
Tables 4 and 5 in this appendix provide more detailed information on the results of various analyses we completed for this report, including the upper and lower bounds of confidence intervals for estimated values, as appropriate. Figures 7 through 9 in this appendix provide more detailed information on how agencies addressed the RFA, UMRA, and Executive Order 12866, reported by agencies under the Congressional Review Act (CRA), including confidence intervals for our estimates.

### Table 4: How Often Agencies Published Final Rules without an NPRM, in Whole or in Part, 2003 to 2010

<table>
<thead>
<tr>
<th>Type of final rule and year(s) published</th>
<th>Population total</th>
<th>Point estimate</th>
<th>Lower bound</th>
<th>Upper bound</th>
</tr>
</thead>
<tbody>
<tr>
<td>All major rules 2003-2010</td>
<td>568</td>
<td>35%</td>
<td>28%</td>
<td>41%</td>
</tr>
<tr>
<td>2010 major rules</td>
<td>100</td>
<td>34</td>
<td>a</td>
<td>a</td>
</tr>
<tr>
<td>2009 major rules</td>
<td>84</td>
<td>40</td>
<td>a</td>
<td>a</td>
</tr>
<tr>
<td>2008 major rules</td>
<td>95</td>
<td>26</td>
<td>a</td>
<td>a</td>
</tr>
<tr>
<td>2007 major rules</td>
<td>61</td>
<td>33</td>
<td>a</td>
<td>a</td>
</tr>
<tr>
<td>2003-2006 major rules</td>
<td>228</td>
<td>37</td>
<td>20</td>
<td>57</td>
</tr>
<tr>
<td>All nonmajor rules 2003-2010</td>
<td>30,063</td>
<td>44</td>
<td>39</td>
<td>48</td>
</tr>
<tr>
<td>2010 nonmajor rules</td>
<td>3,483</td>
<td>42</td>
<td>35</td>
<td>49</td>
</tr>
<tr>
<td>2009 nonmajor rules</td>
<td>3,380</td>
<td>44</td>
<td>37</td>
<td>51</td>
</tr>
<tr>
<td>2008 nonmajor rules</td>
<td>3,729</td>
<td>44</td>
<td>37</td>
<td>51</td>
</tr>
<tr>
<td>2007 nonmajor rules</td>
<td>3,540</td>
<td>46</td>
<td>39</td>
<td>53</td>
</tr>
<tr>
<td>2003-2006 nonmajor rules</td>
<td>15,931</td>
<td>43</td>
<td>36</td>
<td>50</td>
</tr>
</tbody>
</table>

Source: GAO.

Our supplemental analysis of the 80 major rules published in 2011 found that agencies issued 28 percent in whole or in part without NPRMs.

*aNot applicable. The frequency for this time period was based on reviewing all rules in the population.*
### Table 5: Exceptions Agencies Cited for Issuing Final Rules without an NPRM, in Whole or in Part, 2003 to 2010

<table>
<thead>
<tr>
<th>Category of final rule/Exception cited</th>
<th>Estimated frequency (percentage)</th>
<th>95 percent confidence intervals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Point estimate</td>
<td>Lower bound</td>
</tr>
<tr>
<td>Major rules, 2003—2010a</td>
<td></td>
<td></td>
</tr>
<tr>
<td>APA good cause</td>
<td>77%</td>
<td>65%</td>
</tr>
<tr>
<td>APA broad categorical</td>
<td>8</td>
<td>2</td>
</tr>
<tr>
<td>Military or foreign affairs function of the United States</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Matter relating to agency management or personnel</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Matter relating to public property, loans, grants, benefits, or contracts</td>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>Interpretive rules</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>General statements of policy</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Rules of agency organization, procedure, or practice</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Other specific statutory exceptions</td>
<td>34</td>
<td>23</td>
</tr>
<tr>
<td>Other reasonb</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>No reason</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Nonmajor rules 2003—2010c</td>
<td></td>
<td></td>
</tr>
<tr>
<td>APA good cause</td>
<td>61</td>
<td>55</td>
</tr>
<tr>
<td>APA broad categorical</td>
<td>11</td>
<td>7</td>
</tr>
<tr>
<td>Military or foreign affairs function of the United States</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Matter relating to agency management or personnel</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Matter relating to public property, loans, grants, benefits, or contracts</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Interpretive rules</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>General statements of policy</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Rules of agency organization, procedure, or practice</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>Other specific statutory exceptions</td>
<td>9</td>
<td>6</td>
</tr>
<tr>
<td>Other reasonb</td>
<td>12</td>
<td>8</td>
</tr>
<tr>
<td>No reason</td>
<td>10</td>
<td>6</td>
</tr>
</tbody>
</table>

Source: GAO.

Note: An agency could have cited more than one exception or reason for a given rule.

aN = 547 final rules.

b"Other reason" includes those rules for which the agency cited a reason other than one of APA’s exceptions or another statutory exception.

cN = 30,039 final rules.
Figure 7: Whether and How Agencies in Our Sample Addressed RFA in Major and Nonmajor Rules without an NPRM, 2003 to 2010

- **Major rules**
  - 98% (±0)° Yes
  - 2% (±0)° No
  - 6% (±1) Agency did something other than a regulatory flexibility analysis
  - 27% (±13) Agency did a regulatory flexibility analysis
  - 37% (±11) Agency said RFA did not apply
  - 45% (±12) Agency certified the rule had no significant economic impact on a substantial number of small entities

- **Nonmajor rules**
  - 29% (±6) Yes
  - 71% (±6) No
  - 2% (±1) Agency did something other than a regulatory flexibility analysis
  - 3% (±2) Agency did a regulatory flexibility analysis
  - 32% (±7) Agency said RFA did not apply
  - 69% (±7) Agency certified the rule had no significant economic impact on a substantial number of small entities

Source: GAO.

°Percentages of responses for rules that addressed RFA exceed 100 percent, because agencies could have responded in more than one way.

For these estimates, the 95 percent confidence is within less than plus or minus 0.5 percentage points of the estimated percentage.

RFA applies to all agencies, but the requirements under RFA to prepare initial and final regulatory flexibility analyses only apply to rules for which an agency is required to publish an NPRM. Nevertheless, agencies often discussed RFA in their rules without NPRMs.
UMRA applies to agencies other than independent regulatory agencies, and UMRA’s requirements only apply to rules for which an agency published an NPRM. Nevertheless, agencies often discussed UMRA in their rules without NPRMs.
Appendix II: Detailed Results of GAO Analyses of Final Rules Issued without an NPRM, 2003 through 2010

Figure 9: Whether and How Agencies in Our Sample Addressed Executive Order 12866 in Major and Nonmajor Rules without an NPRM, 2003 to 2010

Major rules

- 2% (±0)\(^a\)
  Agency said the executive order did not apply
- 5% (±1)
- 95% (±1)

Nonmajor rules

- 2% (±0)\(^a\)
  Agency said the executive order applies and the rule is not economically significant, under the order
- 25% (±6)
- 75% (±6)

- 0% (±1)
  Agency said the executive order applies and the rule is economically significant
- 5% (±4)
  Agency said the executive order applies and the rule is significant, but not economically significant, under the order
- 95% (±4)
  Agency said the executive order did not apply

Yes
No

Source: GAO.

\(^a\)For these estimates, the 95 percent confidence is within less than +/- 0.5 percentage points of the estimated percentage.

Executive Order 12866 procedural and analytical requirements only apply to significant rules, and the requirement to provide the underlying analysis of benefits and costs only applies to rules that are economically significant (generally those with an annual impact of $100 million or more). The executive order does not apply to independent regulatory agencies.
Interim final rules are rules that agencies often, but not always, issue without an NPRM and provide the public an opportunity to comment after the rule has taken effect. APA does not address interim rulemaking, although in 1995, ACUS recommended that agencies adopt a form of interim rulemaking,1 and Congress has expressly authorized this procedure in legislation.2 In our 1998 report on final actions without NPRMs, we had estimated that agencies published about 400 interim final rules per year from 1992 to 1997 (out of approximately 4,000 total final rules each of those years).

Overall, agencies appeared to use interim rulemaking infrequently. Between 2003 and 2010, agencies published about 4 (plus or minus 2) percent of nonmajor rules as interim rules. There was relatively little variation across the individual years in the percentage of nonmajor interim rules (see fig. 14). However, for major rules, we found that 15 percent (actual) of all major rules from 2003 through 2010 were issued as interim rules. The number of major interim rules increased starting in 2008 and was highest in 2010, when 23 of 100 major rules were an interim rule or included an interim rule among other final rules. A few of the cases involving interim rules that we reviewed (17 of the 120) had prior proposed rules.

---


Appendix III: Frequency of Interim Rulemaking, 2003 through 2010

Figure 10: Frequency of Interim Rulemaking Increased over Time for Major Rules but was More Consistent for Nonmajor Rules, 2003 to 2010

<table>
<thead>
<tr>
<th>Major interim rules(^a)</th>
<th>Nonmajor interim rules</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Percentage</strong></td>
<td><strong>Percentage</strong></td>
</tr>
<tr>
<td>25</td>
<td>25</td>
</tr>
<tr>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

\(^a\)Data points for major interim rules are based on reviewing 100 percent of the population, so have no variance. Our supplemental review of all major rules published in 2011 found that 14 percent of those rules were interim rules, or included interim rules along with other final rules.

We reviewed a total of 120 interim rules within our sample, 56 of which were major and 64 nonmajor. Three agencies issued more than half of the major interim rules we reviewed, with the Department of Health and Human Services (HHS) accounting for 23 percent, the Department of Agriculture (USDA) 18 percent, and the Department of Homeland Security (DHS) 11 percent. All other agencies in our sample accounted for less than 7 percent each of the total major interim rules we reviewed. For the nonmajor interim rules, four agencies accounted for approximately two-thirds of these rules, with USDA accounting for 22 percent, DHS 22 percent, the Department of Defense (DOD) 14 percent, and HHS 11 percent. All others counted for less than 5 percent each of
Appendix III: Frequency of Interim Rulemaking, 2003 through 2010

There may be other agencies that issued interim rules that did not appear in our sample. Table 6 provides the detailed results of our analysis, by time period, with confidence intervals.

Table 6: Frequency with which Agencies Issued Interim Rules, 2003 to 2010

<table>
<thead>
<tr>
<th>Type of final rule and year(s) published</th>
<th>Population total</th>
<th>Point estimate</th>
<th>Lower bound</th>
<th>Upper bound</th>
</tr>
</thead>
<tbody>
<tr>
<td>All major rules 2003-2010</td>
<td>568</td>
<td>14%</td>
<td>a</td>
<td>a</td>
</tr>
<tr>
<td>• 2010 major rules</td>
<td>100</td>
<td>22</td>
<td>a</td>
<td>a</td>
</tr>
<tr>
<td>• 2009 major rules</td>
<td>84</td>
<td>13</td>
<td>a</td>
<td>a</td>
</tr>
<tr>
<td>• 2008 major rules</td>
<td>95</td>
<td>11</td>
<td>a</td>
<td>a</td>
</tr>
<tr>
<td>• 2007 major rules</td>
<td>61</td>
<td>8</td>
<td>a</td>
<td>a</td>
</tr>
<tr>
<td>• 2006 major rules</td>
<td>56</td>
<td>14</td>
<td>a</td>
<td>a</td>
</tr>
<tr>
<td>• 2005 major rules</td>
<td>56</td>
<td>16</td>
<td>a</td>
<td>a</td>
</tr>
<tr>
<td>• 2004 major rules</td>
<td>66</td>
<td>12</td>
<td>a</td>
<td>a</td>
</tr>
<tr>
<td>• 2003 major rules</td>
<td>50</td>
<td>12</td>
<td>a</td>
<td>a</td>
</tr>
<tr>
<td>All nonmajor rules 2003-2010</td>
<td>30,063</td>
<td>4</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>• 2010 nonmajor rules</td>
<td>3,483</td>
<td>4</td>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td>• 2009 nonmajor rules</td>
<td>3,380</td>
<td>7</td>
<td>5</td>
<td>9</td>
</tr>
<tr>
<td>• 2008 nonmajor rules</td>
<td>3,729</td>
<td>3</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>• 2007 nonmajor rules</td>
<td>3,540</td>
<td>6</td>
<td>4</td>
<td>8</td>
</tr>
<tr>
<td>• 2003-2006 nonmajor rules</td>
<td>15,931</td>
<td>4</td>
<td>2</td>
<td>8</td>
</tr>
</tbody>
</table>

Source: GAO.

Note: Our supplemental analysis of the 80 major rules published in 2011 found that agencies issued 14 percent as interim rules.

*Not applicable. The frequency for this time period was based on reviewing all rules in the population.

There is no general requirement for agencies to finalize interim rules, but we did a "look forward" analysis for each of the 120 interim rules in our sample to determine how many of those rules agencies had subsequently finalized and, if so, whether the agencies reported receiving comments or making changes to those rules. By the end of June 2012, agencies in our sample had finalized almost half of the interim rules—29 of the 56 major interim rules in our sample and 37 of the 64 nonmajor interim rules. It took
these agencies on average 452 days (about 1 year, 3 months) after publication of the original interim rules to finalize the rules, so agencies may eventually finalize additional interim rules from our sample. Agencies in our sample frequently reported receiving comments on and making changes to interim rules that they finalized, especially in the case of major interim rules. These agencies received public comments on all but 2 of the major interim rules that were subsequently finalized. In addition, agencies in our sample made changes to the text of 15 of the 29 major interim rules when they were finalized, most often in response to public comments.

The range was from 63 days (about 3 months) to 2,307 days (about 6 years, 4 months).
The following tables provide information about each of the 123 major rules issued without an NPRM from 2003 through 2010 that we reviewed for this report. Rules for which agencies waived NPRMs for only part of the rule are designated with (P) where we identify the exceptions to NPRMs that were cited. The narratives on each rule are summarized primarily from the relevant major rule reports that we submitted to Congress under CRA. CRA requires us to report on the issuing agency’s compliance with procedural steps required by various acts and executive orders governing the rulemaking process. Links to those reports are provided in the Rule column. In some cases where the published rule contained other relevant summary information on estimated economic effects that was not reflected in the major rule report, we added that information to the summary. The entries are sorted by agency and presented chronologically by the published date of the rule. Joint rules issued by more than one agency are listed at the end of each table. Because of differences in methods and assumptions (for example, discount rates, inflation), the agencies’ estimates may not be comparable.

### Table 7: Summary Information on Major Rules that We Reviewed that Agencies Issued without an NPRM, in Whole or in Part, from 2003 to 2010

<table>
<thead>
<tr>
<th>Rule</th>
<th>Description</th>
<th>Summary of benefits, costs, and other economic effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department of Agriculture (USDA)</td>
<td>The interim rule amends the Conservation Reserve Program (CRP) regulations to set forth the terms and conditions of enrolling acreage in the CRP, update program eligibility requirements, eliminate unnecessary regulations, and improve the remaining regulations. The rule implements changes made to the CRP by the 2002 Farm Bill.</td>
<td>CCC performed a cost-benefit analysis of the interim rule. Total CRP outlays are estimated to increase $1.5 billion, while commodity program outlays are estimated to decline about $1.7 billion during fiscal years 2003 through 2012, primarily due to a $1.5 billion counter-cyclical payment decline. The additional 2.8 million-acre enrollment is estimated to decrease combined CRP and commodity program outlays by $208 million annually during the 10-year period. Total estimated impacts for the additional CRP enrollment, including $326 million annual economic losses due to higher crop prices and reduced crop supplies (buyers’ loss) and estimated average annual economic benefits (increased farm incomes and environmental benefits), results in estimated net economic benefits of $131 million per year.</td>
</tr>
<tr>
<td>Rule</td>
<td>Rule title</td>
<td>Description</td>
</tr>
<tr>
<td>------</td>
<td>------------</td>
<td>-------------</td>
</tr>
<tr>
<td>2</td>
<td>User Fees for Agricultural Quarantine and Inspection Services</td>
<td>The interim rule adjusts the user fees charged for certain agricultural quarantine and inspection (AQI) services that are provided in connection with certain commercial vessels, commercial trucks, commercial railroad cars, commercial aircraft, and international airline passengers arriving at port in the customs territory of the United States. The adjusted AQI user fees cover fiscal years 2005 through 2010.</td>
</tr>
<tr>
<td>3</td>
<td>Tobacco Transition Payment Program</td>
<td>The final rule provides regulations for the Tobacco Transition Payment Program (TTPP), as required by the American Jobs Creation Act of 2004, ending the tobacco marketing quota and price support loan programs. The TTPP will continue to provide payments over a 10-year period during the transition from the federally-regulated program.</td>
</tr>
<tr>
<td>4</td>
<td>2005 Section 32 Hurricane Disaster Programs; 2006 Livestock Assistance Grant Program</td>
<td>The final rule provides for the establishment of four hurricane disaster programs and one grant program to provide funds to eligible producers who suffered eligible losses in counties affected by the 2005 hurricanes Katrina, Ophelia, Rita, or Wilma, the drought during March through August 2006; or a related condition.</td>
</tr>
</tbody>
</table>
### Appendix IV: Summary Information on Final Major Rules Issued without an NPRM, in Whole or in Part—2003 through 2010

<table>
<thead>
<tr>
<th>Rule</th>
<th>Description</th>
<th>Summary of benefits, costs, and other economic effects</th>
</tr>
</thead>
</table>
| 5    | **Rule title:** 2006 Emergency Agricultural Disaster Assistance Programs  
**Date:** February 12, 2007  
**Sub-agency:** Commodity Credit Corporation  
**Action:** Final rule  
**Exception(s) to NPRM cited:** Statutory  
**GAO major rule report:** [http://www.gao.gov/products/GAO-07-511R](http://www.gao.gov/products/GAO-07-511R) | The final rule implements the Emergency Agricultural Disaster Assistance Act of 2006 and establishes seven disaster programs to provide funds to eligible producers in counties affected by the 2005 hurricanes Katrina, Ophelia, Rita, or Wilma, or a related condition. To be eligible, counties must have been designated or declared a major disaster or emergency area, or be contiguous counties. The named hurricanes severely limited the purchasing power of farmers engaged in the production of agricultural commodities. The final rule provides for the establishment of seven hurricane disaster programs to be administered by FSA in order to provide funds to eligible producers who suffered eligible losses, thus reestablishing these producers’ purchasing power. FSA performed a cost-benefit analysis of this final rule for each of the seven disaster programs under which funds are available. |
| 6    | **Rule title:** Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle; Prohibition of the Use of Certain Stunning Devices Used To Immobilize Cattle During Slaughter  
**Date:** July 13, 2007  
**Sub-agency:** Food Safety and Inspection Service (FSIS)  
**Action:** Affirmation of interim final rules with amendments  
**Exception(s) to NPRM cited:** Good cause  
**GAO major rule report:** [http://www.gao.gov/products/GAO-07-1123R](http://www.gao.gov/products/GAO-07-1123R) | The final rule affirms two interim final rules published in January 2004. The interim rules and this final rule are measures taken to minimize human exposure to cattle materials that could potentially contain the bovine spongiform encephalopathy (BSE) agent. This final rule designates certain materials from cattle as specified risk materials, and, prohibits their use for human food. The rule prohibits the slaughter for human food of any non-ambulatory disabled cattle. The rule also prohibits the use of “air-injection” stunning. FSIS analyzed costs and benefits of this rule in its regulatory impact analysis. The benefits of the final rule primarily result from the relative reduction in human exposure to BSE infectivity and the restoration of beef exports. FSIS estimates that the total average annual cost of this final rule to be $171.2 million annualized over 5 years. There are no costs associated with the prohibition of air-injection stunning because that method is no longer used in the United States. |
<table>
<thead>
<tr>
<th>Rule</th>
<th>Rule title: Emergency Agricultural Assistance, 2007; Crop Disaster and Livestock Indemnity Programs</th>
<th>Description</th>
<th>Summary of benefits, costs, and other economic effects</th>
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<td>7</td>
<td>The final rule established regulations for a Crop Disaster Program which applies to 2005, 2006, and 2007 crop producers and a Livestock Indemnity Program (LIP) that applies to livestock producers in counties designated as a major disaster or emergency area between January 1, 2005, and February 28, 2007.</td>
<td>FSA prepared a cost-benefit analysis and published a summary of the analysis with this final rule. FSA estimates that total crop disaster payments will range from $1.6 billion to $2. billion. FSA expects payment rates to be lower than past crop disaster programs because of program changes. Changes include making insurable crops that were not insured and crops that were eligible for but not covered by the Noninsured Crop Disaster Assistance Program ineligible for payment and requiring at least 25-percent quality loss for compensation. FSA expects payment rates may be higher due to provisions that allow production of a commodity sold through marketing contracts to be eligible for quality loss assistance based on the prices specified in the contracts. FSA estimates that claims under the 2005-2007 LIP will be $14.4 million. FSA does not expect the impact on any sector of the economy to be measurable nor does it expect any significant change in aggregate social welfare. FSA expects that participants and their local communities may benefit by losses that are offset or reduced by the LIP payments.</td>
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<td>8</td>
<td>The final rule implements legislation that provides for the continuation of the Livestock Compensation Program and the Catfish Grant Program (CGP). The programs will provide financial assistance to producers in counties designated as a major or natural disaster between January 1, 2005, and February 28, 2007.</td>
<td>FSA prepared a cost-benefit analysis and published a summary of the analysis with this final rule. FSA estimates that claims under the 2005-2007 Livestock Compensation Program (LCP) will be $684 million. FSA does not expect the impact on any sector of the economy to be measurable nor does it expect any significant change in aggregate social welfare. FSA expects that participants and their local communities may benefit by losses that are offset or reduced by the LCP payments. FSA estimates that the expected value of the block grants necessary to compensate expected feed losses under the CGP will be $3.7 million. FSA expects that grant assistance should help catfish producers to restore their purchasing power from feed losses incurred by disasters that occurred after January 1, 2005, but before February 28, 2007.</td>
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<tr>
<td>Rule</td>
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<td>Summary of benefits, costs, and other economic effects</td>
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<td>9</td>
<td>Cotton World Price Determination</td>
<td>The final rule revises the Upland Cotton regulations to use the Far East (FE) prices instead of Northern Europe prices in determining the adjusted world price (AWP). CCC prepared a cost-benefit analysis of this final rule. CCC states that the final rule changes its regulations to recognize the shift in world cotton trade to the FE market that has occurred over time. In addition, it allows the program to operate in the manner that CCC and market participants have found consistently provides a smooth transition between crop years, while reducing potential CCC budgetary outlays. CCC states that the switch to FE as the basis for determining the cotton AWP is expected to generate modest savings as lower transportation costs to the FE. The net effect will likely raise the AWP, reducing CCC’s exposure on marketing loan benefits.</td>
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<tr>
<td>10</td>
<td>Mandatory Country of Origin Labeling of Beef, Pork, Lamb, Chicken, Goat Meat, Perishable Agricultural Commodities, Peanuts, Pecans, Ginseng, and Macadamia Nuts</td>
<td>The interim final rule implements requirements in the Farm Security and Rural Investment Act of 2002 (the 2002 Farm Bill) and the Food, Conservation, and Energy Act of 2008 (the 2008 Farm Bill). This interim final rule requires retailers to notify customers of the country of origin of certain commodities including muscle cuts of beef, lamb, chicken, goat, and pork; ground beef, lamb, chicken, goat, and pork; perishable agricultural commodities; macadamia nuts; pecans; ginseng; and peanuts. USDA analyzed the costs and benefits of this interim final rule. USDA determined that the estimated benefits associated with this interim final rule are likely to be small, difficult to quantify, and accrue mainly to those consumers who desire country of origin information. USDA estimated that the first-year incremental costs for directly affected firms will be $2.5 billion and the overall net costs to the U.S. economy in the 10th year after promulgation to be $211.9 million.</td>
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<td>Rule</td>
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| 11   | **Rule title:** Direct and Counter-Cyclical Program and Average Crop Revenue Election Program  
**Date:** December 29, 2008  
**Sub-agency:** Commodity Credit Corporation  
**Action:** Final rule  
**Exception(s) to NPRM cited:** Statutory  
**GAO major rule report:** [http://www.gao.gov/products/GAO-09-890R](http://www.gao.gov/products/GAO-09-890R) | The final rule implements provisions of the 2008 Farm Bill regarding the direct and counter-cyclical payment program for the 2008 through 2012 crop years as well as the Average Crop Revenue Election (ACRE) program payments for the 2009 through 2012 crop years.  
CCC performed a cost-benefit analysis in conjunction with the final rule. Overall, CCC estimates that the final rule will result in an increase of $487 million in average annual government outlays for the payments in fiscal years 2008 through 2012. Direct payments are projected to average $4.749 billion in fiscal years 2008 through 2014 for crop years 2008 through 2012. These payments represent a decrease of about $0.484 billion each crop year compared with direct payments under the 2002 Farm Bill. Counter-cyclical payments are projected to average $0.089 billion in FY 2008 through 2014 for crop years 2008 through 2012, which represents a decrease of $0.043 billion compared with counter-cyclical payments under the 2002 Farm Bill. ACRE program payments are projected to average $1.014 billion each crop year. The final rule continues the policy of planting flexibility by decoupling the payments from the production decisions of individual farmers, and continues marketing assistance loan provisions at higher levels for some crops in some years. |
### Appendix IV: Summary Information on Final Major Rules Issued without an NPRM, in Whole or in Part—2003 through 2010

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<th>Rule</th>
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| **12** | **Rule title:** Wetlands Reserve Program  
**Date:** January 15, 2009  
**Sub-agency:** Commodity Credit Corporation  
**Action:** Interim final rule with request for comment  
**Exception(s) to NPRM cited:** Statutory  
**GAO major rule report:** [http://www.gao.gov/products/GAO-09-960R](http://www.gao.gov/products/GAO-09-960R) | The interim final rule sets forth how the Wetlands Reserve Program will be implemented in response to changes made by the 2008 Farm Bill and incorporates other changes for clarification or program administration improvement. Those changes include raising the enrollment cap to 3.04 million acres through 2012, limiting program eligibility to private lands and acreage owned by Indian tribes, and determining the rate of compensation for easements of 30-year contracts enrolled in the program. CCC prepared a cost-benefit analysis in conjunction with this interim final rule. The main program costs associated with the interim final rule are for the purchase of easements and wetland restoration expenses with the program. CCC stated that approximately 89.8 percent of the Wetlands Reserve Program funding has been used for permanent easement projects, which have an associated fiscal year 2007 average per acre cost of $3,000, about 7.9 percent for 30-year easement projects, with a fiscal year 2007 average per acre cost of almost $1,100, and 2.4 percent for restoration cost-share agreement projects, with a fiscal year 2007 average per acre cost of nearly $670. The benefits associated with the interim final rule include creation of high-value wetlands, control of sheet and rill erosion as lands are converted from cropland to wetlands, creation and protection of habitat for fish and wildlife, improving water quality by filtering sediments and chemicals, and providing opportunities for educational, scientific, and recreational activities. According to CCC, many of the benefits are difficult to quantify. However, CCC was able to conclude that the monetary and non-monetary benefits from the Wetlands Reserve Program, as discussed in the interim final rule, can exceed total program costs. |
| **13** | **Rule title:** Environmental Quality Incentives Program  
**Date:** January 15, 2009  
**Sub-agency:** Commodity Credit Corporation  
**Action:** Interim final rule with request for comment  
**Exception(s) to NPRM cited:** Statutory  
**GAO major rule report:** [http://www.gao.gov/products/GAO-09-959R](http://www.gao.gov/products/GAO-09-959R) | The interim final rule amends the Environmental Quality Incentives Program (EQIP) to incorporate changes authorized by the 2008 Farm Bill. Those changes include extending EQIP's implementation through Fiscal Year 2012, providing payments for conservation practices related to organic production, providing an increased payment rate to historically underserved producers, and establishing a national target to set aside 5 percent of EQIP funds for socially disadvantaged farmers or ranchers and an additional 5 percent of EQIP funds for beginning farmers or ranchers. CCC prepared a cost-benefit analysis in conjunction with this interim final rule. For purposes of the analysis, CCC compared the increased EQIP funding against previous levels of EQIP funding. CCC stated that the expanded funding will result in an estimated $10.4 in benefits over the period of fiscal year 2007 through 2012, with $0.8 billion attributable to improved animal waste management and $9.6 billion to land treatment. Estimated net benefits for that period were $57 million above total costs. Ultimately, CCC determined that the interim final rule will provide $18 million in additional net benefits due to the expansion of EQIP funds in the 2008 Farm Bill. |
## Appendix IV: Summary Information on Final Major Rules Issued without an NPRM, in Whole or in Part—2003 through 2010

<table>
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<th>Rule</th>
<th>Rule title: Mandatory Country of Origin Labeling of Beef, Pork, Lamb, Chicken, Goat Meat, Wild and Farm-Raised Fish and Shellfish, Perishable Agricultural Commodities, Peanuts, Pecans, Ginseng, and Macadamia Nuts</th>
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<td>14</td>
<td>The final rule implements provisions in the 2002 Farm Bill and 2008 Farm Bill that require retailers to notify their customers of the country of origin of covered commodities. Covered commodities include muscle cuts of beef (including veal), lamb, chicken, goat, and pork; ground beef, ground lamb, ground chicken, ground goat, and ground pork; wild and farm-raised fish and shellfish; perishable agricultural commodities; macadamia nuts; pecans; ginseng; and peanuts.</td>
<td>USDA conducted a cost-benefit analysis of this final rule. USDA concluded that the estimated economic benefits of this final rule are difficult to quantify but likely to be small. The estimated first-year incremental costs for growers, producers, processors, wholesalers, and retailers are $2.6 billion. The estimated cost to the United States economy in higher food prices and reduced food production in the 10th year after implementation of the final rule is $211.9 million.</td>
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<td>15</td>
<td>The final rule implements provisions in the 2008 Farm Bill administering changes to the sugar loan and sugar marketing allotment program through 2012. The changes include new loan rates for raw cane sugar and beet sugar, new provisions to guarantee domestic suppliers an 85 percent market share, and revised procedures for granting allocations for new entrants.</td>
<td>CCC prepared a cost-benefit analysis of this final rule. CCC states that this final rule implements two major changes in the sugar program resulting from the 2008 Farm Bill, higher loan rates and a guaranteed market share. CCC concludes that these are expected to have zero impact on federal costs for fiscal years 2009 and 2010 because baseline assumptions project fiscal year 2011 to be the first year of surplus sugar in the marketplace. However, over the course of fiscal years 2009 through 2018, CCC concludes that federal net expenditures are expected to be $1.055 billion more than if the 2002 Farm Bill provisions were still in place. CCC also concludes that the loan rate increase is expected to increase sugar costs to consumers and sugar users by $1.4 billion from 2009 to 2018.</td>
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### Rule 14
- **Rule title:** Mandatory Country of Origin Labeling of Beef, Pork, Lamb, Chicken, Goat Meat, Wild and Farm-Raised Fish and Shellfish, Perishable Agricultural Commodities, Peanuts, Pecans, Ginseng, and Macadamia Nuts
- **Date:** January 15, 2009
- **Sub-agency:** Agricultural Marketing Service
- **Action:** Interim final rule with request for comment
- **Exception(s) to NPRM cited:** Good cause (P)

### Rule 15
- **Rule title:** Sugar Program
- **Date:** April 6, 2009
- **Sub-agency:** Farm Service Agency and Commodity Credit Corporation
- **Action:** Final rule
- **Exception(s) to NPRM cited:** Statutory
### Rule

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<th>Rule</th>
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| 16   | **Rule title:** Marketing Assistance Loans and Loan Deficiency Payments  
**Date:** April 7, 2009  
**Sub-agency:** Commodity Credit Corporation  
**Action:** Final rule  
**Exception(s) to NPRM cited:** Statutory  
**GAO major rule report:** http://www.gao.gov/products/GAO-09-892R | The final rule implements changes to the Marketing Assistance Loans (MAL) and Loan Deficiency Payments (LDP) programs for wheat, feed grains soybeans, other oilseeds, peanuts, pulse crops, honey, wool, and mohair. CCC is making these changes to comply with the 2008 Farm Bill. The legislation extended the MAL and LDP programs through 2012. This rule also provides separate rates for long and medium grain rice beginning in crop year 2008.  
CCC prepared a cost-benefit assessment of the changes made by this final rule. The assessment includes discussions of the statutorily-mandated and discretionary changes for the MAL and LDP programs. CCC expects the projected impacts from the use of its discretionary authority to be relatively minor. Projected outlays impacts were discussed in a cost-benefit analysis completed for a prior rulemaking. That analysis stated that the average annual change in government outlays for fiscal years 2008 to 2012 would be $487 million. CCC determined that the impacts of the regulatory changes addressed in this final rule and the prior rule are inherently interrelated and therefore did not address the impact of the rules individually. | |
| 17   | **Rule title:** Conservation Reserve Program  
**Date:** June 29, 2009  
**Sub-agency:** Commodity Credit Corporation  
**Action:** Interim final rule with request for comments  
**Exception(s) to NPRM cited:** Statutory  
**GAO major rule report:** http://www.gao.gov/products/GAO-10-271R | The interim rule amends the terms and conditions of enrolling acreage in the Conservation Reserve Program to implement provisions of the 2008 Farm Bill. This rule also updates other eligibility requirements to implement legislative changes.  
CCC analyzed the costs and benefits of this interim rule. Based on estimates concerning the amount of land that will be eligible, assumed participation rates and annual enrollment, and estimated per-acre costs, CCC estimates the costs of implementing the changes considered in the interim rule will total $79.6 million through fiscal year 2012 and $191.2 million through fiscal year 2018, which averages to $19.1 million per year over 10 years. According to CCC, the extent of environmental benefits derived from this rule will depend on participation rates and the specific conservation measures adopted. CCC offers the following examples of benefits: (1) tree thinning has the potential to enhance wildlife habitat, provide for carbon sequestration, and reduce the risk of wildfires; (2) enrollment of aquaculture ponds and flooded farmland and associated buffers can increase migratory waterfowl and other wildlife species populations, and potentially reduce flood damage, protect water quality, and provide for carbon sequestration; and (3) constructed wetlands and buffers can reduce nitrate loadings, reduce down-stream flood damages, and increase wildlife habitat. | |
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<th>Rule</th>
<th>Description</th>
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| 18   | **Rule title:** Conservation Stewardship Program  
**Date:** July 29, 2009  
**Sub-agency:** Commodity Credit Corporation  
**Action:** Interim final rule with request for comment  
**Exception(s) to NPRM cited:** Statutory  
This interim final rule implements changes to policies, procedures, and requirements necessary to implement the Conservation Stewardship Program as authorized by the 2008 Farm Bill.  
The National Resources Conservation Service (NRCS) prepared a cost-effectiveness analysis (CEA) of this interim final rule. The CEA describes how financial assistance and technical assistance are made available through the Conservation Stewardship Program, with the program objective being to have producers adopt additional conservation activities. The CEA attempts to compare the impact of these activities in generating environmental benefits with program costs. Since the Conservation Stewardship Program is a voluntary program, it is not expected to impose any obligation or burden upon agricultural producers and non-industrial private forestland owners who chose not to participate. |
| 19   | **Rule title:** Farm Storage Facility Loan and Sugar Storage Facility Loan Programs  
**Date:** August 18, 2009  
**Sub-agency:** Commodity Credit Corporation  
**Action:** Final rule  
**Exception(s) to NPRM cited:** Statutory  
The final rule amends the regulations governing the Farm Storage Facility Loan (FSFL) and Sugar Storage Facility Loan (SSFL) programs. The final rule implements changes from the 2008 Farm Bill including adding hay and renewable biomass as eligible FSFL commodities, extending the maximum loan term to 12 years, and increasing the maximum loan amount to $500,000. The final rule also adds fruits and vegetables (including nuts) as eligible facility loan commodities and adds cold storage facilities as eligible facilities.  
CCC prepared a cost-benefit analysis in conjunction with the final rule. CCC determined that the changes to the FSFL program will add costs of $6 million in 2009, $28 million in 2010, $30 million in 2011, and $32 million in 2012 over the cost of the existing program. If the full costs of the program are considered, rather than the changes made by the final rule, the financial impact will be over $100 million per year. |
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<th>Rule</th>
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| 20   | Rule title: Livestock Forage Disaster Program and Emergency Assistance for Livestock, Honeybees, and Farm-Raised Fish; Supplemental Agricultural Disaster Assistance  
**Date:** September 11, 2009  
**Sub-agency:** Farm Service Agency  
**Action:** Final rule  
**Exception(s) to NPRM cited:** Statutory  
The final rule implements requirements for the Emergency Assistance for Livestock, Honeybees, and Farm-Raised Fish Program (ELAP) and the Livestock Forage Disaster Program (LFP) authorized by the 2008 Farm Bill. LFP provides payments to eligible livestock producers that have suffered livestock grazing losses due to qualifying drought or fire. ELAP provides emergency assistance to eligible producers of livestock, honeybees, and farm-raised fish that have losses due to disease, adverse weather, or other conditions, including losses due to blizzards and wildfires. This rule specifies how LFP and ELAP payments are calculated, what losses are eligible, and when producers may apply for payments.  
FSA analyzed the costs and benefits of this final rule. FSA estimates that the ELAP is likely to result in costs of the entire authorized $50 million per year each year, providing benefits of $50 million each year to producers of livestock, honeybees, and farm-raised fish. The benefits of the honeybee loss compensation aspect of the program could also include substantial indirect benefits to the agricultural sector as a whole, because honeybees pollinate more than $14 billion worth of fruits, vegetables, and other crops in the United States. The honeybee portion of the program is expected to be the most expensive part of ELAP, due to losses resulting from colony collapse disorder. The LFP is expected to cost about $409 million per year, providing the same amount in benefits to livestock producers. The indirect benefit of the program is to reduce income variability of livestock producers due to drought and fire losses beyond their control. |
| 21   | Rule title: Dairy Economic Loss Assistance Payment Program  
**Date:** December 21, 2009  
**Sub-agency:** Farm Service Agency  
**Action:** Final rule  
**Exception(s) to NPRM cited:** Statutory  
The final rule implements the new Dairy Economic Loss Assistance Payment (DELAP) program, which will assist dairy producers by providing payments to producers who produced and marketed milk in the United States at some time from February through July 2009. The payments are intended to offset a portion of the dairy producers' losses resulting from milk prices that were far below production costs.  
FSA prepared a cost-benefit analysis in conjunction with the final rule. FSA expects that the DELAP program will provide $290 million in payments to dairy producers during fiscal year 2010, which represents both the cost of the program and the benefit to the participants. All payments under the program are expected to be made in fiscal year 2010. The DELAP program provides payment to dairy producers in fiscal year 2010 based on production in February through July 2009. FSA does not expect that the final rule will result in a significant change in the price of milk for consumers, because it is not subsidizing the cost of current production or providing price support. |
### Rule 22
**Rule title:** Supplemental Revenue Assistance Payments Program  
**Date:** December 28, 2009  
**Sub-agency:** Farm Service Agency  
**Action:** Interim final rule; solicitation of comments  
**Exception(s) to NPRM cited:** Statutory  

**Description:** The final rule implements requirements for the new Supplemental Revenue Assistance Payments Program (SURE) authorized by the 2008 Farm Bill. SURE provides disaster assistance to eligible participants who have experienced qualifying crop production losses or crop quality losses, or both, occurring in crop year 2008 through September 30, 2011.

**Summary of benefits, costs, and other economic effects:** FSA prepared a cost-benefit analysis in conjunction with the final rule. FSA expects that payments from the SURE Program for 2008 through 2011 will total $3.4 billion, an average of $0.85 billion per crop year, which represents both the cost of the program and the benefit to the participants. FSA states that this is less than the average of $1.14 billion per year for previous ad hoc crop disaster programs from 1998 to 2007. The overall costs for SURE are expected to be less than the cost of previous ad hoc programs for several reasons. First, unlike ad hoc disaster programs, SURE, in general, is additional compensation for established losses under crop insurance or noninsured crop disaster assistance program (NAP), and is not a benefit that replaces or duplicates previously received crop insurance or NAP payments. Additionally, SURE payments are based on farm revenue losses, rather than losses in particular crops or individual units; therefore, participants with losses in one crop but not others may or may not qualify for a SURE payment. Finally, the SURE guarantee cap is 90 percent of expected revenue, while previous programs had a cap of 95 percent of normal crop value.

### Rule 23
**Rule title:** Conservation Stewardship Program  
**Date:** June 3, 2010  
**Sub-agency:** Commodity Credit Corporation, Natural Resources Conservation Service  
**Action:** Final rule  
**Exception(s) to NPRM cited:** Statutory  

**Description:** The final rule makes changes to the Conservation Stewardship Program. The program provides financial and technical assistance to eligible producers to conserve and enhance soil, water, air, and related natural resources on their land, which can include cropland, grassland, rangeland, non-industrial private forest, and agricultural land under the jurisdiction of an Indian tribe.

**Summary of benefits, costs, and other economic effects:** CCC prepared a cost-effectiveness analysis (CEA) of the final rule, which is an approach used when benefits are not well understood or difficult to measure, but activity costs are available. The CEA compares the impact of these conservation activities in generating environmental benefits with program costs. The CEA describes how the improvements can produce beneficial impacts concerning onsite resource conditions, such as conserving soil, and significant offsite benefits, such as cleaner water, improved air quality, and enhanced wildlife habitat. The total cumulative program costs for four program ranking periods are estimated to be $2.99 billion in constant 2005 dollars, discounted at 7 percent, or $3.52 billion in constant 2005 dollars discounted at 3 percent. Since the Conservation Stewardship Program is a voluntary program, it is not expected to impose any obligation or burden upon agricultural producers and non-industrial private forestland owners who chose not to participate.
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<td>24</td>
<td>Conservation Reserve Program</td>
<td>The interim rule amends the Conservation Reserve Program (CRP) to implement provisions of the 2008 Farm Bill, including extending CRP through 2012 and making some changes in eligibility requirements. The purpose of CRP is to cost-effectively assist producers in conserving and improving soil, water, wildlife, and other natural resources by converting environmentally-sensitive acreage from the production of agricultural commodities to a long-term vegetative cover and to address issues raised by state, regional, and national conservation initiatives.</td>
<td>CCC states that the changes to CRP in this rule are expected to cost about $6.7 million per year over 10 years (2011–2020). CCC explains that this is a net cost that reflects roughly $77 million in additional CRP payments to participants over the next 10 years for additional land enrolled through the county maximum acreage waivers to exclude certain acreage and revised cropping history requirements and payments for pollinator habitat practices, minus roughly $10 million in reduced payments for the revised permissive uses. CCC states that the benefits to participants will be the net additional $6.7 million per year over the next 10 years. CCC notes that there are expected to be additional non-quantifiable environmental benefits from the waivers to exclude that will allow more environmentally sensitive acres to be enrolled through continuous signup, from additional highly erodible land enrollment that could result from making land in long-term hay rotations eligible, and from the incentives for pollinator habitat. Additionally, CCC states that the other provisions in this rule, such as local preference, are expected to have little to no cost. CCC believes that these provisions will largely substitute one CRP 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 CRP as a whole.</td>
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<td>25</td>
<td>Crop Assistance Program</td>
<td>The interim rule provides 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. This rule specifies the eligibility requirements, payment calculations, and application procedures for the Crop Assistance Program, which will provide up to $550 million to eligible producers.</td>
<td>FSA analyzed the costs and benefits of this interim rule. FSA estimated that the total cost to the government, and the corresponding benefit to producers, for the Crop Assistance Program will be between $137 million and $543 million, depending on how many producers in disaster counties apply for payment.</td>
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### Appendix IV: Summary Information on Final Major Rules Issued without an NPRM, in Whole or in Part—2003 through 2010

#### Rule Description

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<th>Rule</th>
<th>Department of Commerce</th>
<th>Summary of benefits, costs, and other economic effects</th>
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| 26   | Rule title: Public Safety Interoperable Communications (PSIC) Grant Program  
**Date:** July 23, 2007  
**Sub-agency:** National Telecommunications and Information Administration (NTIA)  
**Action:** Notice of Availability of Funds  
**Exception(s) to NPRM cited:** Matter relating to public property, loans, grants, benefits or contracts  
**GAO major rule report:** [http://www.gao.gov/products/GAO-07-1141R](http://www.gao.gov/products/GAO-07-1141R) | The final rule implements a $1 billion grant program to assist public safety agencies in the acquisition of, deployment of, or training for the use of interoperable communications systems that utilize—or enable interoperability with communications systems that can utilize—reallocated public spectrum for radio communications. This grant program was authorized by the Deficit Reduction Act of 2005 and the Call Home Act of 2006. This is a one-time transfer program where funds will be awarded no later than September 30, 2007. |
| 27   | Rule title: Amendments to the Digital-to-Analog Converter Box Program to Implement the DTV Delay Act  
**Date:** March 12, 2009  
**Sub-agency:** National Telecommunications and Information Administration  
**Action:** Final rule  
**Exception(s) to NPRM cited:** Good cause  
**GAO major rule report:** [http://www.gao.gov/products/GAO-09-502R](http://www.gao.gov/products/GAO-09-502R) | The final rule implements changes to the Digital-to-Analog Converter Box Program Coupon Program to conform to the DTV Delay Act which extended the deadline for the digital conversion and the coupon application period by four months. The final rule also provided NTIA additional flexibility in how it distributes coupons to households, so that NTIA is no longer required to distribute coupons via the United States Postal Service. The final rule also permits NTIA to prioritize the distribution of coupons to over-the-air only households in the event that a waiting list becomes necessary. NTIA prepared a cost-benefit analysis in conjunction with this final rule. As a baseline, NTIA considered the effects if there were no extension of the DTV Converter Box Coupon Request Deadline. NTIA noted that its waiting list contained more than 4.2 million coupon requests, and that those combined households, without the extension, would incur a total cost exceeding $210 million if they had to purchase converter boxes without the coupon subsidy. NTIA also cited a Nielson Company study indicating that, as of February 18, 2009, more than 5 million households were fully unprepared for the transition to fully digital broadcasting, with the highest lack of preparation among viewers under 35 years old, African American and Hispanic households. The total costs to these households of purchasing a converter box without subsidy would be $250 million. NTIA notes that enactment of the DTV Delay Act and the ARRA reflect a commitment to assisting eligible households in retaining access to broadcast television programming following the digital television conversion. Consistent with its responsibility to administer the Coupon Program to achieve this goal, NTIA's final rule seeks to expedite coupon distribution as effectively and efficiently as possible. Therefore, NTIA concluded the benefits of the final rule exceed its costs and NTIA supported adoption of the final rule to facilitate the digital transition for America's families. |
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<tr>
<td>28</td>
<td>State Broadband Data and Development Grant Program</td>
<td>The notice announces the availability of funds pursuant to the American Recovery and Reinvestment Act of 2009 and the Broadband Data Improvement Act for the State Broadband Data and Development Grant Program. The Program is a competitive, merit-based matching grant program that funds projects that collect comprehensive and accurate state-level broadband mapping data, develops state-level broadband maps, aids in the development and maintenance of a national broadband map, and funds statewide initiatives directed at broadband planning.</td>
<td>NTIA did not prepare a cost-benefit analysis in conjunction with this final rule. However, the final rule states that the program will make approximately $240 million available for eligible entities to develop and implement statewide initiatives to identify and track the availability and adoption of broadband services within each state.</td>
</tr>
<tr>
<td></td>
<td>Office of the Secretary</td>
<td>The interim final rule expands the Homeowners Assistance Program (HAP) to provide assistance to wounded members of the Armed Forces (30 percent or greater disability), surviving spouses of fallen warriors, wounded DOD civilian homeowners reassigned in furtherance of medical treatment or rehabilitation or due to retirement in connection with their disability.</td>
<td>The rule did not include estimates of the costs, benefits, or transfer amounts.</td>
</tr>
<tr>
<td>30</td>
<td>Retroactive Stop Loss Special Pay Compensation</td>
<td>The interim final rule provides for retroactive stop loss special pay as authorized and appropriated by the Supplemental Appropriations Act of 2009.</td>
<td>The Supplemental Appropriations Act, 2009 appropriated $534,4 million to DOD, to remain available for obligation until expended for the payment of claims specified by this law.</td>
</tr>
<tr>
<td>Rule</td>
<td>Description</td>
<td>Summary of benefits, costs, and other economic effects</td>
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| 31   | **Rule title:** Retroactive Stop Loss Special Pay Compensation  
**Date:** April 16, 2010  
**Sub-agency:** Office of the Under Secretary of Defense for Personnel and Readiness  
**Action:** Final rule  
**Exception(s) to NPRM cited:** Good cause; other reason  
The Supplemental Appropriations Act, 2009 appropriated $534.4 million to DOD, to remain available for obligation until expended: provided that such funds shall be available to the secretaries of the military departments only to make payment of claims specified by this law. |
| 32   | **Rule title:** Homeowners Assistance Program—Application Processing  
**Date:** November 16, 2010  
**Sub-agency:** Office of the Deputy Under Secretary of Defense  
**Action:** Final rule  
**Exception(s) to NPRM cited:** Other reason  
**GAO major rule report:** [http://www.gao.gov/products/GAO-11-222R](http://www.gao.gov/products/GAO-11-222R) | The final rule continues to authorize the Homeowners Assistance Program (HAP) to financially compensate eligible military and civilian federal employee homeowners when the real estate market is adversely affected directly related to the closure or reduction-in-scope of operations due to Base Realignment and Closure (BRAC). The American Recovery and Reinvestment Act of 2009 expanded the HAP to provide assistance to: wounded members of the Armed Forces (30 percent or greater disability), surviving spouses of fallen warriors, and wounded DOD civilian homeowners reassigned in furtherance of medical treatment or rehabilitation or due to medical retirement in connection with their disability; BRAC 2005 impacted homeowners relocating during the mortgage crisis; and service member homeowners undergoing Permanent Change of Station moves during the mortgage crisis.  
The rule did not include estimates of the costs, benefits, or transfer amounts. |
### Appendix IV: Summary Information on Final Major Rules Issued without an NPRM, in Whole or in Part—2003 through 2010

**Rule** | **Description** | **Summary of benefits, costs, and other economic effects**
--- | --- | ---
33 | **Rule title:** Federal Student Aid Programs  
**Date:** August 9, 2006  
**Sub-agency:** Office of Postsecondary Education  
**Action:** Interim final regulations; request for comments  
**Exception(s) to NPRM cited:** Good cause  
**GAO major rule report:** [http://www.gao.gov/products/GAO-06-1063R](http://www.gao.gov/products/GAO-06-1063R) | The interim final rule amends the Federal Student Aid Program to implement changes made by the Higher Education Reconciliation Act of 2005. Education states that the interim final rule will impose increased costs on some borrowers, such as an increase in the loan interest rate for Federal Family Education Loans PLUS borrowers, the elimination of in-school and joint consolidation loans, and the mandatory imposition of the previously optional 1-percent guaranty agency default insurance premium. Education estimates that the annualized monetary transfers from the federal government to postsecondary students and from student aid program participants to the federal government will be $976 million.

34 | **Rule title:** Federal Perkins Loan Program, Federal Family Education Loan Program, and William D. Ford Federal Direct Loan Program  
**Date:** November 1, 2007  
**Sub-agency:** Office of Postsecondary Education  
**Action:** Final regulations  
**Exception(s) to NPRM cited:** Good cause  
**GAO major rule report:** [http://www.gao.gov/products/GAO-08-293R](http://www.gao.gov/products/GAO-08-293R) | The final rule makes a number of changes to the federal loan programs authorized under title IV of the Higher Education Act of 1965 to strengthen and improve the administration of the programs. This final rule also incorporates changes enacted in the College Cost Reduction and Access Act (CCRAA). Education analyzed the costs and benefits of this final rule. Education determined that, of the regulatory changes in this final rule not implementing the CCRAA, only the mandatory assignment of defaulted Perkins Loans will have a substantial economic effect, with an impact of approximately $23 million annually. Education estimates that the provisions of this final rule implementing CCRAA which reduce costs will decrease federal costs by $23.3 billion over fiscal years 2007 to 2012. The Department also estimates that the provisions of this final rule implementing CCRAA which expand benefits will increase federal costs by $5.9 billion over fiscal years 2007 to 2012.

35 | **Rule title:** Federal Perkins Loan Program, Federal Family Education Loan Program, and William D. Ford Federal Direct Loan Program  
**Date:** October 23, 2008  
**Sub-agency:** Office of Postsecondary Education  
**Action:** Final regulations  
**Exception(s) to NPRM cited:** Good cause  
**GAO major rule report:** [http://www.gao.gov/products/GAO-09-191R](http://www.gao.gov/products/GAO-09-191R) | The final rule amends the regulations governing the Federal Perkins Loan Program, the Federal Family Education Loan Program, and the William D. Ford Federal Direct Loan Program. This final rule implements various provisions of the College Cost Reduction and Access Act, including the establishment of the Income-Based Repayment plan and the Public Service Loan Forgiveness Program. Education analyzed the costs and benefits of this final rule. Education estimates that the parts of this final rule that implement provisions of the College Cost Reduction and Access Act (CCRAA) will have a net budget impact of $650 million in 2008 and $9.2 billion over fiscal years 2008 to 2012.
## Rule 36

**Rule title:** Student Assistance General Provisions; Teacher Education Assistance for College and Higher Education (TEACH) Grant Program; Federal Pell Grant Program; Academic Competitiveness Grant Program and National Science and Mathematics Access To Retain Talent Grant Program

**Date:** May 1, 2009

**Sub-agency:** Office of Postsecondary Education

**Action:** Interim final rule; request for comments

**Exception(s) to NPRM cited:** Good cause


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**Description:** The interim final rule implements changes to the Academic Competitiveness Grant (ACG) and National Science and Mathematics Access to Retain Talent Grant (National SMART Grant) programs. As required by recent amendments to the Higher Education Act of 1965, the interim final rule makes ACGs and National SMART Grants available to eligible non-citizens and students enrolled at least half-time and provides that maximum awards for part-time students be proportionally reduced consistent with the requirements in the Federal Pell Grant Program and that grant awards be based on a student’s grade level rather than academic year.

**Summary of benefits, costs, and other economic effects:**

Education prepared an accounting statement showing the classification of the expenditures associated with the interim final rule. The Department estimates that the interim final rule will increase federal grant payments to students by $448 million.
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<tr>
<th>Rule</th>
<th>Description</th>
<th>Summary of benefits, costs, and other economic effects</th>
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<tr>
<td>37</td>
<td><strong>Rule title:</strong> General and Non-loan Programmatic Issues</td>
<td>Education has assessed the potential costs and benefits and determined that the benefits justify the costs. Education states that benefits include greater transparency about consumer information and campus safety for prospective and current students at institutions participating in the federal student financial assistance programs, copyright infringement policies, requirements for readmission of service members, explanation of extenuating circumstances under which TEACH Grant service obligations may be excused, requirements for programs serving students with intellectual disabilities, and additional guidelines for federal grant and work-study programs. Education states that costs include requiring regulated entities to develop new disclosures and other materials, as well as accompanying dissemination processes in order to implement the statutory provisions. These changes are estimated to increase burden on entities or individuals participating in the federal student assistance programs by 253,718 hours. According to Education, virtually all of the increased burden is associated with institutions. A small amount, 384 hours, is associated with students. The monetized cost of this additional burden, using loaded wage data developed by the Bureau of Labor Statistics, is $4.7 million.</td>
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<td><strong>Date:</strong> October 29, 2009</td>
<td>[Education also estimated that this rule would result in annualized monetized transfers from the government to student loan borrowers of $281 million (7 percent discount rate) or $277 million (3% discount rate).]</td>
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<td><strong>Sub-agency:</strong> Office of Postsecondary Education</td>
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<td><strong>Action:</strong> Final regulations</td>
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<td><strong>Exception(s) to NPRM cited:</strong> Good cause (P)</td>
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<tr>
<td>Rule</td>
<td>Description</td>
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<tr>
<td>38</td>
<td><strong>Rule title:</strong> Student Assistance General Provisions; Teacher Education Assistance for College and Higher Education (TEACH) Grant Program; Federal Pell Grant Program; Academic Competitiveness Grant Program and National Science and Mathematics Access To Retain Talent Grant Program  &lt;br&gt;<strong>Date:</strong> November 23, 2009  &lt;br&gt;<strong>Sub-agency:</strong> Office of Postsecondary Education  &lt;br&gt;<strong>Action:</strong> Final regulations  &lt;br&gt;<strong>Exception(s) to NPRM cited:</strong> Good cause  &lt;br&gt;<strong>GAO major rule report:</strong> <a href="http://www.gao.gov/products/GAO-10-427R">http://www.gao.gov/products/GAO-10-427R</a></td>
<td>The final rule adopts regulations for the Academic Competitiveness and National Science and Mathematics to Retain Talent Grant programs; Student Assistance General Provisions; Federal Pell Grant Program; and Teacher Education Assistance for College and Higher Education Grant Program. This rule implements provisions of the Higher Education Act of 1965, as amended by the Ensuring Continued Access to Student Loans Act of 2008 and the Higher Education Opportunity Act of 2008. Education estimates that this final rule will result in 538,000 additional awards totaling $448 million over award years 2009 through 2010 and 2010 through 2011. These changes will increase federal costs by the same amount.</td>
</tr>
<tr>
<td>39</td>
<td><strong>Rule title:</strong> Race to the Top Fund  &lt;br&gt;<strong>Date:</strong> April 2, 2010  &lt;br&gt;<strong>Sub-agency:</strong> N/A  &lt;br&gt;<strong>Action:</strong> Interim final requirements; request for comments  &lt;br&gt;<strong>Exception(s) to NPRM cited:</strong> Good cause  &lt;br&gt;<strong>GAO major rule report:</strong> <a href="http://www.gao.gov/products/GAO-10-641R">http://www.gao.gov/products/GAO-10-641R</a></td>
<td>The interim final rule amends the Race to the Top Fund requirements to establish the suggested budget ranges as mandatory funding limits for Phase 2 of the competition. Education determined that this interim final rule will not impose additional costs to state applicants, grantees, or the federal government. A state applicant may take additional time to create or revise its Race to the Top budget so that it conforms to the required budget range if the state had intended to request more than the maximum in the range. However, Education believes that the benefits outweigh any potential burden that the interim final rule may cause.</td>
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<td>40</td>
<td><strong>Rule title:</strong> Advanced Technology Vehicles Manufacturing Incentive Program  &lt;br&gt;<strong>Date:</strong> November 12, 2008  &lt;br&gt;<strong>Sub-agency:</strong> Office of the Chief Financial Officer  &lt;br&gt;<strong>Action:</strong> Interim final rule; request for comment  &lt;br&gt;<strong>Exception(s) to NPRM cited:</strong> Statutory  &lt;br&gt;<strong>GAO major rule report:</strong> <a href="http://www.gao.gov/products/GAO-09-196R">http://www.gao.gov/products/GAO-09-196R</a></td>
<td>The interim final rule establishes the Advanced Technology Vehicles Manufacturing Incentive Program authorized by statute, which provides for loans and grants to eligible automobile manufacturers and component suppliers for projects that reequip, expand, and establish manufacturing facilities in the United States to produce light-duty vehicles and provide improvements in fuel economy performance beyond certain specified levels. The Consolidated Security, Disaster Assistance, and Continuing Appropriations Act of 2009 appropriated $7.5 billion for the “Advanced Technology Vehicles Manufacturing Loan Program Account” for the cost of direct loans and states that commitments for direct loans using such amounts shall not exceed $25 billion in total loan principal, and $10 million for DOE’s administrative expenses for implementing the program.</td>
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### Appendix IV: Summary Information on Final Major Rules Issued without an NPRM, in Whole or in Part—2003 through 2010

<table>
<thead>
<tr>
<th>Rule</th>
<th>Department of Health and Human Services (HHS)</th>
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</table>
| **41** | **Rule title:** Medicare Program; Physician Fee Schedule Update for Calendar Year 2003  
**Date:** February 28, 2003  
**Sub-agency:** Centers for Medicare & Medicaid Services (CMS)  
**Action:** Final rule  
**Exception(s) to NPRM cited:** Good cause  
| **Description** | The final rule revises the estimates used to establish the sustainable growth rates for fiscal years 1998 and 1999 for the purposes of determining future updates to the physician fee schedule. It also announces a 1.6-percent increase in the calendar year 2003 physician fee schedule conversion factor for March 1, 2003, to December 31, 2003.  
**Summary of benefits, costs, and other economic effects:** CMS estimates that the changes to the physician fee schedule update will increase Medicare expenditures for physicians' services by $1.1 billion in fiscal year 2003, $2 billion in fiscal year 2004, and $2.8 billion in fiscal year 2005 or an estimated $15.7 billion over 5 years and $49.6 billion over 10 years. |
| **42** | **Rule title:** Medicare Program; Changes to Medicare Payment for Drugs and Physician Fee Schedule Payments for Calendar Year 2004  
**Date:** January 7, 2004  
**Sub-agency:** Centers for Medicare & Medicaid Services  
**Action:** Interim final rule with request for comments  
**Exception(s) to NPRM cited:** Good cause; statutory  
| **Description** | The interim final rule implements provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 that are applicable in 2004 to Medicare payments for covered drugs and physician fee schedule services.  
**Summary of benefits, costs, and other economic effects:** CMS estimates that the changes contained in the interim final rule regarding the physician fee schedule and drug payment rates to increase Medicare spending by more than $1 billion in fiscal year 2004. |
### Appendix IV: Summary Information on Final Major Rules Issued without an NPRM, in Whole or in Part—2003 through 2010

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<tr>
<th>Rule</th>
<th>Description</th>
<th>Summary of benefits, costs, and other economic effects</th>
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<tr>
<td>43</td>
<td><strong>Rule title:</strong> Medicare Program; Health Care Infrastructure Improvement Program; Selection Criteria of Loan Program for Qualifying Hospitals Engaged in Cancer-Related Health Care  &lt;br&gt;<strong>Date:</strong> September 30, 2005  &lt;br&gt;<strong>Sub-agency:</strong> Centers for Medicare &amp; Medicaid Services  &lt;br&gt;<strong>Action:</strong> Interim final rule with comment period  &lt;br&gt;<strong>Exception(s) to NPRM cited:</strong> Good cause; matter relating to public property, loans, grants, benefits, or contracts  &lt;br&gt;<strong>GAO major rule report:</strong> <a href="http://www.gao.gov/products/GAO-06-153R">http://www.gao.gov/products/GAO-06-153R</a>  &lt;br&gt;The interim final rule sets forth the criteria for a loan program for qualifying hospitals engaged in research in the causes, prevention, and treatment of cancer as specified in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. The rule establishes a loan application process by which qualifying hospitals may apply for a loan for the capital costs of health care infrastructure improvement projects.  &lt;br&gt;The interim final rule has $142 million available for the loan program from July 1, 2004, through September 30, 2008. No more than $2 million may be used for the administration of the program during that time period.</td>
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<td>44</td>
<td><strong>Rule title:</strong> Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; CY 2007 Update to the Ambulatory Surgical Center Covered Procedures List; Medicare Administrative Contractors; and Reporting Hospital Quality Data for FY 2008 Inpatient Prospective Payment System Annual Payment Update Program—HCAHPS Survey, SCIP, and Mortality  &lt;br&gt;<strong>Date:</strong> November 24, 2006  &lt;br&gt;<strong>Sub-agency:</strong> Centers for Medicare &amp; Medicaid Services  &lt;br&gt;<strong>Action:</strong> Final rule with comment period and final rule  &lt;br&gt;<strong>Exception(s) to NPRM cited:</strong> Good cause (P)  &lt;br&gt;<strong>GAO major rule report:</strong> <a href="http://www.gao.gov/products/GAO-07-249R">http://www.gao.gov/products/GAO-07-249R</a>  &lt;br&gt;The final rule revises the Medicare hospital outpatient prospective payment system to implement applicable statutory requirements and changes arising from CMS’s continuing experience with the system, including changes to the amounts and factors used to determine Medicare’s payments. The final rule also revises the current list of procedures that are covered when furnished in a Medicare-approved ambulatory surgical center and the emergency medical screening requirements for critical access hospitals.  &lt;br&gt;CMS estimates that the changes made by the final rule will increase Medicare expenditures for calendar year 2007 over the expenditures for calendar year 2006 by $2.24 billion.</td>
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## Appendix IV: Summary Information on Final Major Rules Issued without an NPRM, in Whole or in Part—2003 through 2010

### Rule 45

**Rule title:** Medicare Program; Inpatient Psychiatric Facilities Prospective Payment System Payment Update for Rate Year Beginning July 1, 2007 (RY 2008)  
**Date:** May 4, 2007  
**Sub-agency:** Centers for Medicare & Medicaid Services  
**Action:** Notice  
**Exception(s) to NPRM cited:** Good cause  

This notice updates the prospective payment rates for Medicare inpatient psychiatric facilities (IPF). The changes are applicable to IPF discharges occurring during the year beginning July 1, 2007, through June 30, 2008.

According to CMS’s estimate, the rate changes under this notice will increase payments by approximately $130 million.

### Rule 46

**Rule title:** Medicaid Program; Citizenship Documentation Requirements  
**Date:** July 13, 2007  
**Sub-agency:** Centers for Medicare & Medicaid Services  
**Action:** Final rule  
**Exception(s) to NPRM cited:** Good cause  

The final rule implements the statutory requirement that states obtain satisfactory documentary evidence of a Medicaid applicant’s or recipient’s citizenship and identity.

CMS concluded that this rule will result in $80 million less spent by the federal government and $60 million less spent by state governments per year for the next 5 years. Because the total is greater than $100 million per year, this is a significant rule. The regulatory impact statement did not account for the administrative costs on the states. With respect to administrative costs, CMS states that it provides federal match for administrative expenditures. CMS expects states to experience higher administrative costs during the first year of implementation as they adjust to the new requirements and expects these costs to decrease in later years as current recipients meet the requirements and only new applicants are required to submit documentation.

### Rule 47

**Rule title:** Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities for FY 2008  
**Date:** August 3, 2007  
**Sub-agency:** Centers for Medicare & Medicaid Services  
**Action:** Final rule  
**Exception(s) to NPRM cited:** Good cause (P)  

The final rule updates the payment rates used under the prospective payment system for skilled nursing facilities (SNF) for fiscal year 2008. In addition, the final rule revises and rebases the SNF market basket and modifies the threshold for the adjustment to account for market basket forecast error.

CMS estimates that the impact of the final rule will be to increase payments to SNFs by approximately $690 million.
<table>
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<tr>
<th>Rule</th>
<th>Description</th>
<th>Summary of benefits, costs, and other economic effects</th>
</tr>
</thead>
</table>
| 48   | **Rule title:** Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates  
**Date:** August 22, 2007  
**Sub-agency:** Centers for Medicare & Medicaid Services  
**Action:** Final rule with comment period  
**Exception(s) to NPRM cited:** Good cause (P)  
**GAO major rule report:** [http://www.gao.gov/products/GAO-07-1200R](http://www.gao.gov/products/GAO-07-1200R) | The final rule revises the Medicare hospital inpatient prospective payment system for operating and capital-related costs. These changes arise from CMS’s continuing experience with these systems and implement provisions of three statutes. The rule sets limits on the rate of increase for certain hospitals and hospital units that are excluded from the inpatient prospective payment system.  
CMS determined that this rule will result in an approximately $3.8 billion increase in fiscal year 2008 operating and capital payments. |
| 49   | **Rule title:** Medicare Program; Medicare Part B Monthly Actuarial Rates, Premium Rate, and Annual Deductible Medicare Program; Medicare Part B Monthly Actuarial Rates, Premium Rate, and Annual Deductible Beginning January 1, 2008  
**Date:** October 5, 2007  
**Sub-agency:** Centers for Medicare & Medicaid Services  
**Action:** Notice  
**Exception(s) to NPRM cited:** Good cause  
**GAO major rule report:** [http://www.gao.gov/decisions/majrule/d08176r.pdf](http://www.gao.gov/decisions/majrule/d08176r.pdf) | The notice announces the monthly actuarial rates for aged and disabled enrollees for the Part B Medicare Supplementary Medical Insurance) trust fund for January 1, 2008. It also announces the monthly Part B premium to be paid by aged and disabled beneficiaries, as well as the income-related monthly adjustment amounts to be paid by beneficiaries with modified adjusted gross income above certain threshold amounts.  
A cost-benefit analysis was not conducted because the increases were statutorily directed. CMS did estimate that the increase will cost approximately 41.5 million Part B enrollees about $1.4 billion for 2008. |
| 50   | **Rule title:** Medicare Program; Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for Calendar Year 2008  
**Date:** October 5, 2007  
**Sub-agency:** Centers for Medicare & Medicaid Services  
**Action:** Notice  
**Exception(s) to NPRM cited:** Good cause  
**GAO major rule report:** [http://www.gao.gov/products/GAO-08-175R](http://www.gao.gov/products/GAO-08-175R) | The notice announces the inpatient hospital deductible and the hospital and extended care service coinsurance amounts for services furnished in calendar year 2008 under Medicare Part A. The statute specifies the formulae used to determine these amounts.  
A cost-benefit analysis was not conducted because the increases were statutorily directed. CMS did estimate that the total increase in cost to beneficiaries associated with the notice to be approximately $870 million. |
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<th>Rule</th>
<th>Description</th>
<th>Summary of benefits, costs, and other economic effects</th>
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<tr>
<td>51</td>
<td>Rule title: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Amendment of the E-Prescribing Exemption for Computer Generated Facsimile Transmissions</td>
<td>The final rule makes changes to the Medicare Part B payment policy to implement provisions of the Tax Relief and Health Care Act of 2006. The changes are intended to ensure that payment systems are updated to reflect changes in medical practice and the relative value of services. The rule also finalizes the calendar year 2007 interim relative value units (RVU) and issues interim RVUs for new and revised procedure codes for calendar year 2008. Finally, the rule announces that (1) the physician fee schedule update for calendar year 2008 is negative 10.1 percent, (2) the initial estimate for the sustainable growth rate for calendar year 2008 is negative 0.1 percent, and (3) the conversion factor (CF) for calendar year 2008 is $34.0682. CMS prepared a regulatory impact analysis of the final rule that concludes that the final rule will have an impact of reducing program expenditures by $6 billion and a $140 million increase in payments for ambulance services over calendar year 2007.</td>
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<tr>
<td>52</td>
<td>Rule title: Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates, the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates, the Hospital Inpatient Prospective Payment System and FY 2008 Payment Rates; and Payments for Graduate Medical Education for Affiliated Teaching Hospitals in Certain Emergency Situations Medicare and Medicaid Programs: Hospital Conditions of Participation; Necessary Provider Designations of Critical Access Hospitals</td>
<td>The final rule revises the Medicare hospital outpatient prospective payment system to implement statutory requirements and changes arising from CMS’s continuing experience with the system, including changes to the amounts and factors used to determine Medicare’s payments. The final rule sets forth the applicable relative payment weights and amounts for services furnished in Ambulatory Surgical Centers (ASC). The final rule also includes changes made to the 2008 hospital inpatient provider payment system as required by statute. Finally, CMS has included an interim final rule modifying the regulations relating to graduate medical education payments made to teaching hospitals that have Medicare affiliation agreements for certain emergency situations. CMS estimates that the changes made by the final rule changing the outpatient prospective payment system (OPPS) payment rates will increase Medicare expenditures for calendar year 2008 over the expenditures for calendar year 2007 by $3.4 billion. The changes made to the ASC payment system are expected to have no net effect on Medicare expenditures in calendar year 2008. CMS estimates that the changes in inpatient prospective payment system (IPPS) payment rates will increase Medicare payments to IPPS providers for calendar year 2008 over the expenditures for calendar year 2007 by $4.635 billion.</td>
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<td>Rule</td>
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| 53   | **Rule title:** Medicaid Program; Optional State Plan Case Management Services  
      **Date:** December 4, 2007  
      **Sub-agency:** Centers for Medicare & Medicaid Services  
      **Action:** Interim final rule with comment period  
      **Exception(s) to NPRM cited:** Statutory  
      **GAO major rule report:** [http://www.gao.gov/decisions/majrule/d08378r.pdf](http://www.gao.gov/decisions/majrule/d08378r.pdf) | CMS prepared a cost-benefit analysis in conjunction with the interim final rule with comment period. CMS estimates that between fiscal years 2008 and 2012, the regulation will reduce federal Medicaid spending on case management and targeted case management services by $1.28 billion and increase federal spending on title IV-E foster care services by $369 million. |
| 54   | **Rule title:** Medicare Program; Standards for E-Prescribing Under Medicare Part D and Identification of Backward Compatible Version of Adopted Standard for E-Prescribing and the Medicare Prescription Drug Program (Version 8.1)  
      **Date:** April 7, 2008  
      **Sub-agency:** Centers for Medicare & Medicaid Services  
      **Action:** Final rule  
      **Exception(s) to NPRM cited:** Good cause  
      **GAO major rule report:** [http://www.gao.gov/products/GAO-08-690R](http://www.gao.gov/products/GAO-08-690R) | CMS performed a cost-benefit analysis of the final rule. CMS contends that prescribers and dispensers that are now e-prescribing have already largely invested in the hardware, software, and connectivity necessary to e-prescribe. CMS does not anticipate that the retirement of NCPDP SCRIPT 5.0 in favor of NCPDP SCRIPT 8.1 Medication History Standard for the exchange of medication history information, the adoption of the NCPDP Formulary and Benefits 1.0 for formulary and benefits transactions, the adoption of NPI for use in e-prescribing transactions, and the adoption of NCPDP SCRIPT 8.1 (RxFill) for electronic fill status notification purposes will result in significant costs. CMS anticipates that the ability to utilize electronic formulary and benefits inquiries will result in administrative efficiencies and increased prescribing of generic drugs versus brand name drugs, and the access to medication history at the point of care will result in reduced adverse drug events. The benefits accruing from using the adopted standards in these transactions will have an economically significant effect on Medicare Part D program cost and patient safety.  
      (The agency also concluded that the cost of implementing these standards is minimal, with quantifiable benefits reaped by dispensers, prescribers, and beneficiaries. Over 5 years, the agency expected these groups will see average net benefits in a range from $218 million to $863.9 million from the utilization of formulary and benefits and medication history transactions, and the promulgation of these standards.) |
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<tr>
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<tbody>
<tr>
<td>55</td>
<td><strong>Rule title:</strong> Medicare Program; Inpatient Psychiatric Facilities Prospective Payment System Payment Update for Rate Year Beginning July 1, 2008 (RY 2009) <strong>Date:</strong> May 7, 2008 <strong>Sub-agency:</strong> Centers for Medicare &amp; Medicaid Services <strong>Action:</strong> Notice <strong>Exception(s) to NPRM cited:</strong> Good cause <strong>GAO major rule report:</strong> <a href="http://www.gao.gov/products/GAO-08-777R">http://www.gao.gov/products/GAO-08-777R</a></td>
<td>The notice updates the prospective payment rates for Medicare inpatient psychiatric facilities (IPF). The changes are applicable to IPF discharges occurring during the rate year beginning July 1, 2008, through June 30, 2009. CMS performed a cost-benefit analysis of this final rule. CMS concludes that the effect of the updates described in this notice results in an overall $120 million increase in payments from rate year 2008 to rate year 2009. CMS does not expect changes in the quality of care or access to services for Medicare beneficiaries due to the rate changes. CMS contends that access to IPF services will be enhanced due to patient and facility level adjustment factors, all of which are intended to adequately reimburse IPFs for expensive cases. Also, the outlier policy in the final rule is intended to assist IPFs that experience high-cost cases.</td>
</tr>
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<td>56</td>
<td><strong>Rule title:</strong> State Children’s Health Insurance Program (SCHIP); Retrospective Adjustment for Additional Allotments To Eliminate Fiscal Year (FY) 2007 Funding Shortfalls; Final SCHIP Allotments for FYS 2008 and 2009; Redistribution of Unused SCHIP FY 2005 Allotments To Eliminate FY 2008 Funding Shortfalls; Additional Allotments To Eliminate FY 2008 Funding Shortfalls; and Provisions for Continued Authority for Qualifying States To Use a Portion of Certain SCHIP Funds for Medicaid Expenditures <strong>Date:</strong> May 23, 2008 <strong>Sub-agency:</strong> Centers for Medicare &amp; Medicaid Services <strong>Action:</strong> Notice <strong>Exception(s) to NPRM cited:</strong> Good cause <strong>GAO major rule report:</strong> <a href="http://www.gao.gov/products/GAO-08-952R">http://www.gao.gov/products/GAO-08-952R</a></td>
<td>The notice describes the implementation of certain funding under SCHIP as amended. The funding provisions include retrospective adjustment of the additional allotments to eliminate fiscal year 2007 SCHIP funding shortfalls; the final fiscal years 2008 and 2009 SCHIP allotments; the redistribution of the amounts of states’ unused fiscal year 2005 allotments to eliminate fiscal year 2008 SCHIP funding shortfalls; the provision of additional allotments to eliminate fiscal year 2008 SCHIP funding shortfalls; the provision of additional allotments to eliminate fiscal year 2008 SCHIP funding shortfalls; the provision for “qualifying States” to elect to use a portion of their available SCHIP allotments as increased federal matching funds for certain expenditures in their Medicaid programs. CMS provides tables identifying SCHIP allotments for fiscal years 2008 and 2009. However, since the availability of such allotment funds were calculated based on methodologies specified in statute and does not put forward any discretionary administrative policies, CMS determined that there are no policy options that require an analysis beyond that which is presented in the tables.</td>
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<td>Rule</td>
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<td><strong>57</strong></td>
<td><strong>Rule title</strong>: Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates; Payments for Graduate Medical Education in Certain Emergency Situations; Changes to Disclosure of Physician Ownership in Hospitals and Physician Self-Referral Rules; Updates to the Long-Term Care Prospective Payment System; Updates to Certain IPPS-Excluded Hospitals; and Collection of Information Regarding Financial Relationships Between Hospitals</td>
<td>The notice lists the final wage indices, hospital reclassifications, payment rates, impacts, and other related items for fiscal year 2009 pursuant to the Medicare Improvement for Patients and Providers Act of 2008.</td>
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<tr>
<td><strong>58</strong></td>
<td><strong>Rule title</strong>: Medicare Program; Revisions to the Medicare Advantage and Prescription Drug Benefit Programs</td>
<td>The interim final rule changes the Medicare Advantage regulations to conform to statutory requirements regarding special needs plans, private-fee-for-service plans, regional preferred provider organizations plans, and Medicare medical savings accounts plans. It also implements statutory provisions governing cost-sharing for dual-eligible enrollees in the Medicare Advantage program prescription drug pricing, coverage, and payment processes in the Part D program. The interim final rule also sets forth new requirements governing the marketing of Part C and D plans.</td>
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<td>Rule</td>
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<td>59</td>
<td>Rule title: Medicare Program; Part A Premium for Calendar Year 2009 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement. <strong>Date:</strong> September 24, 2008. <strong>Sub-agency:</strong> Centers for Medicare &amp; Medicaid Services. <strong>Action:</strong> Notice. <strong>Exception(s) to NPRM cited:</strong> Good cause. <strong>GAO major rule report:</strong> <a href="http://www.gao.gov/decisions/majrule/d0969r.pdf">http://www.gao.gov/decisions/majrule/d0969r.pdf</a>.</td>
<td>The notice announces Medicare’s Part A premium for uninsured enrollees in calendar year 2009. CMS estimates that the aggregate cost to enrollees paying the premiums will be about $142 million in calendar year 2009 over the amount paid in 2008.</td>
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<td>60</td>
<td>Rule title: Medicare Program; Medicare Part B Monthly Actuarial Rates, Premium Rate, and Annual Deductible Beginning January 1, 2009. <strong>Date:</strong> September 24, 2008. <strong>Sub-agency:</strong> Centers for Medicare &amp; Medicaid Services. <strong>Action:</strong> Notice. <strong>Exception(s) to NPRM cited:</strong> Good cause. <strong>GAO major rule report:</strong> <a href="http://www.gao.gov/products/GAO-09-66R">http://www.gao.gov/products/GAO-09-66R</a>.</td>
<td>The notice announces the monthly actuarial rates for aged and disabled beneficiaries enrolled in Medicare Part B beginning January 1, 2009. In addition, this notice announces the monthly premium for aged and disabled beneficiaries as well as the income-related monthly adjustment amounts to be paid by beneficiaries with modified adjusted gross income above certain threshold amounts. CMS estimated that the increase will cost approximately 1.7 million Part B enrollees about $770 million.</td>
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<tr>
<td>61</td>
<td>Rule title: Medicare Program; Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for Calendar Year 2009. <strong>Date:</strong> September 24, 2008. <strong>Sub-agency:</strong> Centers for Medicare &amp; Medicaid Services. <strong>Action:</strong> Notice. <strong>Exception(s) to NPRM cited:</strong> Good cause. <strong>GAO major rule report:</strong> <a href="http://www.gao.gov/products/GAO-09-65R">http://www.gao.gov/products/GAO-09-65R</a>.</td>
<td>The notice announces the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in calendar year 2009 under Medicare Part A. CMS estimated that the total increase in costs to beneficiaries will be about $680 million, due to the increase in the deductible and coinsurance amounts and the changes in the number of deductibles and daily coinsurance amounts paid.</td>
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| 62   | **Rule title:** Medicare Program; Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates: Final Fiscal Year 2009 Wage Indices and Payment Rates Including Implementation of Section 124 of the Medicare Improvement for Patients and Providers Act of 2008  
**Date:** October 3, 2008  
**Sub-agency:** Centers for Medicare & Medicaid Services  
**Action:** Final rule  
**Exception(s) to NPRM cited:** Other reason  
The notice lists the final wage indices, hospital reclassifications, payment rates, impacts, and other related items for fiscal year 2009 pursuant to the Medicare Improvement for Patients and Providers Act of 2008.  
CMS examined the costs and benefits of this notice. CMS projects that the increase in operating payments in fiscal year 2009, compared to 2008, will be approximately $4.97 billion and the increase in capital payments over the same period to be $60 million. CMS, therefore, expects a net increase of $5.03 billion in the operating and capital payments to inpatient prospective payment system providers. |  |
| 63   | **Rule title:** Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and CY 2009 Payment Rates; Changes to the Ambulatory Surgical Center Payment System and CY 2009 Payment Rates; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers To Perform Organ Transplants— Clarification of Provider and Supplier Termination Policy Medicare and Medicaid Programs: Changes to the Ambulatory Surgical Center Conditions for Coverage  
**Date:** November 18, 2008  
**Sub-agency:** Centers for Medicare & Medicaid Services  
**Action:** Final rule with comment period; final rules  
**Exception(s) to NPRM cited:** Good cause  
This final rule revises the Medicare hospital outpatient prospective payment system to implement changes made by the Medicare Improvement for Patients and Providers Act of 2008 and changes arising from experience with the system. This final rule also revises the Medicare ambulatory surgical center (ASC) payment system. These changes are applicable to services furnished on or after January 1, 2009.  
CMS performed a cost-benefit analysis of the final rule. CMS estimates that the total increase (from changes in this final rule as well as enrollment, utilization, and case-mix changes) in expenditures under the hospital outpatient prospective payment system (OPPS) for calendar year 2009 compared to calendar year 2008 will be approximately $1.6 billion. CMS also estimates that the effects of the changes to the ASC payment system provisions for calendar year 2009 will have no net effect on Medicare expenditures in CY 2009 compared to the level of expenditures in CY 2008. |  |
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| 64   | **Rule title:** Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; E-Prescribing Exemption for Computer-Generated Facsimile Transmissions; and Payment for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)  
**Date:** November 19, 2008  
**Sub-agency:** Centers for Medicare & Medicaid Services  
**Action:** Interim final rules with request for comments  
**Exception(s) to NPRM cited:** Good cause (P)  
**GAO major rule report:** http://www.gao.gov/products/GAO-09-218R | **CMS performed a cost-benefit analysis of the final rule. CMS estimates that the final rule will increase expenditures for calendar year 2009 over the expenditures for calendar year 2008 by $3 billion.** |
| 65   | **Rule title:** Medicare Program; Medicare Advantage and Prescription Drug Benefit Programs: Negotiated Pricing and Remaining Revisions  
**Date:** January 12, 2009  
**Sub-agency:** Centers for Medicare & Medicaid Services  
**Action:** Final rule with comment period  
**Exception(s) to NPRM cited:** Good cause  
**GAO major rule report:** http://www.gao.gov/products/GAO-09-311R | **CMS estimates that the costs associated with revisions to the beneficiary cost sharing and reinsurance subsidy payments will be $30 million in fiscal year 2010, with a total cost of $530 million in fiscal years 2010-2018. CMS estimates that the costs related to other provisions in the final rule will be approximately $4.38 million in fiscal year 2010 and $3.82 million per year in fiscal years 2011 through 2018. CMS states that it has no reliable basis for estimating the economic benefits of the final rule, but expects that the clarifications included in the final rule could contribute to greater plan efficiency and compliance with program regulations.** |
### Appendix IV: Summary Information on Final Major Rules Issued without an NPRM, in Whole or in Part—2003 through 2010

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<th>Rule</th>
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| 66   | **Rule title:** Medicare Program: Medicare Advantage and Prescription Drug Programs MIPPA Drug Formulary & Protected Classes Policies  
      **Date:** January 16, 2009  
      **Sub-agency:** Centers for Medicare & Medicaid Services  
      **Action:** Interim final rule with comment period  
      **Exception(s) to NPRM cited:** Good cause  
      **GAO major rule report:** http://www.gao.gov/products/GAO-09-329R  
      The interim final rule revises the regulations governing the Medicare prescription drug benefit program (Part D). These provisions change the definition of a covered Part D drug and add new requirements that apply to Part D formularies. This rule implements provisions Medicare Improvements for Patients and Providers Act of 2008.  
      CMS analyzed the costs and benefits of this interim final rule. CMS estimates that the formulary requirements with respect to certain categories or classes of drugs will be $4.2 billion from 2010 to 2018. With respect to economic benefits, CMS stated that it has no reliable basis for estimating the effects of the proposals contained in this interim final rule. Accordingly, CMS stated that, while there could be economic benefits associated with these proposals, such benefits are difficult to gauge at this time. |
| 67   | **Rule title:** Medicare Program; Inpatient Psychiatric Facilities Prospective Payment System Payment Update for Rate Year Beginning July 1, 2009 (RY 2010)  
      **Date:** May 1, 2009  
      **Sub-agency:** Centers for Medicare & Medicaid Services  
      **Action:** Notice; request for comments  
      **Exception(s) to NPRM cited:** Good cause  
      **GAO major rule report:** http://www.gao.gov/products/GAO-09-698R  
      The notice updates the prospective payment rates for Medicare inpatient psychiatric facilities (IPF). The changes are applicable to IPF discharges occurring during the rate year beginning July 1, 2009, through June 30, 2010.  
      CMS estimates that the net effect of the updates described in this notice will result in an overall $87 million increase in payments from rate 2009 to rate year 2010. CMS does not expect changes in the quality of care or access to services for Medicare beneficiaries due to this notice. CMS contends that access to IPF services will be enhanced due to the patient- and facility-level adjustment factors, all of which are intended to adequately reimburse IPFs for expensive cases. Also, the outlier policy is intended to assist IPFs that experience high-cost cases. |
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<td>68</td>
<td><strong>Rule title:</strong> Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and Fiscal Year 2010 Rates; and Changes to the Long-Term Care Hospital Prospective Payment System and Rate Years 2010 and 2009 Rates</td>
<td>CMS analyzed the costs and benefits of this final rule. CMS estimates that the market basket update to the inpatient prospective payment systems rates will result in an estimated $1.73 billion increase in fiscal year 2010 operating payments (or 1.6 percent increase), and $171 million increase in fiscal year 2010 capital payments (or 1.9 percent increase). In addition, long-term care hospitals are expected to experience an increase in payments by $153 million (or 3.3 percent).</td>
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<td><strong>Date:</strong> August 27, 2009</td>
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<td><strong>Sub-agency:</strong> Centers for Medicare &amp; Medicaid Services</td>
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<td><strong>Action:</strong> Final rules and interim final rule with comment period</td>
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<td><strong>Exception(s) to NPRM cited:</strong> Good cause; statutory</td>
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<td>69</td>
<td><strong>Rule title:</strong> Medicare Program; Part A Premium for Calendar Year 2010 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement</td>
<td>For calendar year 2010, CMS estimates that the aggregate cost to enrollees paying the premiums will be about $125 million more than the amount they paid in calendar year 2009. The premium for calendar year 2010 of $461 is an increase of approximately 4 percent over the calendar year 2009 premium of $443. CMS estimates that approximately 558,000 enrollees will voluntarily enroll in Medicare Part A by paying the full premium and that an additional 40,000 enrollees will pay the reduced premium.</td>
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<td><strong>Date:</strong> October 22, 2009</td>
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<td></td>
<td><strong>Sub-agency:</strong> Centers for Medicare &amp; Medicaid Services</td>
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<td><strong>Action:</strong> Notice</td>
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<td><strong>Exception(s) to NPRM cited:</strong> Good cause</td>
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### Rule 70

**Rule title:** Medicare Program; Medicare Part B Monthly Actuarial Rates, Premium Rate, and Annual Deductible Beginning January 1, 2010  
**Date:** October 22, 2009  
**Sub-agency:** Centers for Medicare & Medicaid Services  
**Action:** Notice  
**Exception(s) to NPRM cited:** Good cause  

The notice announces the monthly actuarial rates for aged (age 65 and over) and disabled (under age 65) beneficiaries enrolled in Part B of the Medicare Supplementary Medical Insurance (SMI) program beginning January 1, 2010. The notice announces the monthly premium for aged and disabled beneficiaries as well as the income-related monthly adjustment amounts to be paid by beneficiaries with modified adjusted gross income above certain threshold amounts. The monthly actuarial rates for 2010 are $221 for aged enrollees and $270.40 for disabled enrollees. The standard monthly Part B premium rate for 2010 is $110.50, which is equal to 50 percent of the monthly actuarial rate for aged enrollees or roughly 25 percent of the expected average total cost of Part B coverage for aged enrollees. (The 2009 standard premium rate was $96.40.) The Part B deductible for 2010 is $155 for all Part B beneficiaries. A beneficiary who has to pay an income-related monthly adjustment may have to pay a total monthly premium of roughly 35, 50, 65, or 80 percent of the total cost of Part B coverage.

**Summary of benefits, costs, and other economic effects**

CMS estimated that the standard Part B premium rate of $110.50, which is $14.10 higher than the premium for 2009, will result in about $2 billion of additional costs in 2010 for the approximately 12 million Part B enrollees who pay the increase in the Part B premium.

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### Rule 71

**Rule title:** Medicare Program; Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for Calendar Year 2010  
**Date:** October 22, 2009  
**Sub-agency:** Centers for Medicare & Medicaid Services  
**Action:** Notice  
**Exception(s) to NPRM cited:** Good cause  

The notice announces the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in calendar year 2010 under Medicare’s Hospital Insurance Program (Medicare Part A). For calendar year 2010, the inpatient hospital deductible will be $1,100. The daily coinsurance amounts for calendar year 2010 will be: (a) $275 for the 61st through 90th day of hospitalization in a benefit period; (b) $550 for lifetime reserve days; and (c) $137.50 for the 21st through 100th day of extended care services in a skilled nursing facility in a benefit period.

**Summary of benefits, costs, and other economic effects**

CMS determined that the total increase in costs to beneficiaries will be about $730 million, due to the increase in the deductible and coinsurance amounts and the change in the number of deductibles and daily coinsurance amounts paid.
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| 72   | Rule title: Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2010  
Date: November 25, 2009  
Sub-agency: Centers for Medicare & Medicaid Services  
Action: Final rule with comment period  
Exception(s) to NPRM cited: Good cause; other reason  
The final rule implements changes to the physician fee schedule and other Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice and the relative value of services. It also finalizes the calendar year 2009 interim relative value units (RVU) and issues interim RVUs for calendar year 2010. As required by statute, the final rule announces that the physician fee schedule update is negative 21.2 percent for calendar year 2010, the preliminary estimate for the sustainable growth rate for calendar year 2010 is negative 8.8 percent, and the conversion factor (CF) for calendar year 2010 is $28.4061.  
CMS performed a cost-benefit analysis of the final rule. CMS estimates that the final rule will decrease expenditures for calendar year 2010 over the expenditures for calendar year 2009 by more than $20 million. Therefore, CMS is increasing the physician fee schedule conversion factor by 1.00103 to offset this estimated decrease in Medicare physician expenditures due to the calendar year 2010 RVU changes. |
| 73   | Rule title: Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents  
Date: March 19, 2010  
Sub-agency: Food and Drug Administration (FDA)  
Action: Final rule  
Exception(s) to NPRM cited: Statutory  
The FDA is reissuing a final rule restricting the sale, distribution, and use of cigarettes and smokeless tobacco. As required by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), FDA is issuing a final rule that is identical to the provisions of the final rule on cigarettes and smokeless tobacco published by FDA in 1996, with certain required exceptions.  
The rule did not include estimates of the costs, benefits, or transfer amounts.. (Because the Tobacco Control Act directed the Secretary of HHS to issue a final rule identical in its provisions to the final rule issued on August 28, 1996, OMB did not require a Regulatory Impact Analysis beyond that done at that time.) |
| 74   | Rule title: Medicare Program; Inpatient Psychiatric Facilities Prospective Payment System Payment—Update for Rate Year Beginning July 1, 2010 (RY 2011)  
Date: April 30, 2010  
Sub-agency: Centers for Medicare & Medicaid Services  
Action: Notice  
Exception(s) to NPRM cited: Good cause  
The notice updates the prospective payment rates for Medicare inpatient psychiatric facilities (IPF). The changes are applicable to IPF discharges occurring during the rate year beginning July 1, 2010, through June 30, 2011.  
The net effect of the updates described in this notice results in an overall estimated $95 million increase in payments from rate year 2010 to rate year 2011. CMS does not expect changes in the quality of care or access to services for Medicare beneficiaries due to this notice. CMS contends that access to IPF services will be enhanced due to the patient- and facility-level adjustment factors, all of which are intended to adequately reimburse IPFs for expensive cases. Also, the outlier policy is intended to assist IPFs that experience high-cost cases. |
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<tr>
<td>75</td>
<td>Early Retiree Reinsurance Program</td>
<td>The interim final rule implements the Early Retiree Reinsurance Program, which was established by the Patient Protection and Affordable Care Act. The program provides reimbursement to participating employment-based plans for a portion of the cost of health benefits for early retirees and their spouses, surviving spouses and dependents. HHS will reimburse plans for certain claims between $15,000 and $90,000 (with those amounts being indexed for plan years starting on or after October 1, 2011).</td>
<td>HHS analyzed the costs and benefits of this interim final rule. HHS believes that the costs imposed on sponsors that want to receive the early retiree reimbursement will not be significant relative to the payments received. The costs will consist of staff or contractor time to complete the applications to participate, file claims for reimbursement, and to comply with program requirements such as requests related to an audit. (Over the 4 year period for which funds are appropriated for this program, the agency anticipated an overall positive transfer of $5 billion to eligible sponsors (and indirectly a portion of those funds will be transferred for the benefit of plan participants), less administrative costs.)</td>
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<tr>
<td>76</td>
<td>Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and Fiscal Year 2010 Rates and to the Long-Term Care Hospital Prospective Payment System and Rate Year 2010 Rates: Final Fiscal Year 2010 Wage Indices and Payment Rates Implementing the Affordable Care Act</td>
<td>The notice contains the final wage indices, hospital reclassifications, payment rates, impacts, and other related tables effective for the fiscal year 2010 hospital inpatient prospective payment system (IPPS) and the rate year 2010 long-term care hospital (LTCH) prospective payment system. CMS notes that the rates, tables, and impacts included in this notice reflect changes required by or resulting from the implementation of several provisions of the Affordable Care Act.</td>
<td>CMS conducted a cost-benefit analysis of this notice. CMS estimates that the operating payments to the IPPS will increase by approximately $75.7 million in fiscal year 2010; the capital payments will increase by approximately $94.7 million in fiscal year 2010. CMS estimates that payments to the LTCHs will decrease by approximately $11 million in fiscal year 2010. Both of these estimates reflect changes from the previously published estimates for fiscal year 2010.</td>
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| 77   | **Rule title:** Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities for Fiscal Year 2011  
**Date:** July 22, 2010  
**Sub-agency:** Centers for Medicare & Medicaid Services  
**Action:** Notice with comment period  
**Exception(s) to NPRM cited:** Good cause  
| The notice updates the payment rates used under the prospective payment system for skilled nursing facilities for fiscal year 2011. In addition, this notice also implements a provision of the Patient Protection and Affordable Care Act which postpones the implementation of the Resource Utilization Groups, Version 4 (RUG-IV) case-mix classification system, but, notwithstanding the postponement, requires the implementation of the parts of RUG-IV related to concurrent therapy and the look-back period.  
| CMS analyzed the costs and benefits of this notice. CMS estimates that overall payments for skilled nursing facilities will increase by $542 million, or 1.7 percent, in fiscal year 2011 as compared to fiscal year 2010. |
| 78   | **Rule title:** Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2011  
**Date:** July 22, 2010  
**Sub-agency:** Centers for Medicare & Medicaid Services  
**Action:** Notice  
**Exception(s) to NPRM cited:** Good cause  
| This notice updates the payment rates for inpatient rehabilitation facilities (IRF) for fiscal year 2011 (for discharges occurring on or after October 1, 2010, and on or before September 30, 2011) as required by statute. A statute requires the Secretary to publish in the Federal Register on or before the August 1 that precedes the start of each fiscal year, the classification and weighting factors for the IRF prospective payment system’s case-mix groups, and a description of the methodology and date used in computing the prospective payment rates for that fiscal year.  
<p>| CMS prepared a cost-benefit analysis for this notice and estimates that the total impact of these charges for fiscal year 2011 will be a net increase of $135 million in payments to IRF providers. Overall, the estimated payments per discharge for IRFs in fiscal year 2011 are projected to increase by 2.16 percent, compared with revised estimated payments in fiscal year 2010. IRF payments per discharge are estimated to increase 2.17 percent in urban areas, and 2.05 percent in rural areas, compared with the revised estimated fiscal year 2010 payments. |</p>
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<td>79</td>
<td><strong>Rule title:</strong> Pre-Existing Condition Insurance Plan Program  &lt;br&gt;<strong>Date:</strong> July 30, 2010  &lt;br&gt;<strong>Sub-agency:</strong> Office of Consumer Information and Insurance Oversight (OCIIO)  &lt;br&gt;<strong>Action:</strong> Interim final rule with comment period  &lt;br&gt;<strong>Exception(s) to NPRM cited:</strong> Good cause  &lt;br&gt;<strong>GAO major rule report:</strong> <a href="http://www.gao.gov/products/GAO-10-998R">http://www.gao.gov/products/GAO-10-998R</a>  &lt;br&gt;The interim final rule implements a provision of the Patient Protection and Affordable Care Act which requires 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. This program will continue until January 1, 2014. This rule addresses issues such as administration of the program, eligibility and enrollment, benefits, premiums, funding, and appeals and oversight rules.</td>
<td>HHS analyzed the costs and benefits of this interim final rule. In assessing the benefits of this rule, HHS stated that the Pre-existing Condition Insurance Plan (PCIP) will provide uninsured Americans with pre-existing conditions and that have been denied coverage or otherwise excluded from purchasing insurance coverage an opportunity to obtain coverage. HHS determined that providing this insurance option will increase access to health care and reduce financial strain for participants and will likely improve health outcomes and worker productivity. HHS found that individuals who are especially vulnerable as a result of existing health problems and financial status may receive the greatest benefit from this program. HHS estimated that the annual reporting and recordkeeping costs associated with this interim final rule will be $1.94 million. HHS determined that, to the extent PCIP increases access to health care services, increased health care utilization and costs will result due to increased uptake. HHS also identified administrative costs of the rule, including the cost of contractors to apply, the time cost for individuals to apply, and the contractors’ costs of complying with program rules (e.g., conducting appeals, preventing fraud). Finally HHS estimates that under this rule $5 billion in federal funds will be transferred to contractors to aid in administering the program.</td>
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## Appendix IV: Summary Information on Final Major Rules Issued without an NPRM, in Whole or in Part—2003 through 2010

### Rule 80

**Rule title:** 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

**Date:** August 16, 2010

**Sub-agency:** Centers for Medicare & Medicaid Services

**Action:** Final rules and interim final rule with comment period

**Exception(s) to NPRM cited:** Good cause; statutory (P)


The final rule revises the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals to implement changes arising from CMS’s continuing experience with these systems and to implement certain statutory provisions. In addition, the rule describes 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. The rule updates the rate-of-increase limits for certain hospitals excluded from the IPPS that are paid on a reasonable cost basis subject to these limits. Further, this rule updates 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 (LTCH) and sets forth the changes to the payment rates, factors, and other payment rate policies under the LTCH PPS. In addition, the rule finalizes the implementation of statutory provisions relating to payments to LTCHs and LTCH satellite facilities and increases in beds in existing LTCHs and LTCH satellite facilities under the LTCH PPS.

CMS analyzed the costs and benefits of this final rule. CMS estimated that the final applicable percentage increase to the inpatient prospective payment systems (IPPS) rates required by the statute, in conjunction with other final payment changes in this final rule, will result in a $440 million decrease in fiscal year 2011 operating payments (or negative 0.4 percent decrease) and an estimated $21 million decrease in fiscal year 2011 capital payments (or negative 0.5 percent change). In addition, long-term care hospitals (LTCHs) are expected to experience an increase in payments by $22.3 million (or 0.5 percent).

### Rule 81

**Rule title:** Medicare Program; Hospice Wage Index for Fiscal Year 2011

**Date:** October 1, 2010

**Sub-agency:** Centers for Medicare & Medicaid Services

**Action:** Notice with comment period

**Exception(s) to NPRM cited:** Good cause


The notice announces the annual update to the hospice wage index for fiscal year 2011 and continues the phase out of the wage index budget neutrality adjustment factor (BNAF), with an additional 15 percent BNAF reduction, for a total BNAF reduction in fiscal year 2011 of 25 percent. The BNAF phase-out will continue with successive 15 percent reductions from fiscal years 2012 through 2016.

CMS estimates that the total hospice payments will increase by $220 million in fiscal year 2010 when both the 2.6 percent hospital market basket update and the 25 percent reduction in the BNAF and updated wage data are taken into account.
### Rule Description

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<th>Rule</th>
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| 82   | **Rule title:** Medicare Program; Medicare Part B Monthly Actuarial Rates, Premium Rate, and Annual Deductible Beginning January 1, 2011  
**Date:** November 9, 2010  
**Sub-agency:** Centers for Medicare & Medicaid Services  
**Action:** Notice  
**Exception(s) to NPRM cited:** Good cause; agency organization, procedure, or practice  
The notice announces the monthly actuarial rates for aged and disabled beneficiaries enrolled in Part B of the Medicare Supplementary Medical Insurance program beginning January 1, 2011. In addition, this notice announces the monthly premium for aged and disabled beneficiaries as well as the income-related monthly adjustment amounts to be paid by beneficiaries with modified adjusted gross income above certain threshold amounts. The monthly actuarial rates for 2011 are $230.70 for aged enrollees and $266.30 for disabled enrollees. The standard monthly Part B premium rate for 2011 is $115.40, which is equal to 50 percent of the monthly actuarial rate for aged enrollees or approximately 25 percent of the expected average total cost of Part B coverage for aged enrollees. (The 2010 standard premium rate was $110.50.) The Part B deductible for 2011 is $162.00 for all Part B beneficiaries. If a beneficiary has to pay an income-related monthly adjustment, they may have to pay a total monthly premium of about 35, 50, 65, or 80 percent of the total cost of Part B coverage.  
CMS estimates the standard Part B premium rate of $115.40 is $4.90 higher than the premium for 2010, so there will be about $700 million of additional costs in 2011 to the approximately 12 million Part B enrollees who pay the increase in the Part B premium. |  |
| 83   | **Rule title:** Medicare Program; Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for CY 2011  
**Date:** November 9, 2010  
**Sub-agency:** Centers for Medicare & Medicaid Services  
**Action:** Notice  
**Exception(s) to NPRM cited:** Good cause; agency organization, procedure, or practice  
The notice announces the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in calendar year 2011 under Medicare’s Hospital Insurance Program (Medicare Part A). | CMS estimates that the total increase in costs to beneficiaries is about $900 million due to the increase in the deductible and coinsurance amounts and the change in the number of deductibles and daily coinsurance amounts paid. |
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<th>Rule</th>
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| 84   | **Rule title:** Medicare Program: Hospital Outpatient Prospective Payment System and CY 2011 Payment Rates; Ambulatory Surgical Center Payment System and CY 2011 Payment Rates; Payments to Hospitals for Graduate Medical Education Costs; Physician Self-Referral Rules and Related Changes to Provider Agreement Regulations; Payment for Certified Registered Nurse Anesthetist Services Furnished in Rural Hospitals and Critical Access Hospitals  
**Date:** November 24, 2010  
**Sub-agency:** Centers for Medicare & Medicaid Services  
**Action:** Final rule with comment period; final rules; and interim final rule with comment period.  
**Exception(s) to NPRM cited:** Good cause  
**Summary of benefits, costs, and other economic effects:** CMS performed a cost-benefit analysis of the final rule with comment period. CMS estimates that the total increase (from changes in the final rule with comment period as well as enrollment, utilization, and case-mix changes) in expenditures under the hospital OPPS for calendar year 2011 compared to calendar year 2010 will be approximately $3.2 billion. CMS also estimates that the total increase (from changes in the final rule with comment period as well as enrollment, utilization, and case-mix changes) in expenditures under the ASC payment system provisions for calendar year 2011 compared to calendar year 2010 will be approximately $230 million. | The final rule revises the Medicare hospital outpatient prospective payment system (OPPS) to implement applicable statutory requirements and changes arising from CMS’s experience with this system and to implement certain provisions of the Affordable Care Act. The final rule describes the changes to the amounts and factors used to determine the payment rates for Medicare hospital outpatient services paid under the prospective payment system for services furnished on or after January 1, 2011. In addition, this final rule updates the revised Medicare Ambulatory Surgical Center (ASC) payment system to implement applicable statutory requirements and changes arising from CMS’s experience with this system and to implement certain provisions of the Affordable Care Act. |
## Rule 85

**Rule title:** Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B For CY 2011  
**Date:** November 29, 2010  
**Sub-agency:** Centers for Medicare & Medicaid Services  
**Action:** Final rule with comment period  
**Exception(s) to NPRM cited:** Good cause (P)  

### Description

This final rule addresses changes to the physician fee schedule and other Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice and the relative value of services. It finalizes the calendar year 2010 interim relative value units (RVU) and issues interim RVUs for new and revised procedure codes for calendar year 2011. It also addresses, implements, or discusses certain provisions of both the Affordable Care Act (ACA) and the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). In addition, this final rule discusses payments under the Ambulance Fee Schedule (AFS), the Ambulatory Surgical Center (ASC) payment system, and the Clinical Laboratory Fee Schedule (CLFS); payments to end-stage renal disease (ESRD) facilities; and payments for Part B drugs. Finally, this final rule also includes a discussion regarding the Chiropractic Services Demonstration program, the Competitive Bidding Program for durable medical equipment, prosthetics, orthotics, and supplies (CBP DMEPOS), and provider and supplier enrollment issues associated with air ambulances.

### Summary of benefits, costs, and other economic effects

CMS prepared a cost-benefit analysis of the final rule. CMS estimates that the final rule will result in a decrease in expenditures of $17.6 billion for physician fee schedule (PFS) conversion factor update. CMS estimates an increase in expenditures of $1.97 billion for Affordable Care Act provisions.
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<td>86</td>
<td><strong>Rule title:</strong> Health Insurance Issuers Implementing Medical Loss Ratio (MLR) Requirements Under the Patient Protection and Affordable Care Act</td>
<td>In developing this interim final regulation, HHS carefully considered its potential effects including both costs and benefits. Because of data limitations, HHS did not attempt to quantify the benefits of this regulation. Nonetheless, HHS was able to identify several potential benefits. HHS believes one potential benefit to this regulation is greater market transparency and improved ability of consumers to make informed insurance choices. In addition, HHS states that issuers that would not otherwise meet the MLR minimum defined by this regulation may increase spending on quality-promoting activities. According to HHS, these programs, which include case management, care coordination, chronic disease management, and medication compliance, have the potential to create a societal benefit by improving outcomes and population health. HHS notes that issuers that would not otherwise meet the MLR minimum may also expand covered benefits or reduce cost sharing. HHS believes that to the extent that these changes result in increased consumption of effective health services, the regulation could result in improved health outcomes, thereby creating a societal benefit.</td>
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<td><strong>Date:</strong> December 1, 2010</td>
<td>HHS has identified the primary sources of costs associated with this regulation as the costs associated with reporting, recordkeeping, rebate notifications and payments, and other costs. HHS estimates that issuers will incur approximately $33 million to $67 million in one-time administrative costs, and $11 million to $29 million in annual ongoing administrative costs related to complying with the requirements of this interim final regulation from 2011 through 2013. HHS notes that there are two other potential types of costs associated with this regulation: costs of potential increases in medical care use, the cost of additional quality-improving activities, and costs to consumers if some issuers decide to limit offered products as a result of this interim final regulation.</td>
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<td><strong>Sub-agency:</strong> Office of Consumer Information and Insurance Oversight</td>
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<td><strong>Action:</strong> Interim final rule with request for comments</td>
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<td><strong>Exception(s) to NPRM cited:</strong> Good cause; statutory</td>
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<td><strong>Department of Homeland Security (DHS)</strong></td>
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| 87 | **Rule title:** Allocation of Additional H–1B Visas Created by the H–1B Visa Reform Act of 2004  
**Date:** May 5, 2005  
**Sub-agency:** U.S. Citizenship and Immigration Services (USCIS)  
**Action:** Interim final rules with request for comments  
**Exception(s) to NPRM cited:** Good cause  
**GAO major rule report:** [http://www.gao.gov/products/GAO-05-705R](http://www.gao.gov/products/GAO-05-705R) | USCIS estimates that the interim rule will provide it with an additional $36,200,000 in fiscal year 2005 in annual fee revenue over the fee revenue that would be collected under the current fee structure, based on a projected annual fee-paying volume of 20,000 approved petitions. In fiscal year 2006, there would be an additional $138,425,000 in fee revenue based on projected annual fee-paying volume of 85,000 approved petitions (20,000 new exemptions and 65,000 petitions). |
| 88 | **Rule title:** Chemical Facility Anti-Terrorism Standards  
**Date:** April 9, 2007  
**Sub-agency:** N/A  
**Action:** Interim final rule  
**Exception(s) to NPRM cited:** Statutory  
**GAO major rule report:** [http://www.gao.gov/products/GAO-07-747R](http://www.gao.gov/products/GAO-07-747R) | DHS conducted a Regulatory Assessment that estimated the costs of this interim final rule. DHS estimates the costs to be $3.6 billion over the period 2006-2009 and $8.5 billion over the period 2006-2015. DHS estimates that between 1,500 and 6,500 chemical facilities will be impacted by this interim final rule and uses the estimate of 5,000 impacted facilities to generate the cost estimates. According to DHS, this interim final rule gives chemical facilities considerable flexibility, which will lower compliance costs. The benefit of this interim final rule is decreased vulnerability of high-risk chemical facilities to terrorist attack. |
| 89 | **Rule title:** Changes to the Visa Waiver Program To Implement the Electronic System for Travel Authorization (ESTA) Program  
**Date:** June 9, 2008  
**Sub-agency:** Bureau of Customs and Border Protection (CBP)  
**Action:** Interim final rule; solicitation of comments  
**Exception(s) to NPRM cited:** Good cause; military or foreign affairs function; and agency organization, procedure, or practice  
**GAO major rule report:** [http://www.gao.gov/products/GAO-08-906R](http://www.gao.gov/products/GAO-08-906R) | DHS conducted a cost-benefit analysis of this interim final rule. DHS estimates that the annualized costs will be $16 million to $118 million. These costs are for U.S. and foreign-based air and sea carriers. Quantified benefits of $17 million to $29 million to carriers and CBP are for annual travel authorizations denied by ESTA that prevent inadmissible persons from applying for admission under the VWP at a United States port of entry. Non-quantified benefits are enhanced security and efficiency. |
### Appendix IV: Summary Information on Final Major Rules Issued without an NPRM, in Whole or in Part—2003 through 2010

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<th>Rule</th>
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<td>90</td>
<td><strong>Rule title:</strong> Air Cargo Screening</td>
<td>TSA conducted a cost-benefit analysis of this interim final rule. Over the 10-year period of the analysis, TSA estimates that the aggregate costs of this rulemaking to total approximately $2.8 billion, undiscounted. Discounted at 7 percent, the cost is $1.9 billion, and discounted at 3 percent, the cost is $2.4 billion. The cost of this rule would be borne by five relevant parties: certified cargo screening facilities (CCSF), non-CCSF entities that receive screened cargo from CCSFs, validation firms, aircraft operators, and TSA. Additionally, industry will bear a cost for delayed shipment of cargo estimated at $297.1 million over the 10-year analysis period ($203.1 million discounted at 7 percent and $250.4 million discounted at 3 percent). TSA anticipates bearing costs to administer the provisions of the rulemaking at $384 million over the 10-year analysis period. (Regarding benefits, the agency also said that the interim final rule will allow for more standard governance in cargo screening and will provide benefits in terms of increased security of commercial passenger aviation.)</td>
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<td><strong>Date:</strong> September 16, 2009</td>
<td><strong>Sub-agency:</strong> Transportation Security Administration (TSA)</td>
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<td><strong>Action:</strong> Interim final rules with request for comments</td>
<td><strong>Exception(s) to NPRM cited:</strong> Good cause; statutory</td>
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<tr>
<td>91</td>
<td><strong>Rule title:</strong> Electronic System for Travel Authorization (ESTA): Travel Promotion Fee and Fee for Use of the System</td>
<td>DHS conducted a cost-benefit analysis of this interim final rule. DHS concluded that the annualized cost to applicants, primarily in the form of transfers from foreign citizens to the U.S. government, is estimated between $152 million and $258 million. With respect to benefits, DHS states that this interim final rule allows DHS to comply with the Travel Promotion Act of 2009 and enhances security.</td>
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<td><strong>Date:</strong> August 9, 2010</td>
<td><strong>Sub-agency:</strong> U.S. Customs and Border Protection</td>
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<tr>
<td></td>
<td><strong>Action:</strong> Interim final rule; solicitation of comments</td>
<td><strong>Exception(s) to NPRM cited:</strong> Good cause</td>
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<td>Description</td>
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| 92   | Rule title: U.S. Citizenship and Immigration Services Fee Schedule  
Date: September 24, 2010  
Sub-agency: U.S. Citizenship and Immigration Services  
Action: Final rule  
Exception(s) to NPRM cited: Good cause  
The final rule adjusts the USCIS fee schedule to fully recover costs and maintain adequate service. The final rule increases the fees by a weighted average of 10 percent; establishes three new fees and adjusts the premium processing service by the percentage increase in inflation according to the Consumer Price Index-Urban Consumers, published as of July 2010. The final rule also finalizes the interim rule that established the premium processing service and fees.  
The final rule will provide DHS with an average of $209 million in fiscal years 2010 and 2011 annual fee revenue, based on a projected annual fee-paying volume of 4.4 million immigration benefit requests and 1.9 million requests for biometric services, over the fee revenue that would be collected under the current fee structure. The increased revenue will be used to fund the full cost of processing immigration benefit applications and associated support benefits; the full cost of providing similar benefits to asylum and refugee applicants; and the full cost of similar benefits provided to others at no charge. |

**Department of Housing and Urban Development (HUD)**

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<th>Rule</th>
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<th>Summary of benefits, costs, and other economic effects</th>
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| 93   | Rule title: HOPE for Homeowners Program: Program Regulations  
Date: October 6, 2008  
Sub-agency: Board of Directors of the HOPE for Homeowners Program  
Action: Final rule  
Exception(s) to NPRM cited: Matter relating to public property, loans, grants, benefits or contracts  
The final rule sets forth the core requirements for the HOPE for Homeowners Program, a temporary program to insure refinanced loans for homeowners who are at risk of losing their homes to foreclosure.  
The Board of Directors for the HOPE for Homeowners Program prepared an economic analysis in conjunction with this final rule. The Board of Directors anticipates that the net economic benefits will exceed the costs. The Program has the potential to have significant economic benefits, but it is difficult to quantify the benefits because the rate of participation is unknown. The Board of Directors estimates that the net benefit to the lender will be $10,000, but it may be higher; communities will also experience an economic benefit by preventing foreclosures. |

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<th>Rule</th>
<th>Description</th>
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| 94   | Rule title: HOPE for Homeowners Program; Statutory Transfer of Program Authority to HUD and Conforming Amendments To Adopt Recently Enacted Statutory Changes  
Date: January 12, 2010  
Sub-agency: Office of the Assistant Secretary for Housing-Federal Housing Commissioner  
Action: Interim rule  
Exception(s) to NPRM cited: Good cause  
The interim rule implements statutory changes made to the HOPE for Homeowners program. These changes include transferring responsibility for the program to HUD, establishing an exemption for a mortgagor who has inherited property, and revising required mortgagor representations. This rule also requires borrowers’ debt-to-income ratio to be calculated based on mortgages existing at the time of application to the program. In addition, the rule makes changes to the loan-to-value thresholds, the allowable total monthly payments, the appreciation sharing and upfront payment provisions, the upfront and annual mortgage insurance premium requirements, and the property preservation exception to subordinate lien restrictions.  
According to HUD, it did not prepare an analysis of the costs and benefits of this interim rule. HUD did prepare an Economic Analysis for this rule. HUD found that the economic impacts from the changes in this interim rule stem largely from increased participation in the H4H program. HUD estimates that, with 10,000 participants annually, the H4H program will generate $273 million in net benefits to society and that H4H participation could be as high as 137,500 households over the life of the program, with commensurately higher benefits. |
### Rule

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<th>Department of the Interior</th>
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<tr>
<td><strong>Rule</strong></td>
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<td><strong>BOEMRE states that the cost-benefit analysis</strong> for this rule was conducted using a scenario analysis. BOEMRE explains that the cost-benefit analysis considers a regulation designed to reduce the likelihood of a catastrophic oil spill, while the costs are the compliance costs of imposed regulation. BOEMRE notes that if another catastrophic oil spill is prevented, the benefits are the avoided costs associated with a catastrophic oil spill (e.g., reduction in expected natural resource damages owing to the reduction in likelihood of failure). Noting that the estimated costs of this rulemaking, as reflected in the compliance costs of the enumerated requirements of approximately $180 million per year, have a strong foundation and are based on surveys of public and industry sources, BOEMRE states that quantification of the benefits is uncertain. BOEMRE believes the benefits are represented by the avoided costs of a catastrophic spill, which are estimated under the stipulated scenario as being $16.3 billion per spill avoided. According to BOEMRE, these regulations will reduce the likelihood of another blowout and associated spill, but the risk reduction associated with the specific provisions of this rulemaking cannot be quantified because there are many complex factors that affect the risk of a blowout event.</td>
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<tr>
<td><strong>Rule title:</strong> Oil and Gas and Sulphur Operations in the Outer Continental Shelf—Increased Safety Measures for Energy Development on the Outer Continental Shelf <strong>Date:</strong> October 14, 2010 <strong>Sub-agency:</strong> Bureau of Ocean Energy Management, Regulation and Enforcement (BOEMRE) <strong>Action:</strong> Interim final rule with request for comments <strong>Exception(s) to NPRM cited:</strong> Good cause <strong>GAO major rule report:</strong> <a href="http://www.gao.gov/products/GAO-11-155R">http://www.gao.gov/products/GAO-11-155R</a></td>
<td>The interim final rule implements certain safety measures recommended in the report entitled, &quot;Increased Safety Measures for Energy Development on the Outer Continental Shelf&quot; dated May 27, 2010. BOEMRE is amending drilling regulations related to well control, including sub-sea and surface blowout preventers, well casing and cementing, secondary intervention, unplanned disconnects, recordkeeping, well completion, and well plugging.</td>
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## Appendix IV: Summary Information on Final Major Rules Issued without an NPRM, in Whole or in Part—2003 through 2010

### Department of Labor (DOL)

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<tr>
<td><strong>Rule title:</strong> Performance of Functions; Claims for Compensation Under the Energy Employees Occupational Illness Compensation Program Act of 2000, as Amended</td>
<td>The rule finalizes an interim final rule published on June 8, 2005. The rule provided for compensation payable by statute.</td>
<td>DOL performed a cost-benefit analysis of the final rule that resulted in the following estimates of the aggregate cost of benefits and administrative costs (in millions of dollars):</td>
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<tr>
<td><strong>Date:</strong> December 29, 2006</td>
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<td>Fiscal Year</td>
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<td><strong>Sub-agency:</strong> Office of Workers’ Compensation Programs, Employment Standards Administration</td>
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<td>2007</td>
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<td><strong>Action:</strong> Final rule</td>
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<td>2008</td>
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<td><strong>Exception(s) to NPRM cited:</strong> Good cause; Statutory</td>
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<td>2011</td>
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<tr>
<td><strong>Rule title:</strong> Annual Reporting and Disclosure</td>
<td>The final rule amends the annual reporting and disclosure requirements under the Employee Retirement Income Security Act of 1974, as amended (ERISA). The amendments are necessary to conform the annual reporting and disclosure regulations to revisions to the Form 5500, filed for employee pensions and welfare benefit plans under ERISA and the Internal Revenue Code. The Form 5500 changes are intended to facilitate the transition to an electronic filing system; reduce and streamline annual reporting burdens, especially for small businesses; and update the annual reporting forms to reflect current issues, agency priorities, and new requirements under the Pension Protection Act of 2006.</td>
<td>DOL concluded that the use of the 5500 Forms will relieve plans subject to the annual reporting requirements from increased costs and unreasonable administrative burdens by providing a standardized format that facilitates reporting, eliminates duplicative reporting requirements, and simplifies the content of the annual report in general. The 5500 Forms are intended to reduce further the administrative burdens and costs attributable to compliance with the annual reporting requirements. Over the next 10 years, DOL anticipates an average annual reduction in costs of more than $97 million.</td>
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<tr>
<td><strong>Date:</strong> November 16, 2007</td>
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<td>Fiscal Year</td>
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<tr>
<td><strong>Sub-agency:</strong> Employee Benefits Security Administration</td>
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<td>2007</td>
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<tr>
<td><strong>Action:</strong> Interim final rules with request for comments</td>
<td></td>
<td>2008</td>
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<td><strong>Exception(s) to NPRM cited:</strong> Good cause; other reason (P)</td>
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<td>2009</td>
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<td>2011</td>
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<td>Rule</td>
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<td><strong>Department of State (State)</strong></td>
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<td>98</td>
<td><strong>Rule title:</strong> Schedule of Fees for Consular Services, Department of State and Overseas Embassies and Consulates&lt;br&gt;<strong>Date:</strong> January 29, 2008&lt;br&gt;<strong>Sub-agency:</strong> N/A&lt;br&gt;<strong>Action:</strong> Interim final rule&lt;br&gt;<strong>Exception(s) to NPRM cited:</strong> Good cause&lt;br&gt;<strong>GAO major rule report:</strong> <a href="http://www.gao.gov/products/GAO-08-575R">http://www.gao.gov/products/GAO-08-575R</a></td>
<td>The interim final rule revises the Schedule of Fees for Consular Services to reflect an increase in the surcharge related to consular services in support of enhanced border security and a reduction in the execution fee for the passport book. The Department of State performed a cost-benefit analysis in conjunction with this interim final rule. State determined that the net increase per application would provide State with an estimated additional $232 million in fiscal year 2008. State estimates that the increased cost of a passport book over its 10-year lifetime will be minimal. Finally, State estimates that the interim final rule will have the non-quantifiable benefit of enabling State to advance its goal of enhancing border security while simultaneously investing in infrastructure and other developments needed to meet projected level of passport book demand in fiscal year 2008 and beyond.</td>
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<td><strong>Department of Transportation</strong></td>
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<td>99</td>
<td><strong>Rule title:</strong> Hours of Service of Drivers&lt;br&gt;<strong>Date:</strong> December 17, 2007&lt;br&gt;<strong>Sub-agency:</strong> Federal Motor Carrier Safety Administration (FMCSA)&lt;br&gt;<strong>Action:</strong> Interim final rule; request for comments&lt;br&gt;<strong>Exception(s) to NPRM cited:</strong> Good cause&lt;br&gt;<strong>GAO major rule report:</strong> <a href="http://www.gao.gov/products/GAO-08-390R">http://www.gao.gov/products/GAO-08-390R</a></td>
<td>The interim final rule allows commercial motor vehicle drivers up to 11 hours of driving time within a 14-hour, non-extendable window from the start of the workday, following 10 consecutive hours off duty (11-hour limit). The interim final rule also allows motor carriers and drivers to restart calculation of the weekly on-duty time limits after the driver has at least 34 consecutive hours off duty (34-hour restart). The interim final rule was made in response to a decision by the United States Court of Appeals for the District of Columbia Circuit to vacate the portions of the 2005 rule setting the 11-hour limit and the 34-hour restart. FMCSA updated the cost-benefit analysis it had prepared for the 2005 hours of service of drivers rule (<a href="http://www.gao.gov/products/GAO-08-390R">70 Fed. Reg. 49,978 (Aug. 25, 2005)</a>) and included the analysis with the interim final rule. FMCSA determined that the analysis, as updated, continued to support setting the driving limit at 11 hours. FMCSA determined that setting the driving-limit at 10 hours, as opposed to 11 hours, would have a benefit of reducing fatigue crash risk by 5.1 percent, with an estimated value of $85 million per year, but that the costs in terms of productivity would be almost 2 percent, or an estimated $586 million, leaving a net cost of $501 million per year by eliminating the 11th hour.</td>
</tr>
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</table>
### Rule 100

**Rule title:** Hours of Service of Drivers  
**Date:** November 19, 2008  
**Sub-agency:** Federal Motor Carrier Safety Administration  
**Action:** Final rule  
**Exception(s) to NPRM cited:** Good cause  

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<th>Description</th>
<th>Summary of benefits, costs, and other economic effects</th>
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<td>The final rule adopts as final provisions of an interim final rule concerning hours of service for commercial motor vehicle drivers. The final rule allows drivers to continue to drive up to 11 hours within a 14-hour, non-extendable window from the start of the workday, following at least 10 consecutive hours off duty. The final rule also allows drivers to restart calculation of the weekly on-duty limits after a driver has at least 34 consecutive hours off duty.</td>
<td>FMCSA prepared a cost-benefit analysis comparing the current rule, which allows up to 11 hours of driving, allows a new 7 or 8 day period to begin after a 34-hour restart break, and some splitting of off-duty periods using sleeper berths, to a second option that would limit driving to 10 hours in a tour of duty and eliminate the 34-hour restart provision. FMCSA estimated that the second option would result in decreased productivity yielding $2,443 million in annual costs, and that it would reduce crash risk by approximately 0.63 percent yielding a value of $214 million per year. Based on this analysis FMCSA concluded that the total annual net costs resulting from the second option would be approximately $2,229 million. FMCSA also conducted a series of sensitivity analyses, where it revised its assumptions regarding the percentage of all large truck crashes that are fatigue related, the value of a statistical life, and the relative risk of a fatigue-related crash in the 11th hour of driving. FMCSA combined all of the new assumptions in a way that makes the elimination of driving in the 11th hour more favorable from a cost-benefit analysis perspective, and the exercise still found the annual net costs of the second option to be $71 million. Based on its cost-benefit analysis and its sensitivity analyses, FMCSA concluded that eliminating the 11th hour of driving is unlikely to be cost-effective under any reasonable set of circumstances.</td>
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<td>Rule</td>
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| 101  | **Rule title:** Part 121 Pilot Age Limit  
**Date:** July 15, 2009  
**Sub-agency:** Federal Aviation Administration (FAA)  
**Action:** Final rule  
**Exception(s) to NPRM cited:** Good cause  
**GAO major rule report:** [http://www.gao.gov/products/GAO-09-972R](http://www.gao.gov/products/GAO-09-972R) | The final rule amends certain regulations to conform with the “Fair Treatment for Experienced Pilots Act” by raising the upper age limit for pilots serving in domestic, flag, and supplemental operations from age 60 to age 65.  
FAA performed a cost-benefit analysis in conjunction with the final rule, analyzing the costs and benefits of the final rule over a 15-year period and summarizing the net benefits as the discounted present value of the stream of benefits and costs. FAA determined that the increase in the mandatory retirement age to age 65 will result in airlines and consumers incurring “real costs” (which reflect real resource use) and “transfer payments” (which are monetary payments from one group to another that do not affect total resources available to society) totaling $1.8 billion (present value) over 15 years. FAA determined that society will have a cost savings or net benefit of $334 million in terms of real resource use. In addition to the quantified benefits, FAA estimates that the final rule will result in an increase in the supply of pilots of approximately 12 percent over 5 years. |
| 102  | **Rule title:** Requirements and Procedures for Consumer Assistance To Recycle and Save Program  
**Date:** July 29, 2009  
**Sub-agency:** National Highway Traffic Safety Administration (NHTSA)  
**Action:** Final rule  
**Exception(s) to NPRM cited:** Good cause; statutory  
**GAO major rule report:** [http://www.gao.gov/products/GAO-09-981R](http://www.gao.gov/products/GAO-09-981R) | The final rule sets forth the requirements and procedures for the voluntary vehicle trade-in and purchase/lease program under the Consumer Assistance to Recycle and Save Act of 2009 (commonly known as the Cash-for-Clunkers program). This program helps consumers pay for new, more fuel efficient cars and trucks from a participating dealer when they trade in a less fuel efficient car or truck.  
NHTSA analyzed the costs and benefits of this final rule. NHTSA stated that it plans to hire 30 employees and more than 200 contractor employees to administer the program over 6 months. NHTSA determined that the impact of the program governed by this rule will most likely not be large enough to increase production by manufacturers and that dealers will only be selling on average 12 additional vehicles. NHTSA identified the improved fuel efficiency of the on-road vehicle fleet as another benefit. NHTSA noted that this will decrease greenhouse gases and certain pollutants by decreasing fuel consumption, resulting in air pollution benefits. However, these benefits will be dependent upon which types of vehicles consumers purchase. According to NHTSA, dealers may incur certain costs, but that they may retain up to $50 from the scrap value of trade-in vehicles to offset administrative costs. Also, some related industries, such as automotive repair shops, may lose some profit due to foregone repairs. |
## Appendix IV: Summary Information on Final Major Rules Issued without an NPRM, in Whole or in Part—2003 through 2010

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<td><strong>Department of the Treasury</strong></td>
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<td>103</td>
<td><strong>Rule title:</strong> Unfair or Deceptive Acts or Practices; Amendment  <strong>Date:</strong> May 4, 2010  <strong>Sub-agency:</strong> Office of Thrift Supervision (OTS)  <strong>Action:</strong> Final rule  <strong>Exception(s) to NPRM cited:</strong> Good cause  <strong>GAO major rule report:</strong> <a href="http://www.gao.gov/products/GAO-10-912R">http://www.gao.gov/products/GAO-10-912R</a></td>
<td>The final rule amends the regulations on Prohibited Consumer Credit Practices, to avoid duplication and inconsistency with the Credit Card Accountability Responsibility and Disclosure Act of 2009 and the rules of the Board of Governors of the Federal Reserve implementing that statute. The rule did not include estimates of the costs, benefits, or transfer amounts. OTS previously provided a regulatory impact analysis under Executive Order 12,866. 74 Fed. Reg. at 5551—5558. OTS notes that the analysis addressed the impact of the consumer credit card practices in subpart C to part 535. Since this final rule removes subpart C, OTS states that its impact will be eliminated.</td>
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<td><strong>Department of Veterans Affairs (VA)</strong></td>
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<td>104</td>
<td><strong>Rule title:</strong> Traumatic Injury Protection Rider to Servicemembers’ Group Life Insurance  <strong>Date:</strong> March 8, 2007  <strong>Sub-agency:</strong> N/A  <strong>Action:</strong> Final rule  <strong>Exception(s) to NPRM cited:</strong> Good cause  <strong>GAO major rule report:</strong> <a href="http://www.gao.gov/products/GAO-07-619R">http://www.gao.gov/products/GAO-07-619R</a></td>
<td>The final rule implements a statutory requirement to establish an automatic traumatic injury protection rider to the Service members’ Group Life Insurance program for any insured service member who sustains certain serious traumatic injuries. VA included a cost benefit analysis with the publication of the interim final rule. VA estimated that the final rule will produce federal budgetary costs consisting of approximately $400 million in retroactive insurance payments, $68 million in start-up costs, and annual operating costs of approximately $68 million. The final rule will also increase the premium for service members by $1 per month. The final rule will provide benefits between $25,000 and $100,000 to qualifying service members who suffer a traumatic injury.</td>
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<tr>
<td><strong>Federal Reserve System</strong></td>
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<td>105</td>
<td><strong>Rule title:</strong> Capital Adequacy Guidelines: Treatment of Perpetual Preferred Stock Issued to the United States Treasury Under the Emergency Economic Stabilization Act of 2008  <strong>Date:</strong> October 22, 2008  <strong>Sub-agency:</strong> N/A  <strong>Action:</strong> Interim final rule with request for public comment.  <strong>Exception(s) to NPRM cited:</strong> Good cause  <strong>GAO major rule report:</strong> <a href="http://www.gao.gov/products/GAO-09-107R">http://www.gao.gov/products/GAO-09-107R</a></td>
<td>The interim final rule permits bank holding companies that issue new senior perpetual preferred stock to the Treasury under the capital purchase program to include such capital instruments in Tier 1 capital for purposes of the Federal Reserve’s risk-based and leverage capital rules and guidelines for bank holding companies. The Federal Reserve did not prepare a cost-benefit analysis. However, the interim final rule does explain that the Federal Reserve finds strong public policy considerations to allow Senior Perpetual Preferred Stock issued to Treasury under the Troubled Asset Relief Program to be included as Tier 1 capital for the purposes of the Federal Reserve’s risk-based and leverage capital rules and guidelines, as an exception to its longstanding stance regarding the unacceptability of a rate step-up in other regulatory capital instruments.</td>
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**Date:** June 1, 2009  
**Sub-agency:** Board of Governors of the Federal Reserve System (Board)  
**Action:** Interim final rule with request for public comment.  
**Exception(s) to NPRM cited:** Good cause  
The interim final rule permits bank holding companies that have made a valid election to be taxed under Subchapter S of Chapter 1 of the U.S. Internal Revenue Code (S-Corp BHC) and bank holding companies organized in mutual form (Mutual BHC) to include the full amount of any new subordinated debt securities issued to the Treasury under the capital purchase program in Tier 1 capital for purposes of the Board’s risk-based and leverage capital guidelines for bank holding companies, provided that the Subordinated Securities will count toward the limit on the amount of other restricted core capital elements includable in Tier 1 capital. | The Board did not prepare a cost-benefit analysis in conjunction with the interim final rule. |
**Date:** June 1, 2009  
**Sub-agency:** Board of Governors of the Federal Reserve System (Board)  
**Action:** Final rule  
**Exception(s) to NPRM cited:** Good cause  
The final rule permits bank holding companies that issue new senior perpetual preferred stock to the Treasury under the capital purchase program announced by the Secretary of to include such capital instruments in Tier 1 capital for purposes of the Federal Reserve’s risk-based and leverage capital rules and guidelines for bank holding companies. | The Federal Reserve did not prepare a cost-benefit analysis. However, the final rule does explain that the Federal Reserve finds strong public policy considerations to allow Senior Perpetual Preferred Stock issued to Treasury under the Troubled Asset Relief Program to be included as tier 1 capital for the purposes of the Federal Reserve’s risk-based and leverage capital rules and guidelines, as an exception to its longstanding stance regarding the unacceptability of a rate step-up in other regulatory capital instruments. |
| 108  | **Rule title:** Truth in Lending  
**Date:** July 22, 2009  
**Sub-agency:** Board of Governors of the Federal Reserve System (Board)  
**Action:** Interim final rule; request for public comment.  
**Exception(s) to NPRM cited:** Good cause  
The interim final rule amends Regulation Z in order to implement provisions of the Credit Card Accountability Responsibility and Disclosure Act of 2009 that are effective on August 20, 2009. The interim final rule pertains to advance notices of rate increases and changes in terms and the time consumers are given to make payments. | The Board did not prepare a cost-benefit analysis. However, the core provisions of this interim final rule implement the statutory requirements of section 102 of the Credit Card Act that are effective on August 20, 2009. |
### Rule Description

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| **109** | **Rule title:** Electronic Fund Transfers  
**Date:** August 17, 2010  
**Sub-agency:** Board of Governors of the Federal Reserve System (Board)  
**Action:** Interim final rule; request for public comment.  
**Exception(s) to NPRM cited:** Good cause  
In its submission to the Comptroller General, the Board did not include a cost-benefit analysis. |
| **110** | **Rule title:** Amendments to Regulation SHO  
**Date:** October 17, 2008  
**Sub-agency:** N/A  
**Action:** Interim final temporary rule; request for comments  
**Exception(s) to NPRM cited:** Good cause  
**GAO major rule report:** [http://www.gao.gov/products/GAO-09-236R](http://www.gao.gov/products/GAO-09-236R) | The interim final temporary rule addresses abusive “naked” short selling in all equity securities by requiring that participants of a clearing agency deliver securities by settlement date, or if the participants have not delivered shares by settlement date, immediately purchase or borrow securities to close out the fail to deliver position by no later than the beginning of regular trading hours on the settlement day following the day the participant incurred the fail to deliver position.  
SEC prepared a cost-benefit analysis in conjunction with the interim final temporary rule. The rule will help maintain fair and orderly markets against the threat of sudden and excessive fluctuations of securities prices. SEC believes the interim final temporary rule will benefit investors by facilitating the receipt of shares so that more investors receive the benefits associated with ownership and ensuring confidence that trading can be conducted without the influence of illegal manipulation. SEC believes the interim final temporary rule will benefit issuers by increasing investor confidence in the market for their securities which will facilitate investments in their securities. SEC notes that the interim final temporary rule may result in increased short selling costs for investors and the securities lending market. However, SEC believes that the costs are justified by the fact that the temporary rule may help restore, maintain, and enhance investor confidence in the market by preventing potentially abusive “naked” short selling. |
### Rule 111
**Rule title:** Disclosure of Short Sales and Short Positions by Institutional Investment Managers  
**Date:** October 17, 2008  
**Sub-agency:** N/A  
**Action:** Final rule  
**Exception(s) to NPRM cited:** Good cause  

The interim final temporary rule adopts Exchange Act Rule 10a-3T which requires institutional investment managers that exercise investment discretion with respect to accounts holding section 13(f) securities having an aggregate fair market value of at least $100 million to file Form SH following a calendar week in which it effected a short sale in a section 13(f) security, with some exceptions.

The Commission states the benefits of this rule are that non-accelerated filers will be required to complete only management’s assessment of compliance with the Section 404 requirements during the deferral period. The final rule also allows non-accelerated filers more time to better prepare for compliance with the Section 404(b) requirements and for the Section 404(b) audit to be properly planned, scoped and executed. The Commission states the cost of this rule is that investors in non-accelerated filers will have to wait longer than they would in the absence of the deferral for the assurances provided by the auditor’s attestation report and the added investor confidence that could result from obtaining an independent Section 404(b) attestation.

### Rule 112
**Rule title:** Internal Control Over Financial Reporting in Exchange Act Periodic Reports of Non-Accelerated Filers  
**Date:** October 19, 2009  
**Sub-agency:** N/A  
**Action:** Final rules  
**Exception(s) to NPRM cited:** Good cause  

The final rule amends temporary rules which extended compliance dates under the Sarbanes-Oxley Act of 2002. Under Section 404(b) of the act, companies that are non-accelerated filers are required to include in their annual reports an attestation report of their independent auditor on internal control over financial reporting (ICFR) for fiscal years ending on or after December 15, 2009. The final rule postpones for an additional 6 months the date by which a non-accelerated filer must begin to include an auditor’s attestation report on ICFR with its annual report.

SEC prepared a cost-benefit analysis in conjunction with the interim final temporary rule. SEC expects that Rule 10a-3T and Form SH will help restore investor confidence in the markets and reduce manipulative behavior, which should help to alleviate any undue crisis of investor confidence and may strengthen the market’s ability to correctly incorporate accurate information into securities prices. Also, the Form SH disclosure will enable staff to study the impact of short selling on the market in times of financial crisis. SEC estimates the costs will be $93.5 million in filing costs for the 1,000 Form SH Reports that will be filed with SEC each week through August 1, 2009. In addition, SEC notes that many institutional managers faced costs associated with creating a reporting mechanism to capture the data required by Form SH and will face association implementation costs.
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<th>Rule</th>
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<tr>
<td>113</td>
<td>Rule title: Reporting of Security-Based Swap Transaction Data</td>
<td>The interim final temporary rule requires specified counterparties to pre-enactment security-based swap transactions to report certain information relating to pre-enactment security-based swaps to a registered security-based swap data repository or to SEC by the compliance date established in the security-based swap reporting rules required under sections 3C(e) and 13A(a) of the Securities Exchange Act of 1934 (&quot;Exchange Act&quot;), or within 60 days after a registered security-based swap data repository commences operations to receive and maintain data concerning such security-based swaps, whichever occurs first and report information relating to pre-enactment security-based swaps to SEC upon request.</td>
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SEC performed a preliminary cost-benefit analysis in conjunction with the interim final temporary rule and requested comments on the costs and benefits. SEC determined that the interim final temporary rule will provide a means for SEC to gain a better understanding of the security-based swap markets and help SEC analyze the security-based swap market as a whole and identify risks. The interim final temporary rule will also facilitate the reports SEC is required to provide to Congress on security-based swaps and the security-based swaps marketplace, along with having possible benefits in encouraging management review of internal procedures and controls by market participants. SEC preliminarily estimates that the interim final temporary rule could affect more than 1,000 market participants and cover approximately 2.4 million security-based swap transactions. SEC preliminarily estimates that amending internal procedures, reprogramming systems, and implementing compliance processes to ensure that pre-enactment security-based swap transaction data is preserved could result in a cost to each respondent of approximately $6,236 and an aggregate cost of approximately $6.24 million. SEC preliminarily estimates that the requirement to report the transaction confirmation and time, if available, of execution could result in a cost to each reporting entity of approximately $43,900 and an aggregate cost of approximately $43.9 million. Finally, SEC preliminarily estimates that responding to SEC requests for information and documents could result in a cost to each reporting entity of approximately $6,352 and an aggregate cost of approximately $6.35 million. |
### Appendix IV: Summary Information on Final Major Rules Issued without an NPRM, in Whole or in Part—2003 through 2010

#### Rule 114

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<th>Rule title:</th>
<th>Regulation SHO</th>
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<td>Date:</td>
<td>November 9, 2010</td>
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<tr>
<td>Sub-agency:</td>
<td>N/A</td>
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<tr>
<td>Action:</td>
<td>Final rule; extension of compliance date</td>
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<tr>
<td>Exception(s) to NPRM cited:</td>
<td>Good cause</td>
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**Description:**
The final rule extends for a limited period of time the compliance date for the amendments to Rule 201 and Rule 200(g) of Regulation SHO from November 10, 2010, to February 28, 2011.

**Summary of benefits, costs, and other economic effects:**
SEC generally considers the costs and benefits of its rules. According to the Commission, the delay of the compliance date for the amendments to Rule 201 and Rule 200(g) of Regulation SHO will delay the benefits of the rules, but will also delay the ongoing costs of complying with the amendments. SEC determined that the limited extension is necessary and appropriate because it will provide certain exchanges additional time to modify their current procedures for conducting single-priced transactions for covered securities that have triggered Rule 201’s circuit breakers in a manner that is consistent with the goals and requirements of Rule 201, and industry participants additional time for programming and testing for compliance with the requirements of Rule 201 and Rule 200(g).

#### Joint rulemakings

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<tr>
<th>Rule title:</th>
<th>Federal Acquisition Regulation; FAR Case 2008–004, Prohibition on Restricted Business Operations in Sudan and Imports from Burma</th>
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<td>Date:</td>
<td>June 12, 2008</td>
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<tr>
<td>Sub-agency:</td>
<td>N/A</td>
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<tr>
<td>Action:</td>
<td>Interim rule with request for comments</td>
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<td>Exception(s) to NPRM cited:</td>
<td>Statutory</td>
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**Description:**
The interim rule requires every contract entered into by an executive branch agency to contain a certification stating that the contractor does not conduct certain business operations in Sudan. In addition, this interim rule adds Burma to the list of countries from which most imports are prohibited.

**Summary of benefits, costs, and other economic effects:**
The rule did not include estimates of the costs, benefits, or transfer amounts.
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<tr>
<td>116</td>
<td><strong>Department of the Treasury; Department of Labor; Department of Health and Human Services</strong>&lt;br&gt;&lt;br&gt;<strong>Rule title:</strong> Final Rules for Group Health Plans and Health Insurance Issuers Under the Newborns’ and Mothers’ Health Protection Act&lt;br&gt;&lt;br&gt;<strong>Date:</strong> October 20, 2008&lt;br&gt;&lt;br&gt;<strong>Sub-agency:</strong> Internal Revenue Service; Employee Benefits Security Administration (EBSA); Centers for Medicare &amp; Medicaid Services (CMS)&lt;br&gt;&lt;br&gt;<strong>Action:</strong> Final rule&lt;br&gt;&lt;br&gt;<strong>Exception(s) to NPRM cited:</strong> Statutory&lt;br&gt;&lt;br&gt;<strong>GAO major rule report:</strong>&lt;br&gt;<a href="http://www.gao.gov/products/GAO-09-143R">http://www.gao.gov/products/GAO-09-143R</a>&lt;br&gt;&lt;br&gt;The final rule provides protections for mothers and their newborn children with regard to the lengths of hospital stays following childbirth. By statute, group health plans and health insurance issuers generally may not restrict mothers’ and newborns’ benefits for a hospital stay in connection with childbirth to less than 48 hours following a vaginal delivery or 96 hours following a delivery by cesarean section. EBSA and CMS analyzed the costs and benefits of this final rule. EBSA and CMS identified the primary economic benefit of the minimum length stays under this rule as deriving from the reduction in complications linked to the premature discharge of mothers and newborns. ESBA and CMS estimate the cost of enacting federal minimum stay requirements to be between $139 and $279 million annually. However, because this final rule implements an already established statutory requirement, EBSA and CMS conclude that the implementation costs of this final rule should be negligible.</td>
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<td>117</td>
<td><strong>Department of Agriculture; Department of Commerce</strong>&lt;br&gt;&lt;br&gt;<strong>Rule title:</strong> Broadband Initiatives Program; Broadband Technology Opportunities Program&lt;br&gt;&lt;br&gt;<strong>Date:</strong> July 9, 2009&lt;br&gt;&lt;br&gt;<strong>Sub-agency:</strong> Rural Utilities Service (RUS), Agriculture and National Telecommunications and Information Administration, Commerce (NTIA)&lt;br&gt;&lt;br&gt;<strong>Action:</strong> Notice of Funds Availability (NOFA) and solicitation of applications&lt;br&gt;&lt;br&gt;<strong>Exception(s) to NPRM cited:</strong> Good cause&lt;br&gt;&lt;br&gt;<strong>GAO major rule report:</strong>&lt;br&gt;<a href="http://www.gao.gov/products/GAO-09-907R">http://www.gao.gov/products/GAO-09-907R</a>&lt;br&gt;&lt;br&gt;The notice announces general policy and application procedures for broadband initiatives established pursuant to the American Recovery and Reinvestment Act of 2009. In the notice, RUS establishes the Broadband Initiatives Program (BIP) which may extend loans, grants, and loan/grant combinations to facilitate broadband deployment in rural areas. In the notice, the NTIA establishes the Broadband Technology Opportunities Program (BTOP), which makes available grants for deploying broadband infrastructure in unserved and underserved areas in the United States, enhancing broadband capacity and public computer centers, and promoting sustainable broadband adoption programs. RUS and NTIA prepared a cost-benefit analysis for the broadband initiatives announced in the notice. The costs associated with the notice were set by the Recovery Act in its appropriations for the programs. The Recovery Act appropriated $4.7 billion to NTIA for broadband grants and other programs. The Recovery Act also appropriated $2.5 billion to RUS for broadband grants and loans. The benefits include contributing toward stimulating the American economy by creating a variety of jobs for broadband equipment manufacturers and others. Also, the development of a faster, more extensive broadband infrastructure will help U.S. businesses operate more efficiently and better compete with businesses in foreign countries. In addition, the grants to public computer centers will allow vulnerable populations to take advantage of the benefits of broadband. Finally, the overall outreach efforts will help to alleviate the disenfranchisement of certain populations who are currently unaware of the benefits of broadband, cannot afford it, or do not know how to use a computer.</td>
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The interim final rule requires 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 interim final rule also makes conforming changes to reflect statutory modifications regarding parity in aggregate lifetime and annual dollar limits, and incorporates new parity standards.

The departments analyzed the costs and benefits of the rule. According to the departments, the costs include costs associated with increased utilization of mental health and substance use disorder benefits and costs associated with cumulative financial requirements and quantitative treatment limitations, including deductibles. Additionally, the departments include compliance review costs and costs associated with Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) disclosures. The departments expect that the largest benefit associated with MHPAEA and these regulations will be derived from applying parity to cumulative quantitative treatment limitations such as annual or lifetime day or visit limits (visit limitations) to help ensure that vulnerable populations—those accessing substantial amounts of mental health and substance use disorder services—have better access to appropriate care. The departments cannot estimate how large this benefit will be, because sufficient data is not available to estimate the number of covered individuals that had their benefits terminated because they reached their coverage limit. The departments state that another potential benefit associated with MHPAEA and these regulations is that use of mental health and substance use disorder benefits could improve. The departments note that the finding that treatment can help increase the productivity of those suffering from mental illness suggests that increasing access to treatment of mental disorders could have a beneficial impact on lost productivity cost and lost earnings that stem from untreated and under treated mental health conditions and substance use disorders. The departments, however, do not have sufficient data to determine whether this result will occur, and, if it does, the extent to which lost productivity cost and lost earnings could improve. According to the departments, because expenditures on mental health and substance use disorder benefits only comprise 3-6 percent of the total benefits covered by a
Appendix IV: Summary Information on Final Major Rules Issued without an NPRM, in Whole or in Part—2003 through 2010

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<td>119</td>
<td>Department of the Treasury; Department of Labor; Department of Health and Human Services</td>
<td>These interim final rules implement statutory 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 to Age 26 Under the Patient Protection and Affordable Care Act. The Internal Revenue Service, EBSA, and Department of Health and Human Services, Office of the Secretary, analyzed the costs and benefits of these interim final rules. The agencies determined that the benefits are expected to outweigh the costs to the regulated community. For 2011, the agencies estimated the number of previously uninsured individuals who will be covered under their parents’ coverage. The agencies estimated that under their low-range assumptions, 190,000 such individuals would be covered; under their mid-range assumptions, 650,000 such individuals; and under their high-range assumptions, 1.64 million such individuals. According to the agencies, expanding coverage options for the 19 - to - 25 year old population should decrease the number uninsured, which in turn should decrease the cost-shifting of uncompensated care onto those with coverage, increase the receipt of preventive health care, and provide more timely access to high quality care, resulting in a healthier population. In particular, the agencies predict children with chronic conditions or other serious health issues will be able to continue coverage through a parents’ plan until age 26. The agencies also expect that allowing extended dependent coverage will permit greater job mobility for this population as their health coverage will no longer be tied to their own jobs or student status. The agencies estimated the annual monetized costs of these interim final rules for 2011 through 2013 to be $11.2 million at a discount rate of 7 percent and $10.4 million at a discount rate of 3 percent.</td>
</tr>
</tbody>
</table>

Rule title: Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Dependent Coverage of Children to Age 26 Under the Patient Protection and Affordable Care Act

Date: May 13, 2010

Sub-agency: Internal Revenue Service (IRS); Employee Benefits Security Administration (EBSA); & Office of the Secretary

Action: Interim final rules with request for comments

Exception(s) to NPRM cited: Good cause; statutory


Rule Description: Summary of benefits, costs, and other economic effects

Group health plan and 8 percent of overall healthcare costs, the departments expect that group health plans will lower cost-sharing on mental health and substance use disorder benefits instead of raising cost-sharing on medical/surgical benefits. (Over the 10-year period of 2010 to 2019, the total undiscounted cost of the rule is estimated to be $115 million in 2010 dollars. The departments also estimated a transfer of $25.6 billion over the 10-year period.)
### Appendix IV: Summary Information on Final Major Rules Issued without an NPRM, in Whole or in Part—2003 through 2010

<table>
<thead>
<tr>
<th>Rule</th>
<th>Description</th>
<th>Summary of benefits, costs, and other economic effects</th>
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<tbody>
<tr>
<td>120</td>
<td>Department of the Treasury; Department of Labor; Department of Health and Human Services</td>
<td>With an estimated 2.2 million grandfathered plans in 2011, EBSA and the Internal Revenue Service estimate an hour burden of approximately 538,000 hours with equivalent costs of $30.7 million. The departments have estimated this as a one-time cost incurred in 2011, because after the first year, the departments anticipate that any future costs will be de minimis. Overall, for both the grandfathering notice and the recordkeeping requirement, the departments expect there to be a total hour burden of 1.1 million hours and a cost burden of $291,000.</td>
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<td></td>
<td>Rule title: Interim Final Rules for Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan Under the Patient Protection and Affordable Care Act</td>
<td>The interim final rules implement statutory requirements for group health plans and health insurance coverage in the group and individual markets under provisions of the Affordable Care Act regarding status as a grandfathered health plan. These interim final regulations allow family members of individuals already enrolled in a grandfathered health plan to enroll in the plan after March 23, 2010; in such cases, the plan or coverage is also a grandfathered health plan with respect to the family members. New employees (whether newly hired or newly enrolled) and their families can enroll in a grandfathered group health plan after March 23, 2010, without affecting status as a grandfathered health plan.</td>
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<td>Date: June 17, 2010</td>
<td>(The departments also identified qualitative benefits including that the existence of grandfathered health plans will provide individuals with the benefits of plan continuity, could potentially slow the rate of premium growth, depending on the extent to which their current plan does not include the benefits and protections of the new law, and could also provide incentives to employers to continue coverage, potentially reducing new Medicaid enrollment and spending and lowering the number of uninsured individuals. According to the departments, these interim final regulations also provide greater certainty for plans and issuers about what changes they can make without affecting their grandfather status. The departments concluded that, as compared with alternative approaches, these regulations provide significant economic and noneconomic benefits to both issuers and beneficiaries, though these benefits cannot be quantified at this time)</td>
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<td>Sub-agency: Internal Revenue Service, Employee Benefits Security Administration, Office of Consumer Information and Insurance Oversight</td>
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<td>Action: Interim final rules with request for comments</td>
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<td>Exception(s) to NPRM cited: Good cause; statutory</td>
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| 121  | Department of the Treasury; Department of Labor; Department of Health and Human Services  
**Rule title:** Patient Protection and Affordable Care Act: Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, and Patient Protections  
**Date:** June 28, 2010  
**Sub-agency:** Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Office of Consumer Information and Insurance, Department of Health and Human Services  
**Action:** Interim final rules with request for comments.  
**Exception(s) to NPRM cited:** Good cause; statutory  
**GAO major rule report:** [http://www.gao.gov/products/GAO-10-897R](http://www.gao.gov/products/GAO-10-897R) | These interim final rules implement the requirements for group health plans and health insurance coverage in the group and individual markets under provisions of the Patient Protection and Affordable Care Act regarding preexisting condition exclusions, lifetime and annual dollar limits on benefits, rescissions, and patient protections.  
The Internal Revenue Service, EBSA, and HHS analyzed the costs and benefits of these interim final rules. The agencies stated that they crafted these interim final rules in the most economically efficient manner possible. The agencies estimate that these interim final rules will have an annual monetized cost of $4.9 million from 2011 to 2013.  
The agencies expect these interim final rules will expand coverage for children with preexisting conditions and individuals who face rescissions, lifetime limits, and annual limits as a result of high health care costs. The agencies expect these benefits to manifest in a number of ways including: (1) increasing access to health care, improving health outcomes, improving worker productivity, and reducing family financial strain and “job lock”; (2) promoting equity, in the sense that the benefits will be enjoyed by those who are especially vulnerable as a result of health problems and financial status; (3) building better, sustained patient-provider relationships through choice of physician, resulting in decreased malpractice claims and improved medication adherence and health promotion; and (4) reducing administrative and time burdens on both patients and physicians while improving health outcomes by allowing quicker access to medical services when necessary by removing referrals and prior authorizations for primary care, obstetrical and gynecological care, and emergency services. |
### Rule
122 Department of the Treasury; Department of Labor; Department of Health and Human Services

**Rule title:** Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act

**Date:** July 19, 2010

**Sub-agency:** Internal Revenue Service; Employee Benefits Security Administration; Office of Consumer Information and Insurance Oversight

**Action:** Interim final rules with request for comments

**Exception(s) to NPRM cited:** Good cause; statutory


### Description
These interim final rules implement the rules for group health plans and health insurance coverage in the group and individual markets under provisions of the Patient Protection and Affordable Care Act regarding preventive health services. These interim final rules generally apply to group health plans, group health insurance issuers, and individual health insurance issuers for plan years beginning on or after September 23, 2010.

### Summary of benefits, costs, and other economic effects
The agencies analyzed the potential costs and benefits of these interim final regulations. The agencies anticipate the qualitative costs from 2011 to 2013 to include new costs to the health care system resulting when beneficiaries increase their use of preventive services in response to the changes in coverage and cost-sharing requirements of preventive services. The agencies note that the magnitude of this effect on utilization depends on the price elasticity of demand and the percentage change in prices facing those with reduced cost sharing or newly gaining coverage. The agencies anticipate four qualitative benefits from 2011 to 2013. First, individuals will experience improved health as a result of reduced transmission, prevention or delayed onset, and earlier treatment of disease. Second, healthier workers and children will be more productive with fewer missed days of work or school. Third, some of the recommended preventive services will result in savings due to lower health care costs. Fourth, the cost of preventive services will be distributed more equitably.
Rule: 123

**Department of the Treasury; Department of Labor; Department of Health and Human Services**

**Rule title:** Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Internal Claims and Appeals and External Review Processes Under the Patient Protection and Affordable Care Act

**Date:** July 23, 2010

**Sub-agency:** Internal Revenue Service; Employee Benefits Security Administration; and Office of Consumer Information; Insurance Oversight

**Action:** Interim final rules with request for comments

**Exception(s) to NPRM cited:** Good cause; statutory


**Description:** These interim final rules implement the requirements regarding internal claims and appeals and external review processes for group health plans and health insurance coverage in the group and individual markets. The regulations will generally affect health insurance issuers; group health plans; and participants, beneficiaries, and enrollees in health insurance coverage and in group health plans. These rules will generally apply to group health plans, group health insurance issuers, and individual insurance issuers for plan years beginning on or after September 23, 2010.

**Summary of benefits, costs, and other economic effects:**

The Internal Revenue Service, EBSA, and HHS analyzed the costs and benefits of this final rule. In assessing the benefits of this rule, the agencies found the following: A more uniform, rigorous, and consumer friendly system of claims and appeals processing will provide a broad range of direct and indirect benefits that will accrue to varying degrees to all of the affected parties. These interim final regulations could improve the extent to which employee benefit plans provide benefits consistent with the established terms of individual plans. While payment of these benefits will largely constitute transfers, the transfers will be welfare improving, because incorrectly denied benefits will be paid. Greater certainty and consistency in the handling of benefit claims and appeals and improved access to information about the manner in which claims and appeals are adjudicated should lead to efficiency gains in the system, both in terms of the allocation of spending across plans and enrollees as well as operational efficiencies among individual plans. This certainty and consistency can also be expected to benefit, to varying degrees, all parties within the system, particularly consumers, and to lead to broader social welfare gains.

The agencies estimated the costs of this rule to (1) administer and conduct the internal and external review process, (2) prepare and distribute required disclosures and notices, and (3) bring plan and issuers’ internal and external claims and appeals procedures into compliance with the new requirements. The agencies estimate these costs to be between $51.2 million and $51.6 million per year for the period 2011 to 2013, depending on the discount rate. The agencies also estimated the dollar amount of claim denials reversed in the external review process. While this amount is a cost to plans, it represents a payment of benefits that should have previously been paid to participants, but was denied. Part of this amount is a transfer from plans and issuers to those now receiving payment for denied benefits. These transfers will improve equity, because incorrectly denied benefits will be paid. Part of the amount could also be a cost if the reversal leads to services and hence...
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<td>resources being utilized now that had been denied previously. The agencies estimated the amount attributable to reversals to be between $24.4 million and $24.7 million per year for the period 2011 to 2013, depending on the discount rate.</td>
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Source: GAO.
December 13, 2012

Ms. Melissa Emrey-Arras
Acting Director
Strategic Issues
General Government Division
U.S. Government Accountability Office
Washington, D.C. 20548

Dear Ms. Emrey-Arras:

Thank you for your email of November 14, 2012, in which you ask Deputy Director for Management Zients to review the draft General Accountability Act (GAO) report entitled "Federal Rulemaking: Agencies Could Take Additional Steps to Respond to Public Comments.” Deputy Director Zients asked me to respond on his behalf. We appreciate the opportunity to comment on the draft report.

I would like to comment on the draft report’s recommendation “that the Director of OMB, in consultation with the Chairman of ACUS, issue guidance to encourage agencies to respond to comments on final major rules, for which the agency has discretion, that are issued without a prior notice of proposed rulemaking.” We very much welcome the study by the Administrative Conference of the United States (ACUS) of administrative law issues related to the use of interim final rulemaking procedures or other rules that are issued without prior notice of proposed rulemaking. However, for the reasons laid out below, we do not believe it necessary for the Office of Management and Budget to issue guidance on this topic at this time.

Let me first assure you that, consistent with our prior comments to GAO on the issue of interim final rulemaking, the Office of Information and Regulatory Affairs (OIRA) continues to believe firmly in the value of a rulemaking agency obtaining public comment during its development of a rule. Public comment can assist the rulemaking agency, and improve the decision-making process, by providing new factual information, by offering different perspectives on an issue, and by suggesting alternative approaches for addressing a problem. However, as Congress recognized when it enacted the “good cause” exception in 1946, as a part of the original Administrative Procedure Act (APA), there are situations in which it would be “impracticable, unnecessary, or contrary to the public interest” for a rulemaking agency to seek public comment before acting.

With respect to the significant regulatory actions promulgated on an interim final basis, OIRA review typically includes an explanation of the agency’s rationale for that approach, which is generally explained in the rule’s preamble. Other matters addressed by OIRA staff ordinarly
include the length of the comment period that the agency would provide on the interim final rule, whether the rule’s effective date accommodates public comment before the rule becomes effective, and agency plans to respond to comments. In the course of these discussions, OIRA routinely encourages agencies to establish procedures to consider public comments received on interim final rules. To the extent that responding to comments is not required by law, however, the timing and extent of an agency’s responses is a discretionary matter that an agency must consider in the context of the nature and substance of the particular rulemaking, as well as the particular agency’s resource constraints and competing priorities. We believe that this case-specific approach is generally appropriate—even given the often unique circumstances faced by agencies issuing rules without a prior notice of proposed rulemaking—and we are not aware of compelling evidence that a more general, undiscriminating policy, set out in guidance, would offer substantial benefits.

Also, we have identified what we believe to be a minor correction on page 6 of the report. Enclosed is a copy of the draft report with that comment noted.

Lastly, we wanted to take this opportunity to thank you for correcting the report’s description of ACUS Recommendation 55-4.

Thank you again for the opportunity to comment on the draft report.

Sincerely,

Boris Berndtzen
Acting Administrator
Office of Information
and Regulatory Affairs

Enclosure
Appendix VI: GAO Contacts and Staff Acknowledgments

GAO Contacts

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In addition to the individuals named above, Tom Beall, Tim Bober, Sara Daleski, Janet Dolen, Clifton G. Douglas Jr., Denise Fantone, Rob Gebhart, Tim Guinane, Lois Hanshaw, Shirley Jones, Andrea Levine, Donna Miller, Mark Ramage, Beverly Ross, Cynthia Saunders, Wesley Sholtes, Lou V.B. Smith, Andrew Stephens, and Sabrina Streagle made key contributions to this report.
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