Upcoming Rules Pursuant to the Patient Protection and Affordable Care Act

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Summary

Congress delegates rulemaking authority to agencies for a variety of reasons, and in a variety of ways. The Patient Protection and Affordable Care Act (PPACA, P.L. 111-148) is a particularly noteworthy example of congressional delegation of rulemaking authority to federal agencies. A previous CRS report identified more than 40 provisions in PPACA that require or permit the issuance of rules to implement the legislation.

One way for Congress to identify upcoming PPACA rules is by reviewing the Unified Agenda of Federal Regulatory and Deregulatory Actions, which is published twice each year (spring and fall) by the Regulatory Information Service Center (RISC), a component of the U.S. General Services Administration, for the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA). The Unified Agenda lists upcoming activities, by agency, in five separate categories or stages of the rulemaking process: the prerule stage, the proposed rule stage, the final rule stage, long-term actions, and completed actions. All entries in the Unified Agenda have uniform data elements, including the department and agency issuing the rule, the title of the rule, its Regulation Identifier Number (RIN), an abstract describing the nature of action being taken, and a timetable showing the dates of past actions and a projected date for the next regulatory action. Each entry also contains an element indicating the priority of the regulation (e.g., whether it is considered "economically significant" under Executive Order 12866, or whether it is considered a "major" rule under the Congressional Review Act).

This report examines the most recent edition of the Unified Agenda, published on December 20, 2010 (the first edition that RISC compiled and issued after the enactment of PPACA). The report identifies upcoming proposed and final rules listed in the Unified Agenda that are expected to be issued pursuant to PPACA. The **Appendix** lists these upcoming proposed and final rules in a table. The report also briefly discusses the long-term actions listed in the Unified Agenda, as well as some options for congressional oversight over the PPACA rules.

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Introduction

Federal regulations generally start with an act of Congress and are the means by which statutes are implemented and specific requirements are established. Congress delegates rulemaking authority to agencies for a variety of reasons, and in a variety of ways. The Patient Protection and Affordable Care Act (PPACA, P.L. 111-148) is a particularly noteworthy example of congressional delegation of rulemaking authority to federal agencies.[1] PPACA is a comprehensive overhaul of the health care system that includes such provisions as the expansion of eligibility for Medicaid, amendments to Medicare that are intended to reduce its growth, an individual mandate for the purchase of health insurance, and the establishment of insurance exchanges through which individuals and families can receive federal subsidies to help them purchase insurance. A previous CRS report identified more than 40 provisions in PPACA that require or permit the issuance of rules to implement the legislation.[2]

The rules that agencies issue pursuant to PPACA are expected to have a major impact on how the legislation is implemented. For example, in an article entitled "The War Isn't Over" that was posted on the *New England Journal of Medicine's* Health Care Reform Center shortly after PPACA was signed into law, Henry J. Aaron and Robert D. Reischauer wrote:

> Making the legislation a success requires not only that it survive but also that it be effectively implemented. Although the bill runs to more than 2000 pages, much remains to be decided. The legislation tasks federal or state officials with writing regulations, making appointments, and giving precise meaning to many terms. Many of these actions will provoke controversy.... Far from having ended, the war to make health care reform an enduring success has just begun. Winning that war will require administrative determination and imagination and as much political resolve as was needed to pass the legislation.[3]

Mandatory and Discretionary Rulemaking Provisions

The manner in which Congress delegates rulemaking authority to federal agencies determines the amount of discretion the agencies have in crafting the rules and, conversely, the amount of control that Congress retains for itself. Some of the more than 40 rulemaking provisions in PPACA are quite specific, stipulating the substance of the rules, whether certain consultative or rulemaking procedures should be used, and deadlines for their issuance or implementation.[4] Other provisions

[1] For more information on PPACA, see CRS Report R40942, *Private Health Insurance Provisions in the Patient Protection and Affordable Care Act (PPACA)*, by Hinda Chaikind, Bernadette Fernandez, and Mark Newsom; CRS Report R41278, *Public Health, Workforce, Quality, and Related Provisions in PPACA: Summary and Timeline*, coordinated by C. Stephen Redhead and Erin D. Williams; CRS Report R41196, *Medicare Provisions in the Patient Protection and Affordable Care Act (PPACA): Summary and Timeline*, coordinated by Patricia A. Davis; and CRS Report R41210, *Medicaid and the State Children's Health Insurance Program (CHIP) Provisions in PPACA: Summary and Timeline*, coordinated by Julie Stone.

[2] CRS Report R41180, *Regulations Pursuant to the Patient Protection and Affordable Care Act (PPACA)*, by Curtis W. Copeland.

[3] Henry J. Aaron and Robert D. Reischauer, "The War Isn't Over," *New England Journal of Medicine*, Health Care Reform Center, March 24, 2010, available at http://healthcarereform.nejm.org/?p=3223&query=home.

[4] Although the law contains a number of deadlines for the issuance of rules, rulemaking deadlines are generally somewhat difficult to enforce, unless the statute itself contains an enforcement mechanism. None of the provisions in PPACA contain a legislative enforcement mechanism, so the remaining options for enforcement include political (continued...)

in PPACA permit, but do not require, the agencies to issue certain rules (e.g., stating that the head of an agency "may issue regulations" defining certain terms, or "may by regulation" establish guidance or requirements for carrying out the legislation). As a result, the agency head has the discretion to decide whether to issue any regulations at all, and if so, what those rules will contain. Still other provisions in PPACA require agencies to establish programs or procedures, but do not specifically mention regulations.

By December 2010, federal agencies had already issued at least 18 final rules implementing sections of PPACA.[5] Although the legislation specifically required or permitted some of the rules to be published, other rules implemented PPACA provisions that did not specifically mention rulemaking. The use of rulemaking in these cases does not appear to be either improper or unusual; if the requirements in those rules were intended to be binding on the public, rulemaking may have been the agencies' only viable option to implement the related statutory provisions.[6]

Congressional Oversight and the Unified Agenda

In his book *Building a Legislative-Centered Public Administration*, David H. Rosenbloom noted that rulemaking and lawmaking are functionally equivalent (the results of both processes have the force of law), and that when agencies issue rules they, in effect, legislate. He went on to say that the "Constitution's grant of legislative power to Congress encompasses a responsibility to ensure that delegated authority is exercised according to appropriate procedures."[7] Congressional oversight of rulemaking can deal with a variety of issues, including the substance of the rules issued pursuant to congressional delegations of authority and the process by which those rules are issued.

In order for Congress to oversee the regulations being issued to implement PPACA, it would help to have an early sense of what rules the agencies are going to issue, and when. The previously mentioned CRS report identifying the provisions in the act that require or permit rulemaking can be useful in this regard.[8] However, the legislation did not indicate when some of the mandatory rules should be issued, some of the rules that the agencies are permitted (but not required) to issue may never be developed, and many of the rules that the agencies have already issued to implement PPACA were not specifically mentioned in the act.

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pressure on the agencies or civil litigation, although courts often defer to agencies' judgment on the timing of their issuance of a rule.

[5] CRS Report R41346, *Initial Final Rules Implementing the Patient Protection and Affordable Care Act*, by Curtis W. Copeland.

[6] Case law and guidance from OMB indicate that agencies should not attempt to bind affected parties through policy statements and other non-rule documents. See, for example, *Appalachian Power Co. v. Environmental Protection Agency*, 208 F.3d 1015 (D.C. Cir. 2000); and Office of Management and Budget, "Final Bulletin for Agency Good Guidance Practices," 72 *Federal Register* 3432, January 25, 2007, which states (on p. 3433) that "The courts, Congress, and other authorities have emphasized that rules which do not merely interpret existing law or announce tentative policy positions but which establish new policy positions that the agency treats as binding must comply with the (Administrative Procedure Act's) notice-and-comment requirements, regardless of how they initially are labeled."

[7] David H. Rosenbloom, *Building a Legislative-Centered Public Administration: Congress and the Administrative State, 1946-1999* (Tuscaloosa, AL: The University of Alabama Press, 2000), pp. 133-134.

[8] CRS Report R41180, *Regulations Pursuant to the Patient Protection and Affordable Care Act (PPACA)*, by Curtis W. Copeland.

The Unified Agenda

A potentially better way for Congress to identify upcoming PPACA rules is by reviewing the Unified Agenda of Federal Regulatory and Deregulatory Actions (hereafter, Unified Agenda), which is published twice each year (spring and fall) by the Regulatory Information Service Center (RISC), a component of the U.S. General Services Administration, for the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA).[9] The Unified Agenda helps agencies fulfill two current transparency requirements:

- The Regulatory Flexibility Act (5 U.S.C. § 602) requires that all agencies publish semiannual regulatory agendas in the *Federal Register* describing regulatory actions that they are developing that may have a significant economic impact on a substantial number of small entities.[10]
- Section 4 of Executive Order 12866 on "Regulatory Planning and Review" requires that all executive branch agencies "prepare an agenda of all regulations under development or review."[11] The stated purposes of this and other planning requirements in the order are, among other things, to "maximize consultation and the resolution of potential conflicts at an early stage" and to "involve the public and its State, local, and tribal officials in regulatory planning." The executive order also requires that each agency prepare, as part of the fall edition of the Unified Agenda, a "regulatory plan" of the most important significant regulatory actions that the agency reasonably expects to issue in proposed or final form during the upcoming fiscal year.

The Unified Agenda lists upcoming activities, by agency, in five separate categories or stages of the rulemaking process:

- prerule stage (e.g., advance notices of proposed rulemaking that are expected to be issued in the next 12 months);
- proposed rule stage (i.e., notices of proposed rulemaking that are expected to be issued in the next 12 months, or for which the closing date of the comment period is the next step);
- final rule stage (i.e., final rules or other final actions that are expected to be issued in the next 12 months);
- long-term actions (i.e., items under development that agencies do not expect to take action on in the next 12 months); and
- completed actions (i.e., final rules or rules that have been withdrawn since the last edition of the Unified Agenda).

All entries in the Unified Agenda have uniform data elements, including the department and agency issuing the rule, the title of the rule, its Regulation Identifier Number (RIN),[12] an abstract

[9] The current edition of the Unified Agenda is available at http://www.reginfo.gov/public/do/eAgendaMain.

[10] This requirement applies to all agencies covered by the Administrative Procedure Act (5 U.S.C. 551(1)).

[11] Executive Order 12866, "Regulatory Planning and Review," 58 *Federal Register* 51735, Oct. 4, 1993. Although most of the requirements in this executive order do not apply to independent regulatory agencies (e.g., the Securities and Exchange Commission), this section includes these agencies.

[12] RINs are assigned by RISC, and the Office of Management and Budget has asked agencies to include RINs in the (continued...)

describing the nature of action being taken, and a timetable showing the dates of past actions and a projected date (sometimes just the projected month and year) for the next regulatory action. Each entry also contains an element indicating the priority of the regulation (e.g., whether it is considered "economically significant" under Executive Order 12866, or whether it is considered a "major" rule under the Congressional Review Act).[13]

There is no penalty for issuing a rule without a prior notice in the Unified Agenda, and some prospective rules listed in the Unified Agenda never get issued, reflecting the fluid nature of the rulemaking process. Nevertheless, the Unified Agenda can help Congress and the public know what regulatory actions are about to occur, and it arguably provides federal agencies with the most systematic, government-wide method to alert the public about their upcoming proposed rules. A previously issued CRS report indicated that about three-fourths of the significant proposed rules published after having been reviewed by OIRA in 2008 were previously listed in the "proposed rule" section of the Unified Agenda.[14]

This Report

The December 20, 2010, edition of the Unified Agenda and Regulatory Plan is the first edition that RISC has compiled and issued after the enactment of PPACA.[15] Federal agencies were required to submit data to RISC for the Unified Agenda by September 10, 2010, although some of the agencies did not submit the data until early October.[16] Therefore, the information in the Unified Agenda is current as of September/October 2010.

This report examines the December 20, 2010, edition of the Unified Agenda and identifies upcoming proposed and final rules and long-term actions that are expected to be issued pursuant to PPACA. To identify those upcoming rules and actions, CRS searched all fields of the Unified Agenda (all agencies) using the term "affordable care act," focusing on the proposed rule and final rule stages of rulemaking, and also including the "long-term actions" category. CRS excluded from the results any regulatory action that mentioned PPACA or health care reform, but did not appear to be an action taken to implement the legislation.[17]

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headings of their rulemaking documents when they are published in the *Federal Register* to make it easer for the public and agency officials to track the publication history of regulatory actions. For a copy of this memorandum, see http://www.whitehouse.gov/sites/default/files/omb/assets/inforeg/IncreasingOpenness_04072010.pdf.

[13] Section 3(f) of Executive Order 12866 defines a "significant" regulatory action as one that is likely to result in a rule that may "(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order." Regulatory actions meeting the first of these four criteria are considered "economically significant." The definition of a "major" rule under the Congressional Review Act (5 U.S.C. §§801-808) is essentially the same as "economically significant."

[14] CRS Report R40713, *The Unified Agenda: Implications for Rulemaking Transparency and Participation*, by Curtis W. Copeland.

[15] PPACA was enacted on March 23, 2010. Although the spring edition of the Unified Agenda was published after that date, the data were submitted to RISC before PPACA was enacted.

[16] E-mail from John Thomas, Director, Regulatory Information Service Center, January 4, 2010.

[17] For example, one proposed rule entry stated that the regulatory action would help state governments "prepare for the (continued...)

The results of the search for proposed and final rules are provided in the **Appendix** to this report. For each upcoming proposed and final rule listed, the table identifies the department and agency expected to issue the rule, the title of the rule and its RIN, an abstract describing the nature of the rulemaking action, and the date that the proposed or final rule was expected to be issued.[18] The abstracts presented in the table were taken verbatim from the Unified Agenda entries, although CRS sometimes used other information from the entries to identify the section of PPACA being implemented by the regulatory action when the agency-provided abstracts did not do so. Within the proposed and final rule sections of the table, the entries are organized by the expected dates of issuance, with the earliest dates presented first. Regulatory actions that the agencies considered important enough to be part of the regulatory plan are identified with a double asterisk (**) after the RIN.

Upcoming PPACA Proposed Rules

The December 20, 2010, edition of the Unified Agenda listed 29 PPACA-related actions in the "proposed rule stage" (indicating that the agencies expected to issue proposed rules on the topics within the next 12 months, or for which the closing dates of the comment periods are the next step). All but 2 of the 29 upcoming proposed rules were expected to be issued by components of the Department of Health and Human Services (HHS): the Centers for Medicare and Medicaid Policy (CMS, 15 actions); the Office of Consumer Information and Insurance Oversight (OCIIO, 4 actions); the Office of the Secretary (4 actions); the Food and Drug Administration (FDA, 2 actions); the Administration on Aging (AOA, 1 action); and the Health Resources and Services Administration (HRSA, 1 action). One other proposed rule was expected to be issued by the Department of Labor's Employee Benefits Security Administration (EBSA), and one was expected to be issued by the Department of the Treasury's Departmental Offices (DO).

Timing of Upcoming Proposed Rules

The agencies indicated that four of the upcoming proposed rules would be issued in December 2010. One of these, an HHS/CMS proposed rule on "Use of Recovery Audit Contractors," was actually published in November 2010.[19] As of December 31, 2010, the other three upcoming proposed rules had not been published: a CMS rule on "Payment Adjustment for Health Care-Acquired Conditions"; a Treasury/Departmental Offices rule on "Review and Approval Process for Waivers for State Innovation"; and an OCIIO rule on "Affordable Care Act Waiver for State Innovation; Review and Approval Process."

The agencies indicated that eight other proposed rules would be published in the first three months of 2011:

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implementation of health care reform," but the legal authority for the action was not PPACA. Therefore, that entry was not included in the table in the **Appendix**.

[18] In addition to the RINs, CMS included an agency-specific number as part of the title of the rule (e.g., CMS-1345-P). Those numbers are included as part of the title in the table in the **Appendix**.

[19] U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, "Medicaid Program; Recovery Audit Contractors," 75 *Federal Register* 69037, November 10, 2010. PPACA required that the final rule be issued by December 31, 2010, but as of that date the final rule had not been published.

- two CMS rules on "Medicare Shared Savings Program: Accountable Care Organizations," and "Federal Funding for Medicaid Eligibility Determination and Enrollment Activities," which were expected to be published in January 2011;
- two CMS rules on "Community First Choice," and "Requirements for Long-Term Care Facilities: Notification of Facility Closure," which were expected to be published in February 2011;
- two OCIIO rules on "Requirements To Implement American Health Benefit Exchanges and Other Provisions of the Affordable Care Act" and "Transparency Reporting," which were expected to be published in March 2011; and
- two FDA rules on "Food Labeling: Nutrition Labeling for Food Sold in Vending Machines" and "Food Labeling: Nutrition Labeling of Standard Menu Items in Chain Restaurants," which were expected to be published on March 23, 2011.

The HHS Office of the Secretary said it expected to issue three proposed rules in April 2011,[20] and CMS said it expected to issue eight proposed rules between April and July 2011.[21]

Notable Upcoming Proposed Rules

HHS agencies considered 6 of the 29 upcoming proposed rules important enough to be included in the regulatory plan:

- a CMS rule on "Medicare Shared Savings Program: Accountable Care Organizations," which the agency indicated would be issued sometime during the month of January 2011;
- a CMS rule on "Requirements for Long-Term Care Facilities: Notification of Facility Closure," which the agency said it expected to issue sometime during the month of February 2011;
- an OCIIO rule on "Transparency Reporting," which the agency said would be issued sometime during the month of March 2011;
- an FDA rule on "Food Labeling: Nutrition Labeling for Food Sold in Vending Machines," which is required to be issued by March 23, 2011 the one-year anniversary of the enactment of PPACA;
- an FDA rule on "Food Labeling: Nutrition Labeling of Standard Menu Items in Chain Restaurants," which is also required to be issued by March 23, 2011; and

[20] These upcoming proposed rules are "Exceptions to the Beneficiary Inducement Prohibition for Certain Arrangements," "Revisions to the Office of Inspector General's (OIG) Exclusion Authorities," and "Safe Harbors to the Anti-Kickback Statute for Certain Arrangements."

[21] These upcoming proposed rules are "Covered Outpatient Drugs," "Request for Information on Availability of Medicare Data for Performance Measurement," "Home Health Physician Encounter," "Omnibus Physician and Supplier Enrollment," "Medicaid Automated Data System Requirements and Data Elements Necessary for Program Integrity, Program Oversight, and Administration," "5-Year Period Approvals and Renewals for Waivers and Demonstration Projects," "Medicaid Reconsideration of Disallowance," and "Home and Community-Based Services (HCBS) State Plan Services Program."

- an AOA rule on "Community Living Assistance Services and Supports Enrollment and Eligibility Rules Under the Affordable Care Act," which the agency expected to issue sometime during the month of September 2011.

Economically Significant or Major Proposed Rules

In addition to the upcoming PPACA-related proposed rules that were listed in the regulatory plan, the Unified Agenda lists six other upcoming PPACA-related proposed rules that the agencies considered "economically significant" or "major" (one definition of "economically significant" or "major," for example, is that the rule is expected to have at least a $100 million annual effect on the economy):

- a CMS rule on "Federal Funding for Medicaid Eligibility Determination and Enrollment Activities," which was published on November 8, 2010, with comments due by January 7, 2011;[22]
- a CMS rule on "Use of Recovery Audit Contractors," which was expected to be issued sometime during December 2010 (but was actually issued on November 10, 2010);[23]
- an OCIIO rule on "Affordable Care Act Waiver for State Innovation; Review and Approval Process," which was expected to have been issued sometime during December 2010;
- an OCIIO rule on "Requirements To Implement American Health Benefit Exchanges and Other Provisions of the Affordable Care Act," which was expected to be issued sometime during March 2011;
- a CMS rule on "Home and Community-Based Services (HCBS) State Plan Services Program," which was expected to be issued sometime during July 2011; and
- an OCIIO rule on "Public Use Files of Health Plan Data," which was expected to be issued sometime during September 2011.

"Other Significant" Upcoming Proposed Rules

In addition to the above-mentioned rules, the agencies characterized several other upcoming proposed rules implementing PPACA as "other significant" in the Unified Agenda, indicating that although they were not listed in the regulatory plan or expected to be "economically significant," they were expected to be significant enough to be reviewed by OIRA under Executive Order 12866.[24] These proposed rules included

[22] U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, "Medicaid; Federal Funding for Medicaid Eligibility Determination and Enrollment Activities," 75 *Federal Register* 68583, November 8, 2010.

[23] U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, "Medicaid Program; Recovery Audit Contractors," 75 *Federal Register* 69037, November 10, 2010.

[24] Executive Order 12866 requires covered agencies (all except independent regulatory agencies like the Securities and Exchange Commission) to submit their "significant" rules to OIRA for review before publication as a proposed or final rule. For more information, see CRS Report RL32397, *Federal Rulemaking: The Role of the Office of Information and Regulatory Affairs*, by Curtis W. Copeland.

- an HHS Office of the Secretary rule on "Exceptions to the Beneficiary Inducement Prohibition for Certain Arrangements," which was expected to be issued sometime during March 2011;
- a DOL/EBSA rule "Ex Parte Cease and Desist and Summary Seizure Orders Under ERISA Section 521," which was expected to be issued sometime during July 2011; and
- a CMS rule on "Long-Term Care Facility Quality Assessment and Performance Improvement," which was expected to be issued sometime during January 2012.

Effects on Small Entities

The Regulatory Flexibility Act (5 U.S.C. §§ 601-612) generally requires federal agencies to assess the impact of their forthcoming regulations on "small entities" (i.e., small businesses, small governments, and small not-for-profit organizations).[25] Three of the previously mentioned upcoming PPACA-related proposed rules were expected to affect small businesses, small governments, or both, and were expected to require a regulatory flexibility analysis:

- the FDA rules on "Food Labeling: Nutrition Labeling for Food Sold in Vending Machines," and "Food Labeling: Nutrition Labeling of Standard Menu Items in Chain Restaurants"; and
- the CMS rule on "Federal Funding for Medicaid Eligibility Determination and Enrollment Activities."

In addition to these rules, five other upcoming proposed rules were expected to have an effect on small businesses, small governments, or small not-for-profits, but were not expected to trigger the requirements of the Regulatory Flexibility Act. These included

- a CMS proposed rule on "Long-term Facility Quality Assessment and Performance Improvement";
- an HHS/Office of the Secretary proposed rule on "Exceptions to the Beneficiary Inducement Prohibition for Certain Arrangements"; and
- a Treasury/DO proposed rule on "Review and Approval Process for Waivers for State Innovation."

Upcoming PPACA Final Rules

The December 20, 2010, edition of the Unified Agenda listed 18 PPACA-related actions in the "final rule stage" (indicating that the agency expected to issue final rules on the subjects within the next 12 months). Eight of the upcoming final rules were expected to be issued by CMS; four by OCIIO; two by DOL/EBSA; and one each by HRSA, the Internal Revenue Service within the Department of the Treasury, the Occupational Safety and Health Administration (OSHA) within DOL, and the Social Security Administration.

[25] For more information, see CRS Report RL34355, *The Regulatory Flexibility Act: Implementation Issues and Proposed Reforms*, by Curtis W. Copeland.

Timing of Upcoming Final Rules

The agencies indicated that 6 of the 18 upcoming final rules would be issued during the month of December 2010. Two of these rules were published before the Unified Agenda was issued on December 20, 2010:

- a CMS rule on "Changes to the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System for CY 2011," which was published in late November 2010;[26] and
- a Social Security Administration rule on "Regulations Regarding Income-Related Monthly Adjustment Amounts to Medicare Beneficiaries' Prescription Drug Premiums," which was published in early December 2010.[27]

As of December 31, 2010, the other four final rules that the agencies indicated would be published during December 2010 had not been published:

- an IRS rule on "Indoor Tanning Services";[28]
- an OCIIO rule on "Rate Review";[29]
- an OCIIO rule on "Health Care Reform Insurance Web Portal Requirements"; and
- a CMS rule on "Adult Health Quality Services."

The agencies indicated that nine other final rules would be published in the first seven months of 2011:

- two CMS rules scheduled for January 2011 on "Additional Screening, Application Fees, and Temporary Moratoria for Providers and Suppliers,"[30] and "Children's Health Insurance Program (CHIP); Allotment Methodology and States' Fiscal Year 2009 CHIP Allotments";
- an OCIIO rule scheduled for March 2011 on "Uniform Explanation of Benefits, Coverage Facts, and Standardized Definitions";
- a CMS rule scheduled for March 2011 on "Civil Money Penalties for Nursing Homes";
- two DOL/EBSA rules scheduled for April 2011 on "Group Health Plans and Health Insurance Issuers Relating to Dependent Coverage of Children to Age 26

[26] U.S. Department of Health and Human Services, Centers for Medicare and Medicaid, "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; Final Rule," 75 *Federal Register* 71800, November 24, 2010.

[27] U.S. Social Security Administration, "Regulations Regarding Income-Related Monthly Adjustment Amounts to Medicare Beneficiaries' Prescription Drug Coverage Premiums," 75 *Federal Register* 75884, December 7, 2010.

[28] A related proposed rule and a "final and temporary regulation" were published on June 15, 2010.

[29] OCIIO did, however, publish a proposed rule regarding this issue on December 23, 2010.

[30] CMS published a proposed rule on this issue on September 23, 2010.

Under the Patient Protection and Affordable Care Act," and "Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act";[31]

- two CMS rules scheduled for June 2011 on "Administrative Simplification: Adoption of Authoring Organizations for Operating Rules and Adoption of Operating Rules for Eligibility and Claims Status," and "Proposed Changes to the Demonstration Review and Approval Process";[32] and
- a CMS rule scheduled for July 2011 on "Administrative Simplification: Standard Unique Identifier for Health Plans."

Notable Upcoming Final Rules

The agencies considered 3 of the 18 upcoming PPACA-related final rules important enough to be included in the regulatory plan:

- an OCIIO rule that was scheduled for December 2010 on "Rate Review";
- a CMS rule scheduled for March 2011 on "Civil Money Penalties for Nursing Homes"; and
- an OCIIO rule scheduled for March 2011 on "Uniform Explanation of Benefits, Coverage Facts, and Standardized Definitions."

Economically Significant or Major Final Rules

In addition to the upcoming PPACA-related final rules that were listed in the regulatory plan, the Unified Agenda lists five other upcoming PPACA-related final rules that the agencies considered "economically significant" or "major" (e.g., that are expected to have at least a $100 million annual effect on the economy):

- three CMS rules on "Changes to the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System for CY 2011," "Children's Health Insurance Program (CHIP); Allotment Methodology and States' Fiscal Year 2009 CHIP Allotments," and "Additional Screening, Application Fees, and Temporary Moratoria for Providers and Suppliers";
- an OCIIO rule on "Medical Loss Ratios"; and
- a DOL/EBSA rule on "Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act."

"Other Significant" Final Rules

In addition to the above-mentioned rules, five other upcoming final rules implementing PPACA were characterized as "other significant" in the Unified Agenda, indicating that although they

[31] Both of these final rules would finalize interim final rules that had been issued in 2010.

[32] CMS published a proposed rule on this issue on September 17, 2010.

were not listed in the regulatory plan or expected to be "economically significant," they were expected to be significant enough to be reviewed by OIRA under Executive Order 12866. These final rules were

- a HRSA rule on "Designation of Medically Underserved Populations and Health Professional Shortage Areas";
- two CMS rules on "Adult Health Quality Services" and "Proposed Changes to the Demonstration Review and Approval Process";
- a DOL/OSHA rule on "Procedures for the Handling of Retaliation Complaints Under Section 1558 of the Affordable Care Act of 2010"; and
- a Social Security Administration rule on "Regulations Regarding Income-Related Monthly Adjustment Amounts to Medicare Beneficiaries' Prescription Drug Premiums."

Effects on Small Entities

Two of the upcoming final rules were expected to trigger the requirements of the Regulatory Flexibility Act because of their effects on small businesses: the IRS rule on "Indoor Tanning Services," and the CMS rule on "Changes to the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System for CY 2011." Four other CMS rules were expected to have an effect on small businesses, governments, or other organizations, but were not expected to require a regulatory flexibility analysis: (1) "Children's Health Insurance Program (CHIP); Allotment Methodology and States' Fiscal Year 2009 CHIP Allotments"; (2) "Administrative Simplification: Adoption of Authoring Organizations for Operating Rules and Adoption of Operating Rules for Eligibility and Claims Status"; (3) "Administrative Simplification: Standard Unique Identifier for Health Plans"; and (4) "Additional Screening, Application Fees, and Temporary Moratoria for Providers and Suppliers."

PPACA Long-Term Actions

As noted earlier in this report, the Unified Agenda also identifies "long-term actions" (i.e., regulatory actions that are under development in the agencies that the agencies do not expect to take action on in the next 12 months). The December 20, 2010, edition of the Unified Agenda listed 24 long-term actions related to PPACA. In comparison to the proposed and final rules previously discussed, it is much less clear when the PPACA-related long-term actions are expected to occur; in 15 of the 24 cases, the agencies said that the dates for the actions were "to be determined." Of the remaining nine long-term actions, six were expected in December 2011, and one each in calendar years 2012, 2013, and 2014.

Nature of the Long-Term Actions

Of the 24 long-term actions, 11 were upcoming final rules that were expected to be issued once the agency had considered the comments received in response to previously issued interim final rules.[33] These actions included

- a DOL/EBSA rule on "Group Health Plans and Health Insurance Issuers Relating to Internal and External Appeals Processes Under the Patient Protection and Affordable Care Act;" with the date of the final rule "to be determined";[34] and
- an HHS/OSCIIO rule on "Internal Claims, Appeals, and External Review Processes Under the Affordable Care Act," with the date of the final rule "to be determined."[35]

Five other long-term actions were upcoming IRS final rules that the agency expected to issue by the end of calendar year 2011 after considering the comments received in response to a previously issued notice of proposed rulemaking. These actions included

- "Requirements Applicable to Grandfathered Health Plans Under the Patient Protection and Affordable Care Act";[36] and
- "Requirements Applicable to Group Health Plans and Health Insurance Issuers Under the Patient Protection and Affordable Care Act."[37]

Other examples of PPACA-related long-term actions included

- an HHS/Indian Health Service advance notice of proposed rulemaking (ANPRM) on "Standards for the Planning, Design, Construction and Operation of Health Care and Sanitation Facilities," with the publication date "to be determined";[38]
- two IRS upcoming final rules on "Prohibition of Preexisting Condition Exclusions or Other Discrimination Based on Health Status Under the Patient Protection and Affordable Care Act," and "Coverage of Preventive Services Under the Patient Protection and Affordable Care Act;" both of which were expected to be published sometime during December 2011; and
- a DOL/Office of Workers' Compensation Program upcoming proposed rule entitled "Regulations Implementing Amendments to the Black Lung Benefits

[33] Interim final rules are a particular application of the "good cause" exception to notice-and-comment rulemaking (5 U.S.C. § 553), in which the agency issues a final rule without a prior notice of proposed rulemaking, but with a post-promulgation opportunity for the public to comment. Interim final rules often take effect immediately, but the effective dates may also be delayed.

[34] The associated interim final rule was published on June 17, 2010 (75 *Federal Register* 34538), but subsequently amended on November 17, 2010 (75 *Federal Register* 70114).

[35] The associated interim final rule was published on July 23, 2010 (75 *Federal Register* 43330).

[36] The associated notice of proposed rulemaking was published on June 17, 2010 (75 *Federal Register* 34571).

[37] The associated notice of proposed rulemaking was published on May 13, 2010 (75 *Federal Register* 27141).

[38] According to the Unified Agenda, an ANPRM is "a preliminary notice, published in the *Federal Register*, announcing that an agency is considering a regulatory action. An agency may issue an ANPRM before it develops a detailed proposed rule. An ANPRM describes the general area that may be subject to regulation and usually asks for public comment on the issues and options being discussed. An ANPRM is issued only when an agency believes it needs to gather more information before proceeding to a notice of proposed rulemaking."

Act: Determining Coal Miners and Survivors Entitlement to Benefits," with an expected publication sometime during the month of March 2012.

Notable Long-Term Actions

The agencies identified 7 of the 24 PPACA-related long-term actions as both "economically significant" and "major" rulemaking actions. All seven of these actions were cases in which the agencies had issued interim final rules and were reviewing the comments received. These included

- HHS/OSCIIO actions covering such topics as a "Pre-Existing Condition Insurance Plan," "Preventive Services Under the Affordable Care Act" and "Dependent Coverage of Children to Age 26 Under the Patient Protection and Affordable Care Act"; and
- a DOL/EBSA action entitled "Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan Under the Patient Protection and Affordable Care Act."

The agencies considered 11 of the 24 actions to be "other significant," meaning that the agencies considered them significant enough to be reviewed by OIRA under Executive Order 12866, but not "economically significant." These actions included

- two CMS actions entitled "Administrative Simplification: Adoption of Standard and Operating Rule for Electronic Funds Transfer (EFT) and Operating Rule for Remittance Advice" and "State Option to Provide Health Homes for Enrollees with Chronic Conditions"; and
- an HHS/HIS action on "Confidentiality of Medical Quality Assurance Records; Qualified Immunity for Participants."

Congressional Oversight Options

As noted earlier in this report, when federal agencies issue substantive regulations, they are carrying out legislative authority delegated to them by Congress. Therefore, it is appropriate for Congress to oversee the rules that agencies issue to ensure that they are consistent with congressional intent and the rulemaking requirements established in various statutes and executive orders. In order for Congress to oversee the rules being issued pursuant to PPACA, it must first know that they are being issued—ideally as early as possible. The Unified Agenda is perhaps the best vehicle to provide that early information, describing not only what rules are expected to be issued, but also providing information regarding their significance and timing.

Congress has a range of tools available to oversee the rules that federal agencies are expected to issue to implement PPACA, including oversight hearings and confirmation hearings for the heads of regulatory agencies. Individual members of Congress may also participate in the rulemaking process by, among other things, meeting with agency officials and filing public comments.[39]

[39] For example, in *Sierra Club v. Costle* (657 F.2d 298, D.C. Cir. 1981), the D.C. Circuit concluded (at 409) that it was "entirely proper for congressional representatives vigorously to represent the interests of their constituents before administrative agencies engaged in informal, general policy rulemaking, so long as the individual Members of (continued...)

Congress, committees, and individual members can also request that the Government Accountability Office (GAO) evaluate the agencies' rulemaking activities.

Another option is the Congressional Review Act (CRA, 5 U.S.C. §§801-808), which was enacted in 1996 to establish procedures detailing congressional authority over rulemaking "without at the same time requiring Congress to become a super regulatory agency."[40] The act generally requires federal agencies to submit all of their covered final rules to both houses of Congress and GAO before they can take effect.[41] It also established expedited legislative procedures (primarily in the Senate) by which Congress may disapprove agencies' final rules by enacting a joint resolution of disapproval.[42] The definition of a covered rule in the CRA is quite broad, arguably including any type of document (e.g., legislative rules, policy statements, guidance, manuals, and memoranda) that the agency wishes to make binding on the affected public.[43] After these rules are submitted, Congress can use the expedited procedures specified in the CRA to disapprove any of the rules. CRA resolutions of disapproval must be presented to the President for signature or veto.

For a variety of reasons, however, the CRA has been used to disapprove only one rule in the 14 years since it was enacted.[44] Perhaps most notably, it is likely that a President would veto a resolution of disapproval to protect rules developed under his own administration, and it may be difficult for Congress to muster the two-thirds vote in both houses needed to overturn the veto. Congress can also use regular (i.e., non-CRA) legislative procedures to disapprove agencies' rules, but such legislation may prove even more difficult to enact than a CRA resolution of disapproval (primarily because of the lack of expedited procedures in the Senate), and if enacted may also be vetoed by the President.

Although the CRA has been used only once to overturn an agency rule, Congress has regularly included provisions in the text of agencies' appropriations bills directing or preventing the development of particular regulations. Such provisions include prohibitions on the finalization of particular proposed rules, restrictions on certain types of regulatory activity, and restrictions on implementation or enforcement of certain provisions.[45] Appropriations provisions can also be used to prompt agencies to issue certain regulations, or to require that certain procedures be

(...continued)

Congress do not frustrate the intent of Congress as a whole as expressed in statute, nor undermine applicable rules of procedure."

[40] Joint statement of House and Senate Sponsors, 142 *Cong. Rec.* E571, at E571 (daily ed. April 19, 1996); 142 *Cong. Rec.* S3683, at S3683 (daily ed. April 18, 1996).

[41] If a rule is considered "major" (e.g., has a $100 million annual effect on the economy), then the CRA generally prohibits it from taking effect until 60 days after the date that it is submitted to Congress.

[42] For a detailed discussion of CRA procedures, see CRS Report RL31160, *Disapproval of Regulations by Congress: Procedure Under the Congressional Review Act*, by Richard S. Beth.

[43] For more on the potential scope of the definition of a "rule" under the CRA, see CRS Report RL30116, *Congressional Review of Agency Rulemaking: An Update and Assessment of The Congressional Review Act after a Decade*, by Morton Rosenberg.

[44] The rule overturned in March 2001 was the Occupational Safety and Health Administration's ergonomics standard. This reversal was the result of a unique set of circumstances in which the incoming President (George W. Bush) did not veto the resolution disapproving the outgoing President's (William J. Clinton's) rule. See CRS Report RL30116, *Congressional Review of Agency Rulemaking: An Update and Assessment of The Congressional Review Act after a Decade*, by Morton Rosenberg, for a description of several possible factors affecting the CRA's use, and for other effects that the act may have on agency rulemaking.

[45] See CRS Report RL34354, *Congressional Influence on Rulemaking and Regulation Through Appropriations Restrictions*, by Curtis W. Copeland.

followed before or after their issuance. The inclusion of regulatory provisions in appropriations legislation as a matter of legislative strategy appears to arise from two factors: (1) Congress's ability via its "power of the purse" to control agency action, and (2) the fact that appropriations bills are considered "must pass" legislation. Congress's use of regulatory appropriations restrictions has fluctuated somewhat over time, and previous experience suggests that they may be somewhat less frequent when Congress and the President are of the same party.[46]

[46] Ibid., p. 35. This report indicated that some appropriations restrictions were repeated every year for 10 years, some were repeated several years in a row but then stopped, and some appeared in only one appropriations bill. Some restrictions appeared to be intended to stop particular rules issued at the end of presidential administrations.

Appendix. Upcoming Proposed and Final Rules Pursuant to the Patient Protection and Affordable Care Act

Department/ Agency	Title of Rule (RIN)	Abstract	Expected Publication Date
Proposed Rules			
HHS/CMS	Payment Adjustment for Health Care-Acquired Conditions (CMS-2400-P) (0938-AQ34)	This rule, under the Affordable Care Act of 2010, would adjust Medicaid payment for services related to health care acquired conditions. [Section 2702]	12/2010 (Note: Final rule required by 07/01/2011.)
TREAS/DO	Review and Approval Process for Waivers for State Innovation (1505-AC30)	This rule implements the procedures for developing, submitting and reviewing a Wavier for State Innovation described in section 1332 of the Patient Protection and the Affordable Care Act.	12/2010
HHS/OCIIO	Affordable Care Act Waiver for State Innovation; Review and Approval Process (0950-AA10)	The Affordable Care Act requires that the Secretary issue regulations regarding the Waiver for State Innovation. This regulation provides a process for public notice and comment at the State level, including public hearings, sufficient to ensure a meaningful level of public input; a process for the submission of an application that ensures the disclosure of the provisions of law that the state involved seeks to waive and the specific plans of the State to ensure that the waiver will be in compliance with subsection (b) of section 1332 of the Affordable Care Act; a process for providing public notice and comment after the application is received by the Secretary, that is sufficient to ensure a meaningful level of public input and that does not impose requirements that are in addition to, or duplicative of, requirements imposed under the Administrative Procedures Act, or requirements that are unreasonable or unnecessarily burdensome with respect to state compliance; a process for the submission to the Secretary of periodic reports by the state concerning the implementation of the program under the waiver; and a process for the periodic evaluation by the Secretary of the program under the waiver.	12/2010

Department/ Agency	Title of Rule (RIN)	Abstract	Expected Publication Date
HHS/CMS	Use of Recovery Audit Contractors (CMS-6034-P) (0938-AQ19)	This proposed rule would provide guidance to States related to Federal/State funding of State start-up, operation and maintenance costs of Medicaid Recovery Audit Contractors (Medicaid RACs), and the payment methodology for State payments to Medicaid RACs in accordance with section 6411 of the Affordable Care Act. In addition, this rule proposes requirements for States to assure that adequate appeals processes are in place for providers to dispute adverse determinations made by Medicaid RACs. Finally, the rule proposes that States and Medicaid RACs coordinate efforts with existing contractors and entities auditing Medicaid providers and with State and Federal law enforcement agencies.	12/2010 (Note: The proposed rule was actually issued 11/10/2010. Final rule was required by 12/31/2010.)
HHS/CMS	Medicare Shared Savings Program: Accountable Care Organizations (CMS-1345-P) (0938-AQ22) **	This rule would propose a shared savings program for provider groups to establish Accountable Care Organizations, agree to meet quality measures, and share in savings generated for Medicare by meeting certain benchmarks. Consistent with section 3022 of the Affordable Care Act of 2010, the shared savings program must be established by January 1, 2012.	01/2011 (Note: The proposed rule was issued 11/17/2010. Final rule required by 01/01/2012.)
HHS/CMS	Federal Funding for Medicaid Eligibility Determination and Enrollment Activities (CMS-2346-P) (0938-AQ53)	The Affordable Care Act requires States' residents to apply, enroll, receive determinations, and participate in the State health subsidy programs known as "the Exchange". The ACA requires many changes to State eligibility and enrollment systems and each State is responsible for developing a secure, electronic interface allowing the exchange of data. Existing legacy eligibility systems are not able to implement the numerous requirements. This proposed rule is key to informing States about the higher rates that CMS will provide to help them update or build legacy eligibility systems that meet the ACA requirements. [Section 1413]	01/07/2011 (Note: Proposed rule was issued 11/08/2010; next step is end of the comment period on 01/07/2011.)
HHS/CMS	Community First Choice (CMS-2337-P) (0938-AQ35)	This rule, under the Affordable Care Act of 2010, establishes an optional Medicaid benefit through which States could offer community-based attendant services and supports to Medicaid beneficiaries with disabilities who would otherwise require the level of care offered in a hospital, nursing facility, or intermediate care facility for the mentally retarded. [Section 2401]	02/2011 (Note: Final rule required by 10/01/2011.)
HHS/CMS	Requirements for Long-Term Care Facilities: Notification of Facility Closure (CMS-3230-IFC) (0938-AQ09) **	This rule would ensure that, in the case of a facility closure, any individual who is the administrator of the facility provides written notification of closure and the plan for the relocation of residents at least 60 days prior to the impending closure, or if the facility's participation in Medicare or Medicaid is terminated, not later than the date the HHS Secretary determines appropriate. [Section 6113]	02/2011 (Note: Final rule required by 03/23/2011.)

Department/ Agency	Title of Rule (RIN)	Abstract	Expected Publication Date
HHS/OCIIO	Requirements To Implement American Health Benefit Exchanges and Other Provisions of the Affordable Care Act (0950-AA02)	The Affordable Care Act requires the establishment of health insurance exchanges –new, competitive, consumer-centered health insurance marketplaces – that will put greater control and greater choice in the hands of individuals and small businesses. The exchanges will make purchasing health insurance easier by providing eligible consumers and businesses with "one-stop-shopping" where they can compare and purchase health insurance coverage. The Affordable Care Act authorized grants to the states to help them design and establish exchanges in time for millions of Americans to choose their coverage for 2014. This proposed rule would establish the requirements for exchanges. [Sections 1301 to 1343, 1401 to 1413]	03/2011
HHS/OCIIO	Transparency Reporting (0950-AA07) **	The Affordable Care Act requires group health plans and health insurance issuers to submit specific information to the Secretary, the State insurance commissioner, and to make the information available to the public. This includes information on claims payment policies, the number of claims denied, data on rating practices and other information as determined by the Secretary. The provision also requires plans and issuers to provide to individuals upon request the amount of cost sharing that the individual would be responsible for paying for a specific item or service provided by a participating provider. This interim final rule would implement information disclosure provisions in section 2715A of the Public Health Service Act, as added by the Affordable Care Act.	03/2011
HHS/FDA	Food Labeling: Nutrition Labeling for Food Sold in Vending Machines (0910-AG56) **	The Food and Drug Administration (FDA) is proposing regulations to establish requirements for nutrition labeling of food sold in vending machines. FDA is also proposing the terms and conditions for registering to voluntarily be subject to the requirements of section 4205. FDA is taking this action to carry out the provisions of section 4205 of the Patient Protection and Affordable Care Act ("Affordable Care Act" or "ACA"), which was signed into law on March 23, 2010.	03/23/2011
HHS/FDA	Food Labeling: Nutrition Labeling of Standard Menu Items in Chain Restaurants (0910-AG57) **	The Food and Drug Administration (FDA) is proposing regulations to establish requirements for nutrition labeling of standard menu items for chain restaurants and similar retail food establishments. FDA is also proposing the terms and conditions for registering to voluntarily be subject to the requirements of section 4205. FDA is taking this action to carry out the provisions of section 4205 of the Patient Protection and Affordable Care Act ("Affordable Care Act" or "ACA"), which was signed into law on March 23, 2010.	03/23/2011

Department/ Agency	Title of Rule (RIN)	Abstract	Expected Publication Date
HHS/OS	Exceptions to the Beneficiary Inducement Prohibition for Certain Arrangements (0991-AB73)	This proposed rule will codify section 6402(d)(2)(B) of the Affordable Care Act of 2010, entitled "Clarification of Treatment of Certain Charitable and Other Innocuous Programs." Section 1128A(a)(5) of the Social Security Act provides for a civil monetary penalty for certain inducements offered to Medicare and Medicaid beneficiaries. Section 6402(d)(2)(B) of the ACA adds four exceptions to the definition of remuneration at section 1128A(i)(6) of the Social Security Act for purposes of section 1128A(a)(5): certain remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs (as defined in section 1128(f) of the Social Security Act and designated by the Secretary under regulations); certain offers or transfers in connection with retail rewards programs; certain unadvertised transfers of items or services to beneficiaries experiencing financial need; and certain waivers by PDP sponsors of Part D plans or MA organizations offering MA-PD plans of copayments otherwise owed by their enrollees for the first fill of a covered Part D drug that is a generic drug.	04/2011
HHS/OS	Revisions to the Office of Inspector General's (OIG) Exclusion Authorities (0991-AB33)	In accordance with section 949 of the Medicare Prescription Drug Improvement and Modernization Act of 2003, and section 6402 of the Affordable care Act 0f 2010, this rule would revise the OIG's exclusion authority to permit any Federal health care program to request a waiver of an OIG exclusion imposed under sections 1128(a)(1), 1128(a)(3), or 1128(a)(4) of the Social Security Act if the exclusion would impose a hardship on beneficiaries. In addition, in accordance with sections 6406 and 6408 of the Affordable Care Act, the proposed rule would revise the OIG's exclusion authority to grant testimonial subpoena authority in exclusion cases; to add a new permissive exclusion authority for making false statements or misrepresentation of materials facts, and; to broaden the scope of certain permissive exclusion authorities. Finally, the proposed rule would revise current exclusion authorities in 42 CFR parts 1001, 1002, and 1005, to further clarify OIG's existing exclusion authorities.	04/2011

Department/ Agency	Title of Rule (RIN)	Abstract	Expected Publication Date
HHS/OS	Safe Harbors to the Anti-Kickback Statute for Certain Arrangements (0991-AB72)	This proposed rule would add safe harbors under the anti-kickback statute addressing arrangements in the following areas (subject to certain conditions): waivers of Federal health care program beneficiary cost-sharing amounts in the context of certain government sponsored clinical trials and in the context of certain emergency medical services furnished by suppliers owned or operated by States or municipalities; certain local transportation provided to Federal health care program beneficiaries; certain waived or reduced cost-sharing amounts under Medicare Part D (codifying in regulations section 101(e) of the Medicare Prescription Drug Improvement and Modernization Act of 2003); and certain discounts in the price of "applicable drugs" of manufacturers furnished to "applicable beneficiaries" under the Medicare Coverage Gap Discount Program (pursuant to section 3301 of the Affordable Care Act of 2010). In addition, this rule would re-propose expanding the existing safe harbor for certain waivers of beneficiary co-insurance and deductible amounts for Part A or Part B services for Medicare SELECT policyholders in accordance with an agreement between the Medicare SELECT issuer and a provider or supplier, in certain contexts.	04/2011
HHS/CMS	Covered Outpatient Drugs (CMS-2345-P) (0938-AQ41)	This proposed rule would implement provisions of the Affordable Care Act of 2010 that revise the rebate for single source and innovator multiple source outpatient prescription drugs. The rule would also revise the definition of average manufacturer price. [Sections 2501 and 2503]	04/2011 (Note: Final rule required by 01/01/2010.)
HHS/CMS	Request for Information on Availability of Medicare Data for Performance Measurement (CMS-0031-P) (0938-AQ17)	Under the Affordable Care Act of 2010, this rule would authorize the release and use of standardized extracts of Medicare claims data to measure the performance of providers and suppliers in ways that protect patient privacy and in accordance with other requirements. [Note: The Unified Agenda lists section 10882 of PPACA as the authority for this measure; no such section exists. See section 10332 instead.]	05/2011 (Note: Final rule required by 01/01/2012.)
HHS/CMS	Home Health Physician Encounter (CMS-2348-P) (0938-AQ36)	This proposed rule would implement a provision under the Affordable Care Act of 2010 that would require a physician to have a face-to-face encounter with an individual prior to issuing a certification for home health services. [Section 6407]	05/2011

Department/ Agency	Title of Rule (RIN)	Abstract	Expected Publication Date
HHS/HRSA	Elimination of Duplication Between the Healthcare Integrity and Protection Data Bank and the National Practitioner Data Bank (0906-AA87)	This rule is required under the Patient Protection and Affordable Care Act of 2010 (P.L. 111-148). The purpose is to eliminate the redundant reporting requirements for two closely related national health care data banks. This rule terminates the Healthcare Integrity and Protection Databank (HIPDB) and transfers all data collected in the HIPDB to the National Practitioner Data Bank (NPDB) established pursuant to the Health Care Quality Improvement Act of 1986. This rule will also provides for the disclosure of information, fee collection, establishment of dispute procedures, and an effective date of no later than one year after enactment or when regulations are published. [Section 6403]	05/2011
HHS/CMS	Omnibus Physician and Supplier Enrollment (CMS-6033-P) (0938-AQ21)	This rule would implement additional provider and supplier enrollment requirements under the Affordable Care Act of 2010. This rule would reduce fraud, waste, and abuse in the Medicare program.	05/2011 (Note: Final rule required by 01/01/2010.)
HHS/CMS	Medicaid Automated Data System Requirements and Data Elements Necessary for Program Integrity, Program Oversight, and Administration (CMS-2317-P) (0938-AQ43)	This proposed rule would implement several provisions of the Affordable Care Act of 2010. It would implement the provision that requires States, for data submitted on or after January 1, 2010, to include data elements from the automated data system that CMS determines to be necessary for program integrity, program oversight, and administration, at such frequency as CMS shall determine. It also would implement the provision that requires for managed care patients that the managed care plans provide data to States at a frequency and level of detail as specified by CMS. In addition, the rule would implement the provision that provides for withholding of Federal Matching Payments to States that fail to report enrollee encounter data in the Medicaid Statistical Information System. [Sections 6402(c), 6504(a), 6504(b)]	06/2011 (Note: Final rule required by 01/01/2010.)
HHS/CMS	5-Year Period Approvals and Renewals for Waivers and Demonstration Projects (CMS-2323-P) (0938-AQ49)	This rule, in response to provisions of the Affordable Care Act of 2010, clarifies that Medicaid waivers for coordinating care for dual eligible beneficiaries could be authorized for as long as five years. Any waiver that provides medical assistance for dual eligible individuals (including any such waivers under which non dual eligible individuals may be enrolled) may be conducted for a period of 5 years and, upon request of the State, may be extended for additional 5-year periods. [Section 2601]	07/2011
HHS/CMS	Medicaid Reconsideration of Disallowance (CMS-2292-P) (0938-AQ32)	This proposed rule would provide policy guidance to States requesting a reconsideration of a disallowance of Medicaid claims under the Medicare Improvements for Patients and Providers Act (MIPPA). Also, this rule would address provisions of the Affordable Care Act concerning the reconsideration process, the change from 60 days to 1-year for overpayments, and changes to the disallowance repayment schedule. [Section 6506]	07/2011 (Note: Final rule required by 03/23/2010.)

Department/ Agency	Title of Rule (RIN)	Abstract	Expected Publication Date
HHS/CMS	Home and Community-Based Services (HCBS) State Plan Services Program (CMS-2249-P2) (0938-AO53)	In 2008, CMS issued a proposed rule that would define and describe State plan home and community-based services (HCBS) plan services implementing new section 1915(i) of the Social Security Act as added by section 6086 of the Deficit Reduction Act of 2005. This section allows States, at their option, to provide home and community-based services (HCBS) under their regular State Medicaid plans. This rule revises that proposed rule to implement provisions of the Affordable Care Act of 2010 that require oversight and assessment of the administration of home and community based services. In addition, this rule would respond to public comments received on the previous proposed rule pertaining to the HCBS benefit under the Medicaid State plan. [Section 2402]	07/2011
DOL/EBSA	Ex Parte Cease and Desist and Summary Seizure Orders Under ERISA Section 521 (1210-AB48)	ERISA section 521, enacted under sec. 6605 of the Affordable Care Act (P.L. 111-148, 124 Stat. 780), authorizes the Secretary of Labor to issue a cease and desist order if it appears that a multiple employer welfare arrangement (MEWA) is fraudulent, creates an immediate danger to public safety or welfare, or can be reasonably expected to cause significant, imminent, and irreparable public injury. This section also authorizes the Secretary to issue a summary seizure order if it appears that a MEWA is in a financially hazardous condition. Regulatory guidance will provide standards for the issuance of such orders.	07/2011
HHS/OS	Nondiscrimination Under the Patient Protection and Affordable Care Act (0991-AB75)	The Department of Health and Human Services Office for Civil Rights will issue rules for covered entities with respect to prohibitions against discrimination on the basis of race, color, national origin, sex, age, and disability, as provided in section 1557 of the Patient Protection and Affordable Care Act (P.L. 111-148).	09/2011
HHS/OCIIO	Public Use Files of Health Plan Data (0950-AA04)	The Affordable Care Act requires generating public use files on data that HHS collects from health plans, and includes specific data and their application (or not) to the Trade Secrets Act. This rule would clarify statutory requirements under the Affordable Care Act.	09/2011
HHS/AOA	Community Living Assistance Services and Supports Enrollment and Eligibility Rules Under the Affordable Care Act (0985-AA07) **	The Department of Health and Human Services will issue rules to implement the Community Living Assistance Services and Supports (CLASS) program included in the Affordable Care Act. Specifically, the rules will define the enrollment and eligibility criteria for the program. Participation in the program is voluntary. [Section 8002]	09/2011 (Note: Final rule expected 10/2012.)

Department/ Agency	Title of Rule (RIN)	Abstract	Expected Publication Date
HHS/CMS	Long-Term Care Facility Quality Assessment and Performance Improvement (CMS-3231-P) (0938-AQ10)	This rule would implement provisions of the Affordable Care Act of 2010 that require long-term care facilities to establish and implement a quality assurance and performance improvement program. [Section 6012]	01/2012
Final Rules			
TREAS/IRS	Indoor Tanning Services (1545-BJ40)	Proposed regulations provide guidance on the indoor tanning services tax made by the Patient Protection and Affordable Care Act of 2010, affecting users and providers of indoor tanning services. [Section 10907]	12/2010 (Note: Proposed rule was issued 06/15/2010)
HHS/CMS	Changes to the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System for CY 2011 (CMS-1504-C) (0938-AP82)	This final rule revises the Medicare hospital outpatient prospective payment system to implement applicable statutory requirements and changes arising from our continuing experience with this system. The rule also describes changes to the amounts and factors used to determine payment rates for services. In addition, the rule changes the Ambulatory Surgical Center Payment System list of services and rates. [Section 1301, 3121(a), 3138, 3401(i), 4103(a), 4104(a), 5503, 5504, 5505, 6001, 10324: these are all cited in the actual rule itself]	12/2010 (Note: Final rule was actually issued on 11/24/2010.)
SSA	Regulations Regarding Income-Related Monthly Adjustment Amounts to Medicare Beneficiaries' Prescription Drug Premiums (3624I) (0960-AH22)	This subpart relates to section 1860D-13(a) of the Social Security Act (the Act), as added by section 3308 of the Patient Protection and Affordable Care Act (P.L. 111-148). Section 3308(a) establishes an income-related monthly adjustment (IRMAA) to the Medicare Part D premium. Beneficiaries enrolled in Medicare Part D who have modified adjusted gross income over a threshold amount established in the statute will pay an IRMAA in addition to the Medicare Part D standard monthly premium and any applicable premium increases as described in 42 CFR 423.286. The regulations in this subpart explain how we decide whether you are required to pay an IRMAA, and if you are, the amount of your adjustment.	12/2010 (Note: Final rule was required by 12/31/2010.)
HHS/OCIIO	Rate Review (0950-AA03) **	The Affordable Care Act requires the Secretary to work with states to establish an annual review of unreasonable rate increases, to monitor premium increases and to award grants to states to carry out their rate review process. This interim final rule would implement the rate review process. [Section 1003]	12/2010 (Note: Interim final rule comment period ended 09/28/2010.)
HHS/OCIIO	Health Care Reform Insurance Web Portal Requirements (0950-AA11)	The Affordable Care Act requires the establishment of an Internet website through which individuals can obtain information about the insurance coverage options that may be available to them in their State. This final rule would further clarify statutory requirements. [Section 1103]	12/2010

Department/ Agency	Title of Rule (RIN)	Abstract	Expected Publication Date
HHS/CMS	Adult Health Quality Services (CMS-2420-NC) (0938-AQ39)	This notice announces a recommended core set of adult health quality measures for Medicaid-eligible adults under the Affordable Care Act of 2010. [Section 2701]	12/2010 (Note: Final rule required by 01/01/2012.)
HHS/CMS	Additional Screening, Application Fees, and Temporary Moratoria for Providers and Suppliers (CMS-6028-F) (0938-AQ20)	This rule would propose a shared savings program for provider groups to establish Accountable Care Organizations, agree to meet quality measures, and share in savings generated for Medicare by meeting certain benchmarks. Consistent with section 3022 of the Affordable Care Act of 2010, the shared savings program must be established by January 1, 2012.	01/2011 (Note: Final rule required by 01/01/2012; proposed rule was issued 09/23/2010.)
HHS/CMS	Children's Health Insurance Program (CHIP); Allotment Methodology and States' Fiscal Year 2009 CHIP Allotments (CMS-2291-F) (0938-AP53)	This final rule describes the implementation of certain funding provisions under the Social Security Act (the Act), the Children's Health Insurance Program (CHIP), as amended by the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA), by the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA), and by other related CHIP legislation. Specifically, this rule addresses methodologies and procedures for determining States' FY2009 through FY2015 allotments and payments in accordance with sections 2104 and 2105 of the Act, as amended by CHIPRA and the Affordable Care Act. [Section 10203]	01/2011 (Note: Proposed rule was issued 09/16/2009.)
HHS/OCIIO	Uniform Explanation of Benefits, Coverage Facts, and Standardized Definitions (0950-AA08) **	The Affordable Care Act requires the Secretary to develop standards for use by group health plans and health insurance issuers in compiling and providing a summary of benefits and coverage explanation that accurately describes benefits and coverage. The Secretary must also set standards for the definitions of terms used in health insurance coverage, including specific terms set out in the statute. Plans and issuers must provide information according to these standards no later than 24 months after enactment. This interim final rule would implement the information disclosure provisions in section 2715 of PHSA, as added by the Affordable Care Act. [Section 1001]	03/2011
HHS/CMS	Civil Money Penalties for Nursing Homes (CMS-2435-F) (0938-AQ02) **	This rule revises and expands current Medicare and Medicaid regulations regarding the imposition of civil money penalties by CMS when nursing homes are not in compliance with Federal participation requirements. [Section 6111]	03/23/2011 (Note: Proposed rule was issued on 07/12/2010.)

Department/ Agency	Title of Rule (RIN)	Abstract	Expected Publication Date
DOL/EBSA	Group Health Plans and Health Insurance Issuers Relating to Dependent Coverage of Children to Age 26 Under the Patient Protection and Affordable Care Act (1210-AB41)	The Patient Protection and Affordable Care Act of 2010 (PPACA) amended title I of ERISA, by adding a new section 715 which encompasses various health reform provisions of the Public Health Service Act (PHS Act). These regulations provide guidance on the extension of dependent coverage for children to age 26 under PHS Act 2714. As mentioned in the previous request, RIN 1210-AB41 was split into additional RINs due to the breadth of issues covered. [Agenda says legal authority for this rule not yet determined; see Section 1001 for the relevant amendments to the Public Health Service Act pertaining to coverage of dependents.]	04/2011 (Note: Interim final rule issued 05/13/2010.)
DOL/EBSA	Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act (1210-AB44)	The Patient Protection and Affordable Care Act of 2010 (the Affordable Care Act) amended title I of ERISA, by adding a new section 715 which encompasses various health reform provisions of the Public Health Service Act. These regulations provide guidance on the rules relating to coverage of preventive services without cost sharing under the Affordable Care Act. As mentioned in previous requests, RIN 1210-AB41 was split into additional RINs due to the breadth of issues covered and this is the fourth request in a series relating to the Affordable Care Act. [Agenda says legal authority for this rule not yet determined; see Section 1001 for the relevant amendments to the Public Health Service Act pertaining to preventive services.]	04/2011 (Note: Interim final rule issued 07/19/2010.)
HHS/CMS	Proposed Changes to the Demonstration Review and Approval Process (CMS-2325-F) (0938-AQ46)	This rule implements provisions of the Affordable Care Act of 2010 and address concerns about transparency in the demonstration review and approval process. This rule establishes requirements for submitting new proposals and the requirements to amend or extend an approved demonstration project. This rule also provides guidance regarding public notice, monitoring, compliance, the evaluation of demonstration projects and the submission of reports to the Secretary for approved demonstrations. [Section 10201]	06/2011 (Note: Final rule required by 09/19/2010; proposed rule was issued 09/17/2010.)
HHS/CMS	Administrative Simplification: Adoption of Authoring Organizations for Operating Rules and Adoption of Operating Rules for Eligibility and Claims Status (CMS-0032-IFC) (0938-AQ12)	This rule implements provisions of the Affordable Care Act of 2010 under Administrative Simplification that require the adoption or authoring organizations for operating rules and the adoption of operating rules for eligibility and claims status, and to consider those operating rules developed by a qualified nonprofit entity that meets specific criteria. [Section 1104]	06/2011 (Note: Final rule required by 07/01/2011.)
HHS/CMS	Administrative Simplification: Standard Unique Identifier for Health Plans (CMS-0040-IFC) (0938-AQ13)	This rule implements provisions of the Affordable Care Act of 2010 under Administrative Simplification that establish a unique health plan identifier. This health plan identifier will be used to identify health plans in HIPAA standard transactions. [Section 1104]	07/2011 (Note: Final rule required by 10/01/2012.)

Department/ Agency	Title of Rule (RIN)	Abstract	Expected Publication Date
DOL/OSHA	Procedures for the Handling of Retaliation Complaints Under Section 1558 of the Affordable Care Act of 2010 (1218-AC55)	OSHA is promulgating procedures for the handling and investigation of retaliation complaints pursuant to section 1558 of the Patient Protection and Affordable Care Act of 2010 (the Affordable Care Act or ACA), which added section 18C to the Fair Labor Standards Act. This section established a new whistleblower protection statute to be administered by OSHA that provides protection from retaliation to employees who engage in protected activities under the ACA. Pursuant to the statute, the procedures will follow those enacted under the Consumer Product Safety Improvement Act, 15 U.S.C. 2087(b), including remedies and legal burdens of proof provisions. Promulgation of a regulation is necessary to govern whistleblower investigations conducted under the new statute.	09/2011
HHS/HRSA	Designation of Medically Underserved Populations and Health Professional Shortage Areas (0906-AA44)	This rulemaking is mandated under the Patient Protection and Affordable Care Act of 2010 (P.L. 111-148). It requires the Secretary to establish a committee to draft an interim final rule for designation of Medically Underserved Populations (MUPs) and Primary Care Health Professions Shortage Areas (HPSAs). A notice of intent to form the negotiated rulemaking committee was published on May 21, 2010 (75 FR 26167) and the Secretary announced committee membership on July 21, 2010. The rulemaking committee consists of technical experts representing stakeholders that will be significantly affected by this rule. A variety of federal and state programs target resources to underserved populations using MUP and HPSA designations. These designations have not been updated in many cases for over 20 years and may not reflect current conditions in many areas. The task of the rulemaking committee is to update the designations, which will likely involve revisions to the current methodologies to reflect changes in the prevailing values of the indicators and availability of data on other indicators of underservice. Prior to passage of the Patient Protection and Affordable Care Act, the Department made several attempts to revise the designations. An initial proposed rule was published on September 1, 1998, but due to the extensive comments received, another notice was published on June 3, 1999 announcing a decision to develop and publish a revised proposed rule for public comment. The second proposed rule was published on February 29, 2008, with the comment period extended twice (first on April 21, 2008, and again on June 2, 2008). Substantial comments were received. A *Federal Register* notice published on July 23, 2008, announcing an Agency decision to carefully review these comments, develop a modified proposal, and publish another proposed rule at a future date. [Section 5602]	11/2011

Department/ Agency	Title of Rule (RIN)	Abstract	Expected Publication Date
HHS/OCIIO	Medical Loss Ratios (0950-AA06)	The Affordable Care Act requires health insurance issuers offering individual or group coverage to submit annual reports to the Secretary on the percentages of premiums that the coverage spends on reimbursement for clinical services and activities that improve health care quality, and to provide rebates to enrollees if this spending does not meet minimum standards for a given plan year. This interim final rule would implement the definition and methodology associated with the calculation of the Medical Loss Ratio (MLR) provisions of the Affordable Care Act and the calculation of the rebate to consumers for plans that do not satisfy the MLR. [Section 1001]	12/2011 (Note: Interim final rule published on 12/01/2010; corrected interim final rule with request for comments published 12/30/2010; final rule required by 12/2011.)

Source: Unified Agenda of Federal Regulatory and Deregulatory Actions, December 20, 2010.

Notes: The table includes only those entries in which the Affordable Care Act was mentioned as the statutory authority. For cases in which the agency did not provide the statutory authority for each rule in its Unified Agenda abstract but the statutory authority was clearly listed or found elsewhere, CRS reported this information in brackets. All information in the table is as reported in the Unified Agenda (e.g., dates of expected proposed or final rules, and dates final rules are required). A double asterisk (**) after the RIN marks those entries that the agencies deemed important enough to also include in the regulatory plan.

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