Upcoming Rules Pursuant to the Patient Protection and Affordable Care Act: Fall 2011 Unified Agenda

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March 20, 2012

Congressional Research Service

www.crs.gov
R42431

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 (ACA, as amended) is a particularly noteworthy example of congressional delegation of rulemaking authority to federal agencies. A previous CRS report identified more than 40 provisions in ACA that explicitly require or permit the issuance of rules to implement the legislation.

One way for Congress to identify upcoming ACA 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 three separate categories:

- "active" actions, including rules in the *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); and *final* rule stage (i.e., final rules or other final actions that are expected to be issued in the next 12 months);
- "completed" actions (i.e., final rules or rules that have been withdrawn since the last edition of the Unified Agenda); and
- "long-term" actions (i.e., items under development that agencies do not expect to take action on in the next 12 months).

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 the action being taken, and a timetable showing the dates of past actions and a projected date for the next regulatory action. Each entry also indicates 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 (Fall 2011), published on January 20, 2012, the third edition since the enactment of ACA. The report identifies upcoming proposed rules that agencies identify as pursuant to ACA, such as an upcoming Centers for Medicare and Medicaid Services (CMS) proposed rule on "Medicaid Eligibility Changes Under the Affordable Care Act." Additionally, this report identifies upcoming final rules listed that are expected to be issued pursuant to ACA, such as a pair of upcoming Food and Drug Administration (FDA) final rules on "Nutrition Labeling for Food Sold in Vending Machines" and "Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments." The **Appendix** lists these upcoming proposed and final rules in a table.

This report also briefly identifies some long-term actions listed in the Unified Agenda, such as the upcoming Health and Human Services/Centers for Medicare and Medicaid Services (HHS/CMS) final rule on "Preventive Services Under the Affordable Care Act." Finally, this report briefly discusses some options for congressional oversight over the ACA rules, including the procedures contained within the Congressional Review Act.

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Introduction

Federal regulations generally result from an act of Congress and are one significant 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 (ACA, as amended) is a particularly noteworthy example of congressional delegation of rulemaking authority to federal agencies.[1] ACA 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 ACA that explicitly require or permit the issuance of rules to implement the legislation.[2]

The rules that agencies issue pursuant to ACA 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 ACA 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 ACA 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] ACA was signed into law on March 23, 2010 (P.L. 111-148, 124 Stat. 119). On March 30, 2010, the President signed the Health Care and Education Reconciliation Act (HCERA; P.L. 111-152,124 Stat. 1029), which amended multiple health care and revenue provisions in ACA. Note that previous CRS reports on the Patient Protection and Affordable Care Act used the acronym PPACA to refer to the law. CRS is now using the more common acronym ACA. For more information on ACA, see CRS Report R41664, *ACA: A Brief Overview of the Law, Implementation, and Legal Challenges* .

[2] CRS Report R41180, *Rulemaking Requirements and Authorities in the Patient Protection and Affordable Care Act (PPACA)* .

[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 ACA contain a legislative enforcement mechanism, so the remaining options for enforcement include political pressure on the agencies or civil litigation, although courts often defer to agencies' judgment on the timing of their issuance of a rule.

in ACA 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 ACA require agencies to establish programs or procedures but do not specifically mention regulations.

According to the Fall 2011 Unified Agenda of Federal Regulatory and Deregulatory Actions (hereafter, Unified Agenda), at least 23 rules have been finalized pursuant to ACA. Although the legislation specifically required or permitted some of the rules to be published, other rules implemented ACA 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.[5]

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."[6] 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 ACA, 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.[7] However, the legislation did not indicate when some of the mandatory rules should be issued. In addition, 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 ACA were not specifically mentioned in the act.

[5] 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."

[6] 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.

[7] CRS Report R41180, *Rulemaking Requirements and Authorities in the Patient Protection and Affordable Care Act (PPACA)* .

The Unified Agenda

A potentially effective way for Congress to identify upcoming ACA rules is by reviewing the Unified Agenda, which is published twice each year (usually in the 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).[8] 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.[9]
- 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."[10] 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 three separate categories:

- "active" actions, including rules in the *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); and *final* rule stage (i.e., final rules or other final actions that are expected to be issued in the next 12 months);
- "completed" actions (i.e., final rules or rules that have been withdrawn since the last edition of the Unified Agenda); and
- "long-term" actions (i.e., items under development that agencies do not expect to take action on in the next 12 months).

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),[11] an abstract

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

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

[10] Executive Order 12866, "Regulatory Planning and Review," 58 *Federal Register* 51735, October 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.

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

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).[12]

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.[13]

This Report

The January 20, 2012, edition of the Unified Agenda is the third edition that RISC has compiled and issued after the enactment of ACA.[14] Federal agencies were required to submit data to RISC for the Unified Agenda by September 9, 2011,[15] but some items may have been subsequently updated during the OIRA review process.[16]

This report examines the January 20, 2012, edition of the Unified Agenda and identifies upcoming proposed and final rules and long-term actions that were expected to be issued pursuant to ACA in the next 12 months. 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, as well as the "long-term actions" category.

[12] 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 similar to the definition of "economically significant," since both definitions are triggered if a rule has, among other things, a $100 million effect on the economy.

[13] CRS Report R40713, *The Unified Agenda: Implications for Rulemaking Transparency and Participation* .

[14] ACA was enacted on March 23, 2010. The first edition of the Unified Agenda following enactment of ACA was issued on December 20, 2010. For the first similar CRS report listing the rules pursuant to ACA that were listed as upcoming in that edition of the Unified Agenda, see CRS Report R41586, *Upcoming Rules Pursuant to the Patient Protection and Affordable Care Act: Fall 2010 Unified Agenda* . For the rules that were listed as upcoming in the July 7, 2011, edition of the Unified Agenda, see CRS Report R41963, *Upcoming Rules Pursuant to the Patient Protection and Affordable Care Act: Spring 2011 Unified Agenda* .

[15] Memorandum from Cass R. Sunstein, Administrator of the Office of Information and Regulatory Affairs, "Memorandum for Regulatory Policy Officers at Executive Departments and Agencies and Managing and Executive Directors of Certain Agencies and Commissions," June 30, 2011.

[16] A previous e-mail from John C. Thomas, RISC Executive Director, August 3, 2011, to CRS indicated that Unified Agenda items are sometimes updated during the OIRA review process.

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.[17] The abstracts presented in the table were taken verbatim from the Unified Agenda entries. Within the proposed and final rule sections of the table, the entries are organized by agency.

Because agencies were compiling the information prior to September 9, 2011, their estimates for when upcoming proposed and final rules would be issued may have been out of date by the time the Unified Agenda was published. To provide the most up-to-date information, on March 20, 2012, CRS electronically searched the *Federal Register* to see whether the proposed and final rules listed in the Unified Agenda had been published. This information is provided in the table. If the proposed or final rule was published as of March 20, 2012, the *Federal Register* citation is also provided.

It should be emphasized that the proposed and final rules and long-term actions identified in the Unified Agenda and summarized in this report do not represent all the ACA-related rulemaking activity within HHS and other federal agencies. In particular, ACA made numerous changes to existing Medicare payment systems, either permanently or on a temporary basis, and required coverage of new Medicare benefits. In most cases CMS has opted to address these changes in its annual rulemaking updates for the various Medicare payment systems. For example, the annual final rules updating Medicare payment policies and rates for physician services and for hospital inpatient services both include multiple sets of provisions to incorporate and implement ACA mandates. These rules, and similar annual updates, are not discussed in this report.

Upcoming ACA Proposed Rules

The January 20, 2012, edition of the Unified Agenda listed 26 ACA-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).[18] Fourteen of the 26 upcoming proposed rules were expected to be issued by components of the Department of Health and Human Services (HHS): the Health Resources and Services Administration (HRSA, one action); Indian Health Service (IHS, three actions); Office of the Inspector General (OIG, one action); and Centers for Medicare and Medicaid Services (CMS, nine actions). Other proposed rules were expected to be issued by the Department of Labor's (DOL's) Employee Benefits Security Administration (EBSA, two actions) and Office of Workers' Compensation Programs (OWCP, one action); the Treasury Department's Internal Revenue Service (IRS, three actions); the Architectural and Transportation Barriers Compliance Board (ATBCB, one action); and the Office of Personnel Management (OPM, five actions).

[17] In addition to the RINs, CMS included an agency-specific number as part of the title of the rule (e.g., CMS-2249-P2). Those numbers are included as part of the title in the table in the **Appendix**.

[18] The number of actions listed in the Unified Agenda and reported here may not necessarily be precisely equivalent to the number of upcoming proposed rules. For example, in a case in which two agencies are working on a joint rule, it is possible that they would each report it separately to the Unified Agenda, and such a rule would appear as two actions.

Timing of the Proposed Rules

The agencies indicated that 9 of the 26 items in the "proposed rule" section of the Unified Agenda would be issued by the end of February 2012.[19] As of March 20, 2012, five of these nine anticipated notices of proposed rulemaking (NPRMs) had been published, and four had not yet been published. The rules for which NPRMs have been published are

- an HHS/CMS rule on "Covered Outpatient Drugs";[20]
- an HHS/CMS rule on "Reporting and Returning of Overpayments";[21]
- a DOL/EBSA rule on "Ex Parte Cease and Desist and Summary Seizure Orders Under ERISA Section 521";[22]
- a DOL/EBSA rule on "Filings Required of Multiple Employer Welfare Arrangements and Certain Other Entities That Offer or Provide Coverage for Medical Care to the Employees of Two or More Employers";[23] and
- an ATBCB rule on "Accessibility Standards for Medical Diagnostics Equipment."[24]

The four proposed rules that were expected to be published by the end of February 2012, but that had not been published as of March 20, 2012, include

- an HHS/CMS rule on "Home and Community-Based State Plan Services Program and Provider Payment Reassignments";
- an HHS/CMS rule on "Payments for Primary Care Services Under the Medicaid Program";
- a TREAS/IRS rule on "Branded Prescription Drug Fee"; and
- a TREAS/IRS rule on "Special Rules Under the Additional Medicare Tax."

Several other proposed rules were expected to be issued later in 2012, including

- an HHS/IHS rule on "Standards for the Planning, Design, Construction and Operation of Health Care and Sanitation Facilities" (expected to be published in July 2012);

[19] For a complete list of all the upcoming proposed rules listed in the Unified Agenda, their expected publication dates, and information on when and if they were published, see the **Appendix** of this report.

[20] U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, "Covered Outpatient Drugs," 77 *Federal Register* 5318, February 2, 2012.

[21] U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, "Reporting and Returning of Overpayments," 77 *Federal Register* 9179, February 16, 2012.

[22] U.S. Department of Labor, Employee Benefits Security Administration, "Ex Parte Cease and Desist and Summary Seizure Orders—Multiple Employer Welfare Arrangements," 76 *Federal Register* 76235, December 6, 2011.

[23] U.S. Department of Labor, Employee Benefits Security Administration, "Filings Required of Multiple Employer Welfare Arrangements and Certain Other Related Entities," 76 *Federal Register* 76222, December 6, 2011.

[24] The Architectural and Transportation Barriers Compliance Board, "Medical Diagnostics Equipment Accessibility Standards," 77 *Federal Register* 6916, February 9, 2012.

- an HHS/CMS rule on "Administrative Simplification: Standard Unique Identifier for Health Plans" (expected to be published in March 2012);
- a TREAS/IRS rule on "Fees on Health Insurance and Self-Insured Plans" (expected to be published in June 2012); and
- an OPM rule on "Federal Employees Health Benefits Program; Disputed Claims and External Review Requirements" (expected to be published in October 2012).

Notable Proposed Rules

HHS agencies considered one of the items in the "proposed rule" section of the Unified Agenda important enough to be included in its regulatory plan. The rule was an ATBCB rule on "Accessibility Standards for Medical Diagnostics Equipment."[25]

Economically Significant or Major Proposed Rules

In addition to the ACA-related proposed rule that was listed in the regulatory plan, the Unified Agenda listed six other actions 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). All six rules were from HHS/CMS. Examples include

- a rule on "Home and Community-Based State Plan Services Program and Provider Payment Reassignments," which was expected to be published as an NPRM sometime during February 2012, but had not been published as of March 20, 2012;
- a rule on "Covered Outpatient Drugs," which the agency published as an NPRM on February 2, 2012;[26]
- a rule on "Payments for Primary Care Services Under the Medicaid Program," which was expected to be published as an NPRM sometime during January 2012, but had not been published as of March 20, 2012; and
- a rule on "Medicaid Eligibility Changes Under the Affordable Care Act—Part II," which is expected to be issued sometime during April 2012.

"Other Significant" Proposed Rules

In addition to the above-mentioned rules, the agencies characterized 12 of the 26 actions that were listed in the "proposed rule" section of the Unified Agenda as "other significant," indicating that although they were not listed in the regulatory plan or expected to be "economically

[25] The Architectural and Transportation Barriers Compliance Board, "Medical Diagnostics Equipment Accessibility Standards," 77 *Federal Register* 6916, February 9, 2012.

[26] U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, "Covered Outpatient Drugs," 77 *Federal Register* 5318, February 2, 2012.

significant," they were expected to be significant enough to be reviewed by OIRA under Executive Order 12866.[27] These proposed rules include

- an HHS/HRSA rule on "Elimination of Duplication Between the Healthcare Integrity and Protection Data Bank and the National Practitioner Data Bank," which the agency published on February 15, 2012;[28]
- an HHS/HIS rule on "Confidentiality of Medical Quality Assurance Records; Qualified Immunity for Participants," which the agency expects to publish sometime during July 2012;
- an HHS/CMS rule on "Administrative Simplification: Standard Unique Identifier for Health Plans," which the agency expects to issue in March 2012; and
- a DOL/OWCP rule on "Regulations Implementing Amendments to the Black Lung Benefits Act: Determining Coal Miners and Survivors Entitlement to Benefits," which the agency expects to issue in March 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).[29] Three of the previously mentioned ACA-related rules listed in the "proposed rule" section were expected to affect small businesses, small governments, or both, and were expected to require a regulatory flexibility analysis:

- an HHS/CMS rule on "Covered Outpatient Drugs";[30]
- a DOL/EBSA rule on "Filings Required of Multiple Employer Welfare Arrangements and Certain Other Entities That Offer or Provide Coverage for Medical Care to the Employees of Two or More Employers";[31] and
- a TREAS/IRS rule on "Special Rules Under the Additional Medicare Tax."

In addition to these rules, in 12 other actions listed in the "proposed rule" the agencies were undecided as to whether they trigger a regulatory flexibility analysis. These actions include

- an HHS/CMS rule on "Establishment of Exchange Program Part II; Appeals of Eligibility Determinations and Oversight and Financial Integrity";

[27] 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* .

[28] U.S. Department of Health and Human Services, Health Resources and Services Administration, "National Practitioner Data Bank," 77 *Federal Register* 9138, February 2, 2012.

[29] For more information, see CRS Report RL32240, *The Federal Rulemaking Process: An Overview* .

[30] U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, "Covered Outpatient Drugs," 77 *Federal Register* 5318, February 2, 2012.

[31] U.S. Department of Labor, Employee Benefits Security Administration, "Filings Required of Multiple Employer Welfare Arrangements and Certain Other Related Entities," 76 *Federal Register* 76222, December 6, 2011.

- an HHS/CMS rule on "Disproportionate Share Hospital Payment Reduction"; and
- a TREAS/IRS rule on "Fees on Health Insurance and Self-Insured Plans."

Upcoming ACA Final Rules

The January 20, 2012, edition of the Unified Agenda listed 25 ACA-related actions in the "final rule stage" section (indicating that the agencies expected to issue final rules on the subjects within the next 12 months).[32] Fifteen of the 25 upcoming final actions were expected to be issued by components of Health and Human Services (HHS): the Health Resources and Services Administration (HRSA, one action); the Food and Drug Administration (FDA, two actions); and the Centers for Medicare and Medicaid Services (CMS, 12 actions). Eight of the upcoming final rules were expected to be issued by two components of the Treasury Department, the Departmental Offices (DO, one action) and the Internal Revenue Service (IRS, seven actions). Other final rules were expected to be issued by the Department of Labor's (DOL's) Occupational Safety and Health Administration (OSHA, one action) and the Social Security Administration (SSA, one action).

Timing of Final Rules

The agencies indicated that 10 of the 25 items in the "final rule" section of the Unified Agenda would be issued by the end of February 2012. As of March 20, 2012, four of these had been issued:

- an HHS/CMS rule on "Administrative Simplification: Adoption of Standards for Electronic Funds Transfer," which was published as an interim final rule on January 10, 2012;[33]
- an HHS/CMS rule on "Review and Approval Process for Section 1115 Demonstrations," which was published as a final rule on February 27, 2012;[34]
- an HHS/CMS rule on "Medicare Shared Savings Program; Final Waivers," which was published as an interim final rule on November 2, 2011;[35] and

[32] The number of "actions" listed in the Unified Agenda and reported here is not exactly the same as the number of upcoming final rules. For example, there are two final rules listed in the **Appendix** as joint rules, but because the actions in the Unified Agenda are listed by agency, the joint rules are listed once in the Unified Agenda by each participating agency. Therefore, the 25 upcoming final actions reported here actually represent 23 final rules. The joint rules are listed at the end of the **Appendix.**

[33] U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, "Administrative Simplification: Adoption of Standards for Health Care Electronic Funds Transfers," 77 *Federal Register* 1556, January 10, 2012.

[34] U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, "Medicaid Program; Review and Approval Process for Section 1115 Demonstrations," 76 *Federal Register* 32186, June 6, 2011.

[35] U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, "Final Waivers in Connection with the Shared Savings Program," 76 *Federal Register* 67992, November 2, 2011.

- an HHS/CMS joint rule with TREAS/DO on "Affordable Care Act Waiver for State Innovation; Review and Approval Process," which was published as a final rule on February 27, 2012.[36]

As of March 20, 2012, six remaining upcoming final items that the agencies indicated would be published by the end of February 2012 had not been published. Examples include

- an HHS/CMS rule on "Community First Choice Option";
- an HHS/CMS rule on "Medicaid Eligibility Expansion Under the Affordable Care Act of 2010";
- an HHS/CMS rule on "State Requirements for Exchange—Reinsurance and Risk Adjustments"; and
- an HHS/CMS joint rule with TREAS/IRS on "Uniform Disclosure to Consumers: Benefit Design, Cost Sharing, & Standards for Definitions."

The agencies indicated that 15 other actions would be issued sometime in the next 12 months. Examples include

- two HHS/FDA rules on "Food Labeling: Nutrition Labeling for Food Sold in Vending Machines" and "Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments," both of which are expected to be published in November 2012;
- an HHS/CMS rule on "Face-to-Face Requirements for Home Health Services; Policy Changes and Clarifications Related to Home Health," which is expected to be published in September 2012;
- a DOL/OSHA rule on "Procedures for the Handling of Retaliation Complaints Under The Affordable Care Act; The Consumer Financial Protection Act; The Seaman's Protection Act; and the FDA Food Safety Modernization Act," which is expected to be published in July 2012; and
- an SSA rule on "Regulations Regarding Income-Related Monthly Adjustment Amounts to Medicare Beneficiaries' Prescription Drug Premiums," which is expected to be published in June 2012.

Notable Final Rules

Five of the items that were listed in the "final rule" section of the Unified Agenda were considered important enough to be included in the agencies' regulatory plans:

- two HHS/FDA rules on "Food Labeling: Nutrition Labeling for Food Sold in Vending Machines" and "Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments";

[36] This interim final rule was a joint rule. U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, and U.S. Department of the Treasury, Departmental Offices, "Application, Review, and Reporting Process for Waivers for State Innovation," 77 *Federal Register* 11700, February 27, 2012.

- an HHS/CMS rule on "Medicaid Eligibility Expansion Under the Affordable Care Act of 2010";
- an HHS/CMS rule on "Establishment of Exchanges and Qualified Health Plans Part I"; and
- an HHS/CMS rule on "State Requirements for Exchange—Reinsurance and Risk Adjustments."

Economically Significant or Major Final Rules

The Unified Agenda listed eight entries in the "final rule" section that were considered "economically significant" and "major" (i.e., that were expected to have at least a $100 million annual effect on the economy). Examples include

- two HHS/FDA rules on "Food Labeling: Nutrition Labeling for Food Sold in Vending Machines" and "Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments";
- an HHS/CMS rule on "Administrative Simplification: Adoption of Standards for Electronic Funds Transfer";
- an HHS/CMS rule on "Community First Choice Option"; and
- an HHS/CMS rule on "Face-to-Face Requirements for Home Health Services; Policy Changes and Clarifications Related to Home Health."

"Other Significant" Final Rules

In addition to the above-mentioned rules, 10 other entries in the "final rule" section of the Unified Agenda were characterized as "other significant," 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. These include

- an HHS/HRSA rule on "340B Orphan Drug Exclusion";
- an HHS/CMS rule on "Affordable Care Act Waiver for State Innovation; Review and Approval Process";
- an HHS/CMS rule on "Student Health Insurance Coverage"; and
- a DOL/OSHA rule on "Procedures for the Handling of Retaliation Complaints Under The Affordable Care Act; The Consumer Financial Protection Act; The Seaman's Protection Act; and the FDA Food Safety Modernization Act."

Effects on Small Entities

Three of the upcoming final rules were expected to trigger the requirements of the Regulatory Flexibility Act because of their effects on small businesses:

- two HHS/FDA rules on "Food Labeling: Nutrition Labeling for Food Sold in Vending Machines" and "Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments"; and

- a TREAS/IRS rule on "Indoor Tanning Services; Cosmetic Services Excise Taxes."

The two FDA rules were also expected to have an effect on small governmental jurisdictions, another potential trigger for the regulatory flexibility analysis requirement.

In seven other upcoming final rules, the agencies indicated that they had yet to determine whether a regulatory flexibility analysis would be triggered. All seven rules were from CMS. Examples include

- a rule on "Medicaid Eligibility Expansion Under the Affordable Care Act of 2010";
- a rule on "Administrative Simplification: Adoption of Operating Rules for Electronic Funds Transfer (EFT) and Remittance Advice (RA)";
- a rule on "State Requirements for Exchange—Reinsurance and Risk Adjustments"; and
- a rule on "Medicare Shared Savings Program; Final Waivers."

ACA 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 which the agencies do not expect to take action on in the next 12 months). The January 20, 2012, edition of the Unified Agenda listed 14 long-term actions related to ACA. In comparison to the proposed and final rules previously discussed, it is much less clear when the ACA-related long-term actions are expected to occur. In 11 of the 14 cases, the agencies said that the dates for the actions were "to be determined." Of the three remaining long-term actions, two are expected in December 2012, and one is expected in May 2013.

Nature of the Long-Term Actions

Of the 14 long-term actions, seven 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.[37] These actions include

- an HHS/CMS rule on "Preventive Services Under the Affordable Care Act," with the final rule expected to be published at a later date to be determined";[38] and

[37] Interim final rules are a particular application of the "good cause" exception to notice-and-comment rulemaking (5 U.S.C. §553). Under certain circumstances when an agency believes it has "good cause" to avoid notice and comment, the agency may choose to invoke this exception. In interim final rulemaking, 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.

[38] Earlier associated interim final rules were published on July 19, 2010 (75 *Federal Register* 41726), and August 3, 2011 (76 *Federal Register* 46621).

- a DOL/EBSA rule on "Group Health Plans and Health Insurance Issuers Relating to Dependent Coverage of Children to Age 26 Under the Patient Protection and Affordable Care Act," with the date of the next action to be determined.[39]

Other ACA-related long-term actions include

- an HHS/HRSA interim final rule on "Designation of Medically Underserved Populations and Health Professional Shortage Areas"; and
- a DOL/EBSA undetermined rulemaking action on "Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions and Patient Protections Under the Affordable Care Act."

Notable Long-Term Actions

The agencies identified two of the ACA-related long-term actions as "economically significant" and "major":

- 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"; and
- a DOL/EBSA action entitled "Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act."

The agencies considered 11 of the 14 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 include

- an HHS/HRSA rule on "Designation of Medically Underserved Populations and Health Professional Shortage Areas"; and
- an HHS/OCR (Office for Civil Rights) rule on "Nondiscrimination Under the Affordable Care Act."

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 ACA, 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.

[39] The associated interim final rule was published on May 13, 2010 (75 *Federal Register* 27121).

Congress has a range of tools available to oversee the rules that federal agencies are expected to issue to implement ACA, 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.[40] 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."[41] 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.[42] 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.[43] 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.[44] 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 of only one rule in the 16 years since it was enacted.[45] 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

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

[41] 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).

[42] 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.

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

[44] 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 (out of print; available upon request from CRS).

[45] 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* (out of print; available upon request from CRS), for a description of several possible factors affecting the CRA's use, and for other effects that the act may have on agency rulemaking.

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.[46] Appropriations provisions can also be used to prompt agencies to issue certain regulations, or to require that certain procedures be 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 such use may be somewhat less frequent when Congress and the President are of the same party.[47]

[46] See CRS Report RL34354, *Congressional Influence on Rulemaking and Regulation Through Appropriations Restrictions* .

[47] 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, as Provided in the Unified Agenda	Expected Publication Date
Proposed Rules			
HHS (Health and Human Services)/HRSA (Health Resources and Services Administration)	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 Affordable Care Act. 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 provide 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.	06/2012 Note: NPRM was published on 02/15/2012 (77 F.R. 9138). Although the Agenda indicates that there is a statutory deadline for publishing this proposed rule, it does not specify what the deadline is.
HHS/IHS (Indian Health Service)	Standards for the Planning, Design, Construction and Operation of Health Care and Sanitation Facilities (0917-AA08)	Section 311(c)(1) of the Indian Health Care Improvement Act, P.L. 94-437 (1976), as amended by the Patient Protection and Affordable Care Act, P.L. 111-148, section 10221 (2010) requires the Secretary, acting though the Indian Health Service (IHS), to establish, by regulation, standards for the planning, design, construction, and operation of health care and sanitation facilities serving Indians under the Indian Health Care Improvement Act. Additionally, these regulations would stipulate which departmental regulations would be applicable to these activities.	07/2012
HHS/IHS	Confidentiality of Medical Quality Assurance Records; Qualified Immunity for Participants (0917-AA09)	Section 805(j) of the Indian Health Care Improvement Act, P.L. 94-437 (1976), as amended by the Patient Protection and Affordable Care Act, P.L. 111-148, section 10221 (2010) requires the Secretary of the Department of Health and Human Services, acting through the Indian Health Service (IHS), to promulgate regulations to implement section 805. Section 805 makes confidential and privileged the medical quality assurance records of Indian health programs and urban Indian organizations, with very limited exceptions. It also prohibits the testimony of individuals that review or create medical quality assurance records, with very limited exceptions. Although section 805 is immediately executable, the Secretary is required to issue regulations which could substantively affect the implementation of this provision.	07/2012

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Unified Agenda	Expected Publication Date
HHS/IHS	Catastrophic Health Emergency Fund (CHEF) (0917-AA10)	Section 202(d) of the Indian Health Care Improvement Act (IHCIA), P.L. 94-437 (1976), as amended by the Patient Protection and Affordable Care Act, P.L. 111-148, section 10221 (2010) requires the Secretary of the Department of Health and Human Services, acting through the Indian Health Service (IHS), to promulgate regulations to implement section 202. Section 202 of the IHCIA amends the IHS Catastrophic Health Emergency Fund (CHEF) to revise the threshold cost for reimbursement of the cost of treatment using contract health services funds to an IHS or Tribally managed facility. The law also describes an annual increase in the threshold that is based on the increase in the medical care expenditure category of the consumer price index for all consumers for the 12 month period ending with December of the previous year.	08/2012
HHS/OIG (Office of the Inspector General)	Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Office of Inspector General's Safe Harbors Under the Antikickback Status, Exclusion Authorities, and Civil Monetary Penalty (0936-AA02)	This rule would: 1) Safe Harbor Provisions: 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 [ACA]). 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. 2) OIG's Authority To Impose Civil Money Penalties and Assessments (610 Review): Revise 42 CFR part 1003, addressing the Office of Inspector General's authority to propose the imposition of civil money penalties and assessments by reorganizing and simplifying existing regulatory text and eliminating obsolete references contained in the current regulations. Among the proposed revisions, this rule would establish separate subparts within part 1003 for various categories of violations; clarify the availability of exclusion for certain violations in addition to civil money penalties and assessments; date various references to managed care organization authorities; and clarify the application of section 1140 of the Social Security Act with respect to the misuse of certain Departmental symbols, emblems, or names through Internet and e mail communications. 3) OIG's Exclusion Authority: 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. 4) Exceptions to the Beneficiary Inducement Prohibition for Certain Arrangements 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	05/2012 Note: Legal deadline for NPRM was 11/2011. No NPRM had been published as of 03/20/2012.

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Unified Agenda	Expected Publication Date
		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.	
HHS/CMS (Centers for Medicare & Medicaid Services)	Home and Community-Based State Plan Services Program and Provider Payment Reassignments (CMS-2249-P2) (0938-AO53)	This proposed rule would amend the Medicaid regulations to define and describe State plan home and community-based services (HCBS) plan services under the Affordable Care Act. This proposed rule offers States new flexibilities in providing necessary and appropriate services to elderly and disabled populations and reflects CMS' commitment to the general principles of the President's Executive Order released January 18, 2011, entitled "Improving Regulation and Regulatory Review." In particular, this rule does not include the existing cumbersome eligibility link between HCBS and institutional care that exists under the Medicaid 1915(c) HCBS waiver program. This regulation would describe Medicaid coverage of a new optional State plan benefit to furnish home and community based State plan services and draw Federal matching funds. As a result, States will be better able to design and tailor Medicaid services to accommodate individual needs. This may result in improved patient outcomes and satisfaction, while enabling States to effectively manage their Medicaid resources.	02/2012 Note: First NPRM was published on 04/04/2008. (73 F.R. 18676). A second NPRM is expected by 02/2012. Legal deadline for final rule was 01/01/2007. A second NPRM had not been published as of 03/20/2012.
HHS/CMS	Administrative Simplification: Standard Unique Identifier for Health Plans (CMS-0040-P) (0938-AQ13)	This rule would implement 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.	03/2012 Note: Legal deadline for final rule is 10/01/2012. No NPRM had been published as of 03/20/2012.
HHS/CMS	Covered Outpatient Drugs (CMS-2345-P) (0938-AQ41)	This proposed rule would revise requirements pertaining to Medicaid reimbursement for covered outpatient drugs to implement provisions of the Affordable Care Act. This proposed rule would also revise other requirements related to covered outpatient drugs, including key aspects of Medicaid coverage, payment, and the drug rebate program.	01/2012 Note: NPRM was published on 02/02/2012 (77 F.R. 5318). Legal deadline for final rule was 01/2010.

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Unified Agenda	Expected Publication Date
HHS/CMS	Reporting and Returning of Overpayments (CMS-6037-P) (0938-AQ58)	This proposed rule would implement section 6402(d) of the Affordable Care Act, which requires the Secretary establish a process for a provider or supplier to return an overpayment to the program, as well as establish a process for CMS and its contractors to receive and apply the overpayment.	01/2012 Note: NPRM was published on 02/16/2012 (77 F.R. 9179).
HHS/CMS	Payments for Primary Care Services Under the Medicaid Program (CMS-2370-P) (0938-AQ63)	This proposed rule would implement section 1202 of the Affordable Care Act that requires payment by State Medicaid agencies of at least the Medicare rates in effect in calendar years (CYs) 2013 and 2014 for primary care services delivered by a physician with a specialty designation of family medicine, general internal medicine, or pediatric medicine. This rule would implement the statutory payment provisions uniformly across all States. Specifically, this proposed rule would define, for purposes of enhanced Federal match, eligible primary care providers and identify eligible primary care services, as well as specify how the enhanced payment should be calculated. This proposed rule would also provide general guidelines for implementing the enhanced payment for managed care services.	01/2012 Note: Legal deadline for final rule is 01/2013. No NPRM had been published as of 03/20/2012.
HHS/CMS	Administrative Simplification: Compliance: Health Plan Certification (CMS-0037-P) (0938-AQ85)	This rule proposes to implement provisions of the Affordable Care Act of 2010 under Administrative Simplification to certify that data and information systems are in compliance with any applicable standards and associated operating rules for electronic funds transfers, eligibility for a health plan, health claim status, and health care payment and remittance advice.	06/2012 Note: First phase of compliance deadline is 12/31/2013; second phase of compliance to occur by 12/31/2015.
HHS/CMS	Establishment of Exchange Program Part II; Appeals of Eligibility Determinations and Oversight and Financial Integrity (CMS-9980-P) (0938-AR03)	This proposed rule would implement section 1311 of the Affordable Care Act. This will be the second rule establishing the Qualified Health Plans and Health Benefit Exchanges as defined in the Affordable Care Act. This rule focuses on requirements for Qualified Health Plans and is more implementation-focused on elements such as the Essential Health Benefits and oversight of the Exchanges.	04/2012 Note: Notice was published 09/14/2011 (76 F.R. 56767). Legal deadline for final rule is 01/01/2014.
HHS/CMS	Medicaid Eligibility Changes Under the Affordable Care Act—Part II (CMS-2334-P) (0938-AR04)	This proposed rule would implement provisions of the Affordable Care Act of 2010. The Affordable Care Act expands access to health insurance through improvements in Medicaid, the establishment of Affordable Insurance Exchanges (Exchanges), and coordination between Medicaid, the Children's Health Insurance Program (CHIP), and Exchanges. This proposed rule would set forth sections of the Affordable Care Act related to appeals, notices, and other Medicaid eligibility changes under the Affordable Care Act and options established by other Federal statutes.	04/2012 Note: Legal deadline for final rule is 01/01/2014.

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Unified Agenda	Expected Publication Date
HHS/CMS	Disproportionate Share Hospital Payment Reduction (CMS-2367-P) (0938-AR31)	The Affordable Care Act amends the Social Security Act by requiring aggregate reductions to state Medicaid DSH allotments from FY 2014 through FY 2020. The annual reduction amounts are specified in statute and must be implemented using a DSH Health Reform methodology determined by the Secretary. This proposed rule will delineate the DSH Health Reform methodology required to implement the reductions.	07/2012 Note: The Affordable Care Act requires aggregate reductions to state Medicaid DSH allotments beginning in FY 2014 (10/01/2013).
DOL (Department of Labor)/EBSA (Employee Benefits Security Administration)	Ex Parte Cease and Desist and Summary Seizure Orders Under ERISA Section 521 (1210-AB48)	ERISA section 521, enacted under section 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.	12/06/2011 Note: NPRM published on 12/06/2011 (76 F.R. 76235).
DOL/EBSA	Filings Required of Multiple Employer Welfare Arrangements and Certain Other Entities That Offer or Provide Coverage for Medical Care to the Employees of Two or More Employers (1210-AB51)	This is a proposed rule under title I of the Employee Retirement Income Security Act (ERISA) that, upon adoption, would implement reporting requirements for multiple employer welfare arrangements (MEWAs) and certain other entities that offer or provide health benefits for employees of two or more employers. The proposal amends existing reporting rules to incorporate new requirements enacted as part of the Patient Protection and Affordable Care Act (Affordable Care Act) and to more clearly address the reporting obligations of MEWAs that are ERISA plans.	12/06/2011 Note: NPRM published on 12/06/2011 (76 F.R. 76222).
DOL/OWCP (Office of Workers' Compensation Programs)	Regulations Implementing Amendments to the Black Lung Benefits Act: Determining Coal Miners and Survivors Entitlement to Benefits (1240-AA04)	The Patient Protection and Affordable Care Act (PPACA) of 2010 amended the Black Lung Benefits Act, 30 U.S.C. 901 to 944, to reinstate two methods of establishing entitlement that were repealed with respect to claims filed after 1981. Specifically, the PPACA reinstated 30 U.S.C. 921(c)(4)(presumption of total disability or death due to pneumoconiosis arising out of coal mine employment where the miner had 15 years of coal mine employment and proof of total disability) and 30 U.S.C. 932(l) (automatic entitlement to benefits for eligible survivors of miners who were awarded benefits based on lifetime claims). The newly amended statutory provisions apply to claims filed after January 1, 2005, that are pending on or after PPACA's March 23, 2010, enactment date, and to all claims filed on or after March 23, 2010. The Department anticipates proposing rules that define the class of claims affected by the amendments and set the criteria for establishing entitlement to benefits under the amendments.	03/2012 Note: No NPRM had been published as of 03/20/2012.

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Unified Agenda	Expected Publication Date
TREAS (Department of the Treasury)/IRS (Internal Revenue Service)	Branded Prescription Drug Fee (1545-BJ39)	Implementation of section 9008 applies to imposition of annual fee on branded prescription pharmaceutical manufacturers and importers, of the Patient Protection and Affordable Care Act of 2010, P.L. 111-148.	12/2011 Note: Notice of original temporary regulations was published on 08/18/2011 (76 F.R. 51310). No subsequent rules were published as of 03/20/2012.
TREAS/IRS	Special Rules Under the Additional Medicare Tax (1545-BK54)	Proposed amendments of sections 31.3101, 31.3102, 31.3111, 31.3121, 1.1401, 31.6205, 31.6011, 31.6205, 31.6402, and 31.6413 of the Employment Tax Regulations provide guidance for employers and employees relating to the implementation of the Additional Medicare Tax, as enacted by the Affordable Care Act, and correction procedures for errors related to the Additional Medicare Tax.	12/2011 Note: No NPRM had been published as of 03/20/2012.
TREAS/IRS	Fees on Health Insurance and Self-Insured Plans (1545-BK59)	The proposed regulations provide guidance under sections 4375 to 4377 of the Internal Revenue Code, as added by section 6301 of the Patient Protection and Affordable Care Act, on fees imposed on health insurance and self-insured health plans.	06/2012
ATBCB (Architectural and Transportation Barriers Compliance Board)	Accessibility Standards for Medical Diagnostic Equipment (3014-AA40)	This regulation will establish minimum technical criteria to ensure that medical equipment used for diagnostic purposes by health professionals in (or in conjunction with) physician's offices, clinics, emergency rooms, hospitals, and other medical settings is accessible to and usable by individuals with disabilities.	02/2012 Note: NPRM was published on 02/09/2012 (77 F.R. 6916). A notice of intent to establish an advisory committee was published on 03/13/2012 (77 F.R. 14706). Legal deadline for final rule is 03/22/2012.
OPM (Office of Personnel Management)	Federal Employees Group Life Insurance Program; Tribes and Tribal Organizations (3206-AM41)	The U.S. Office of Personnel Management (OPM) proposes to amend the Federal Employees Group Life Insurance regulations at 5 CFR chapter 87 to include enrollments for eligible employees of tribes and tribal organizations under the provisions of the Affordable Care Act of 2010.	03/2012 Note: No NPRM had been published as of 03/20/2012.

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Unified Agenda	Expected Publication Date
OPM	Federal Employees Health Benefits Program; Tribes and Tribal Organizations (3206-AM40)	The U.S. Office of Personnel Management (OPM) proposes to amend the Federal Employees Health Benefits (FEHB) regulations at 5 CFR chapter 89 to include enrollments for eligible employees of tribes and tribal organizations under the provisions of the Affordable Care Act of 2010.	03/2012 Note: No NPRM had been published as of 03/20/2012.
OPM	Federal Employees Health Benefits Program; Disputed Claims and External Review Requirements (3206-AM42)	The U.S. Office of Personnel Management (OPM) proposes to amend the Federal Employees Health Benefits (FEHB) regulations at 5 CFR chapter 89 to include changes to resolution of disputed health claims and to provide for external review under the provisions of the Affordable Care Act of 2010.	10/2012
OPM	Federal Employees Health Benefits Program: Miscellaneous Changes Proposed by the Affordable Care Act (3206-AM46)	The U.S. Office of Personnel Management (OPM) is issuing proposed rulemaking amending the Federal Employees Health Benefits (FEHB) regulations at 5 CFR chapter 89 to include changes under the provisions of the Affordable Care Act of 2010.	10/2012
OPM	Multi-State Exchanges; Implementations for Affordable Care Act Provisions (3206-AM47)	The U.S. Office of Personnel Management (OPM) is proposing to implement regulations for the provisions of the Affordable Care Act of 2010, in order for OPM to contract with at least two multi-state plans for the Affordable Insurance Exchanges to be offered in 2014.	03/2012 Note: No NPRM had been published as of 03/20/2012.
Final Rules			
HHS/HRSA	340B Orphan Drug Exclusion (0906-AA94)	Under the changes made by section 2302 Health Care and Education Reconciliation Act (P.L. 111-152), orphan drugs, when used for the rare condition or disease for which that orphan drug was designated under section 526 of the Federal Food, Drug, and Cosmetic Act (FFDCA), are excluded from the definition of covered outpatient drug for the specified newly-eligible covered entity types for purposes of the 340B Program. This regulatory action details how these exclusions will be implemented under the 340B Program. The purpose of issuing this proposed rule is to clarify HHS's stated effort in: (1) Providing clarity in the marketplace, (2) maintaining the 340B savings and interests to the newly-eligible covered entities; and (3) protecting the financial incentives for manufacturing orphan drugs designated for a rare disease or condition as indicated in the Affordable Care Act as intended by Congress.	05/2012 Note: NPRM was published on 05/20/2011 (76 F.R. 29183).

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Unified Agenda	Expected Publication Date
HHS/FDA (Food and Drug Administration)	Food Labeling: Nutrition Labeling for Food Sold in Vending Machines (0910-AG56)	The Food and Drug Administration (FDA) published a proposed rule in the Federal Register of April 6, 2011 (72 FR 19238) to establish requirements for nutrition labeling of certain food items sold in certain vending machines. FDA also proposed the terms and conditions for vending machine operators registering to voluntarily be subject to the requirements. FDA took this action to carry out section 4205 of the Patient Protection and Affordable Care Act ("Affordable Care Act" or "ACA"), which was signed into law on March 23, 2010.	11/2012 Note: NPRM was published on 04/06/2011 (76 F.R. 19238).
HHS/FDA	Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments (0910-AG57)	The Food and Drug Administration (FDA) published a proposed rule in the Federal Register of April 6, 2011 (72 FR 19192), to establish requirements for nutrition labeling of standard menu items in chain restaurants and similar retail food establishments. FDA also proposed the terms and conditions for restaurants and similar retail food establishments registering to voluntarily be subject to the Federal requirements. FDA took this action to carry out section 4205 of the Patient Protection and Affordable Care Act ("Affordable Care Act" or "ACA"), which was signed into law on March 23, 2010.	11/2012 Note: NPRM was published on 04/06/2011 (76 F.R. 19192).
HHS/CMS	Administrative Simplification: Adoption of Standards for Electronic Funds Transfer (EFT) (CMS-0024-IFC) (0938-AQ11)	This rule implements provisions of the Affordable Care Act of 2010 under Administrative Simplification that require the adoption of standards for Electronic Funds Transfers (EFT).	01/01/2012 Note: Interim final rule was published on 01/10/2012 (77 F.R. 1556). Legal deadline for the final rule was 01/01/2012.
HHS/CMS	Community First Choice Option (CMS-2337-F) (0938-AQ35)	This rule implements section 2401 of the Affordable Care Act (ACA) which establishes a new State option to provide home and community-based attendant services and supports. These services and supports may be offered through the Community First Choice State plan option.	02/2012 Note: NPRM was published on 02/25/2011 (76 F.R. 10736). Legal deadline for the final rule was 10/01/2011. No final rule had been published as of 03/20/2012.
HHS/CMS	Face-to-Face Requirements for Home Health Services; Policy Changes and Clarifications	This rule revises the Medicaid home health service definition as required by section 6407 of the Affordable Care Act of 2010 to add a requirement that physicians document the existence of a face-to-face encounter (including through the use of telehealth) with the Medicaid eligible individual within reasonable timeframes. This aligns the timeframes with similar regulatory requirements for Medicare home health services in accordance with section 6407 of the Affordable Care Act and reflects CMS' commitment to the general principles of the President's Executive Order 13563 released January 18, 2011, entitled "Improving Regulation	09/2012 Note: NPRM was published on 07/12/2011 (76 F.R. 41032). Legal deadline for the final

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Unified Agenda	Expected Publication Date
	Related to Home Health (CMS-2348-F) (0938-AQ36)	and Regulatory Review." In addition, this rule amends home health services regulations at section 440.70 to clarify the definitions of included medical supplies, equipment and appliances, and clarify that States may not limit home health services to services delivered in the home, or to services furnished to individuals who are homebound.	rule was 01/01/2010.
HHS/CMS	Review and Approval Process for Section 1115 Demonstrations (CMS-2325-F) (0938-AQ46)	This final rule will implement provisions of the Affordable Care Act of 2010 that set forth transparency and public notice procedures for experimental, pilot, and demonstration projects approved under section 1115 of the Social Security Act relating to Medicaid and the Children's Health Insurance Program (CHIP). This rule will increase the degree to which information about Medicaid and CHIP demonstration applications and approved demonstration projects is publicly available and promote greater transparency in the review and approval of demonstrations. It will also codify existing statutory requirements pertaining to seeking advice from Indian health care providers and urban Indian organizations for section 1115 demonstration projects, and for the first time impose as regulatory requirements tribal consultation standards that were previously only published as guidance documents.	01/2012 Note: Final rule was published on 02/27/2012 (77 F.R. 11678). NPRM was published on 09/17/2010 (75 F.R. 56946). Legal deadline for the proposed rule was 09/19/2010.
HHS/CMS	Medicaid Eligibility Expansion Under the Affordable Care Act of 2010 (CMS-2349-F) (0938-AQ62)	This rule implements provisions of the Affordable Care Act expanding access to health insurance through improvements in Medicaid, the establishment of American Health Benefit Exchanges ("Exchanges"), and coordination between Medicaid, the Children's Health Insurance Program (CHIP), and Exchanges. This rule also implements sections of the Affordable Care Act related to Medicaid eligibility, enrollment simplification, and coordination.	02/2012 Note: NPRM was published on 08/17/2011 (76 F.R. 51148). Legal deadline for final rule is 01/01/2014. No final rule had been published as of 03/20/2012.
HHS/CMS	Establishment of Exchanges and Qualified Health Plans Part I (CMS-9989-F) (0938-AQ67)	This rule implements the new Affordable Insurance Exchanges ("Exchanges"), consistent with title I of the Affordable Care Act of 2010, referred to collectively as the Affordable Care Act. The Exchanges will provide competitive marketplaces for individuals and small employers to directly compare available private health insurance options on the basis of price, quality, and other factors. The Exchanges, which will become operational by January 1, 2014, will help enhance competition in the health insurance market, improve choice of affordable health insurance, and give small businesses the same purchasing clout as large businesses.	02/2012 Note: NPRM was published on 07/15/2011 (76 F.R. 41866). Legal deadline for final rule is 01/01/2014. No final rule had been published as of 03/20/2012.

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Unified Agenda	Expected Publication Date
HHS/CMS	Student Health Insurance Coverage (CMS-9981-F) (0950–AA20)	This rule establishes student health insurance coverage under the Public Health Service Act and the Affordable Care Act. The rule defines "student health insurance coverage" as a type of individual health insurance coverage, and exempts such coverage from certain requirements otherwise applicable to individual health insurance coverage.	01/2012 Note: Unified Agenda appears to have reported the RIN incorrectly for this rule (the corrected RIN is reported here). NPRM was published on 02/11/201 (76 F.R. 7767). No final rule had been published as of 03/20/2012.
HHS/CMS	Administrative Simplification: Adoption of Operating Rules for Electronic Funds Transfer (EFT) and Remittance Advice (RA) (CMS-0028-IFC) (0938-AR01)	This rule implements provisions of the Affordable Care Act of 2010 under Administrative Simplification that require the adoption of operating rules for Electronic Funds Transfer (EFT) and Remittance Advice, and to consideration of those operating rules developed by a qualified nonprofit entity that meets specific criteria.	06/2012 Note: This rule is to be an interim final rule. Legal deadline for the final rule is 07/01/2012.
HHS/CMS	State Requirements for Exchange—Reinsurance and Risk Adjustments (CMS-9975-F) (0938-AR07)	This rule implements requirements for States related to reinsurance, risk corridors, and a permanent risk adjustment. The goals of these programs are to minimize negative impacts of adverse selection inside the Exchanges.	01/2012 Note: NPRM was published on 7/15/2011 (76 F.R. 41930). No final rule had been published as of 03/20/2012.
HHS/CMS	Medicare Shared Savings Program; Final Waivers (CMS-1439-IFC) (0938-AR30)	This interim final rule establishes waivers of the application of the Physician Self-Referral Law, the Federal anti-kickback statute, and certain civil monetary penalties (CMP) law provisions to specified financial arrangements involving accountable care organizations (ACOs) under the Medicare Shared Savings Program. The Affordable Care Act authorizes the Secretary to waive certain fraud and abuse laws as necessary to carry out the provisions of section 1899 of the Act (the Medicare Shared Savings Program).	01/01/2012 Note: Interim final rule was published on 11/02/2011 (76 F.R. 67992). Legal deadline for final rule was 01/01/2012.

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Unified Agenda	Expected Publication Date
DOL/OSHA (Occupational Safety and Health Administration)	Procedures for the Handling of Retaliation Complaints Under The Affordable Care Act; The Consumer Financial Protection Act; The Seaman's Protection Act; and the FDA Food Safety Modernization Act (1218-AC58)	OSHA is promulgating procedures for the handling and investigation of retaliation complaints pursuant to new whistleblower protection provisions of four statutes: (1) 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 (FLSA); (2) the Consumer Financial Protection Act (CFPA), section 1057 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (DFA); (3) the Seaman's Protection Act, 46 U.S.C. section 2114 (SPA); and (4) section 402 of the FDA Food Safety Modernization Act (FSMA). Promulgation of these regulations is necessary to govern whistleblower investigations conducted under the new statutes. Section 18C of the FLSA 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) and will include the same remedies, legal burdens of proof and other rights. CFPA, section 1057 of the DFA, provides protection from retaliation to employees in the consumer financial product and service industries who report alleged violations of Title X of the DFA or any other provision of law that is subject to the jurisdiction of the Bureau of Consumer Financial Protection, an independent bureau within the Federal Reserve System. Pursuant to the statute, the procedures will include remedies and legal burdens of proof provisions, and a "kick-out" provision allowing the complainant to file a complaint in District Court within 90 days after receiving a written determination from OSHA, or if the Secretary has not issued a final determination within 210 days after the filing of the complaint. SPA, as amended by section 611 of the Coast Guard Authorization Act of 2010, transfers to OSHA the administration of the whistleblower protections previously enforced solely via a private right of action. It provides protection from retaliation to seamen who engage in protected activities under SPA. Pursuant to the statute, the procedures will follow those enacted under the Surface Transportation Assistance Act, 49 U.S.C. 31105, including procedures, requirements, and rights. Section 402 of FSMA provides protection from retaliation to employees of entities engaged in manufacturing, processing, packing, transporting, distribution, reception, holding, or importation of food who engage in protected activities under FSMA. Pursuant to the statute, the procedures will include remedies and legal burdens of proof provisions, and a "kick-out" provision allowing the complainant to file a complaint in District Court within 90 days after receiving a written determination from OSHA, or if the Secretary has not issued a final determination within 210 days after the filing of the complaint.	07/2012 Note: This rule is to be an interim final rule.
TREAS/IRS	Indoor Tanning Services; Cosmetic Services Excise Taxes (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.	06/2012 Note: NPRM was published on 06/15/2010 (75 F.R. 33740).
TREAS/IRS	Group Health Plans and Health Insurance Issuers Providing Dependent Coverage of	These proposed regulations provide guidance on the requirements for group health plans and health insurance issuers to provide coverage of dependent children up to age 26 under section 2714 of the Public Health Service Act, incorporated into section 9815 of the Internal Revenue Code by section 1563(f) of the Patient Protection and Affordable Care Act, P.L. 111-148.	06/2012 Note: NPRM was published on 05/13/2010 (75 F.R. 27141).

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Unified Agenda	Expected Publication Date
	Children to Age 26 Under the Patient Protection and Affordable Care Act (1545-BJ45)		
TREAS/IRS	Group Health Plans and Health Insurance Coverage Rules Relating to Status as a Grandfathered Health Plan Under the Patient Protection and Affordable Care Act (1545-BJ50)	These proposed regulations provide guidance on the grandfathered health plan rules of section 1251 of the Patient Protection and Affordable Care Act.	06/2012 Note: NPRM was published on 06/17/2010 (75 F.R. 34571).
TREAS/IRS	Requirements for Group Health Plans and Health Insurance Issuers Under the PPACA Relating to Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, and Patient Protections (1545-BJ57)	These regulations provide guidance on the requirements for group health plans and health insurance issuers under sections 2704 (prohibition against preexisting condition exclusions), 2711 (regarding lifetime and annual dollar limits on benefits), 2712 (regarding restrictions on rescissions), and 2719A (regarding patient protections) of the Public Health Service Act, incorporated into section 9815 of the Internal Revenue Code by section 1563(f) of the Patient Protection and Affordable Care Act, P.L. 111-148.	06/2012 Note: NPRM was published on 06/28/2010 (75 F.R. 37242).

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Unified Agenda	Expected Publication Date
TREAS/IRS	Requirements for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act (1545-BJ58)	These proposed regulations provide guidance requiring coverage of certain preventive health services without cost-sharing under section 2713 of the Public Health Service Act, incorporated into section 9815 of the Internal Revenue Code by section 1563(f) of the Patient Protection and Affordable Care Act, P.L. 111-148.	06/2012 Note: Original NPRM was published on 07/19/2010 (75 F.R. 41787). A second NPRM was published on 03/03/2011 (76 F.R. 46677) and the comment period extended to 10/03/11.
TREAS/IRS	Requirements 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 (1545-BJ62)	These proposed regulations provide guidance appeals under section 2719 of the Public Health Service Act, incorporated into section 9815 of the Internal Revenue Service Code by section 1563(f) of the Patient Protection and Affordable Care Act, P.L. 111-148.	06/2012 Note: NPRM was published on 07/23/2010 (75 F.R. 43109).
SSA	Regulations Regarding Income-Related Monthly Adjustment Amounts to Medicare Beneficiaries' Prescription Drug Premiums (3624F) (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 (Pub. 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.	06/2012 Note: Original interim final rule published 12/07/2010 (75 F.R. 75884). Legal deadline for final rule was 12/30/2010.
HHS/CMS and TREAS/IRS, jointly	Uniform Disclosure to Consumers: Benefit Design, Cost Sharing, &	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	01/2012 Note: NPRM was published on

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Unified Agenda	Expected Publication Date
	Standards for Definitions (CMS-9982-F) (0938-AQ73), (1545-BJ94)	provide information according to these standards no later than 24 months after enactment. This rule implements the information disclosure provisions in section 2715 of the Public Health Service Act, as added by the Affordable Care Act.	08/22/2011 (76 F.R. 52442). Legal deadline for final rule was 03/23/2011. TREAS/IRS estimated that the final rule would be published in 06/2012.
HHS/CMS and TREAS/DO (Departmental Offices), jointly	Affordable Care Act Waiver for State Innovation; Review and Approval Process (CMS-9987-F) (0938-AQ75), (1505-AC30)	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.	01/2012 Note: NPRM was published on 03/14/2011 (76 F.R. 13553). Final rule was published on 02/27/2012 (77 F.R. 11700). Legal deadline for final rule is 01/01/2017.

Source: Information in the first three columns is verbatim as reported in the Unified Agenda of Federal Regulatory and Deregulatory Actions, January 20, available at http://www.reginfo.gov/public/do/eAgendaMain. Information in the fourth column is from the Unified Agenda and the *Federal Register.*

Note: The table includes only those Unified Agenda entries in which the Affordable Care Act was mentioned.

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