



Upcoming Rules Pursuant to the Patient Protection and Affordable Care Act: Spring 2013 Unified Agenda

Maeve P. Carey

Analyst in Government Organization and Management

Michelle D. Christensen

Analyst in Government Organization and Management

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Summary

The Patient Protection and Affordable Care Act (ACA, as amended) was signed into law by President Barack Obama on March 23, 2010. As is often the case with legislation, the ACA granted rulemaking authority to federal agencies to implement many of its provisions. The regulations issued pursuant to the ACA and other statutes carry the force and effect of law. Therefore, scholars and practitioners have long noted the importance of rulemaking to the policy process, as well as the importance of congressional oversight of rulemaking. For example, one scholar noted that the “Constitution’s grant of legislative power to Congress encompasses a responsibility to ensure that delegated authority is exercised according to appropriate procedures.” 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.

Having a sense of what rules agencies are going to issue and when they are going to issue those rules can help Congress to provide oversight over the regulations that are issued pursuant to the ACA. One way in which Congress can identify upcoming ACA rules is by reviewing the Unified Agenda of Federal Regulatory and Deregulatory Actions (hereinafter, Unified Agenda), which is published by the Regulatory Information Service Center (RISC), a component of the U.S. General Services Administration (GSA), for the Office of Management and Budget’s (OMB’s) 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 usually have uniform data elements, which typically include the department and agency issuing the rule, the title of the rule, the 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).

The Spring 2013 Unified Agenda, which was published on July 3, 2013, was the fifth edition of the Unified Agenda following enactment of ACA. In this edition, agencies reported 20 proposed rules and 23 final rules that they expect to issue pursuant to ACA within the next 12 months. Agencies also reported a total of 13 long-term regulatory actions.

The **Appendix** of this report lists the upcoming proposed and final rules published in the Spring 2013 Unified Agenda in a table.

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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 The ACA is a comprehensive reform 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 the ACA that explicitly require or permit the issuance of rules to implement the law.²

The rules that agencies issue pursuant to the ACA are expected to have a major impact on how the law 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 the 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.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 the 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 The 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 the ACA. Several other subsequently enacted bills made more targeted changes to specific ACA provisions. All references to the ACA in this report refer to the law as amended. For more information on the ACA, see CRS Report R41664, *ACA: A Brief Overview of the Law, Implementation, and Legal Challenges*, coordinated by C. Stephen Redhead.

² CRS Report R41180, *Rulemaking Requirements and Authorities in the Patient Protection and Affordable Care Act (PPACA)*, by Curtis W. Copeland. The author of that report has retired from CRS; questions about its content can be directed to the authors of this report.

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 the ACA contain a legislative enforcement mechanism. One potential option for enforcement is civil litigation, although courts often defer to agencies’ judgment on the timing of their issuance of a rule. For more information on agency delay of the issuance of regulations, see CRS Report R43013, *Administrative Agencies and Claims of Unreasonable Delay: Analysis of Court Treatment*, by Daniel T. Shedd.

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

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.”⁵ 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.

Having a sense of what rules agencies are going to issue and when they are going to issue those rules can help Congress to provide oversight over the regulations that are issued pursuant to the ACA. The previously referenced CRS report identifying the provisions in the act that require or permit rulemaking can be useful in this regard.⁶ However, the law does not indicate when some of the mandatory rules should be issued.

The Unified Agenda

A potentially effective way for Congress to identify upcoming ACA rules is by reviewing the Unified Agenda, which is usually published twice each year (in the spring and fall).⁷ The Unified Agenda is published by the Regulatory Information Service Center (RISC), a component of the U.S. General Services Administration (GSA), for the Office of Management and Budget’s (OMB’s) 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*, in April and October of each year, describing regulatory actions that they are developing that may have a significant economic impact on a substantial number of small entities.⁹

⁵ 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.

⁶ CRS Report R41180, *Rulemaking Requirements and Authorities in the Patient Protection and Affordable Care Act (PPACA)*, by Curtis W. Copeland. The author of that report has retired from CRS; questions about its content can be directed to the authors of this report.

⁷ To comply with the requirements of the Regulatory Flexibility Act (5 U.S.C. §602) and Executive Order 12866, the Unified Agenda is usually published twice annually—in the spring and fall. The 2012 Unified Agenda, however, was published as a single edition on December 21, 2012. The fall 2011 edition was published in January 2012.

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)).

- 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 usually have uniform data elements, which typically include the department and agency issuing the rule, the title of the rule, the Regulation Identifier Number (RIN),¹¹ an abstract 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

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 and Federal Reserve Board), this section of the order does include those 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 easier 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.

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.

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, arguably, it provides federal agencies with the most systematic, government-wide method to alert the public about their upcoming proposed rules.¹³

Scope and Methodology of This Report

The Spring 2013 edition of the Unified Agenda, which was published on July 3, 2013, is the fifth edition that RISC has compiled and issued after the enactment of the ACA.¹⁴ Federal agencies were required to submit data to RISC for the Unified Agenda by April 24, 2013, but some items may have been subsequently updated during the OIRA review process.¹⁵

This report examines the Spring 2013 edition of the Unified Agenda and identifies proposed and final rules and long-term regulatory actions that were expected to be issued pursuant to the ACA in the 12 months following its publication. 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.

In this edition, agencies reported 20 proposed rules and 23 final rules that they expect to issue pursuant to the ACA within the 12 months following the Agenda’s publication. Agencies also reported a total of 13 long-term regulatory actions and 17 completed actions.

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 is expected to be issued or was issued.¹⁶ 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.¹⁷

¹³ 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. CRS Report R40713, *The Unified Agenda: Implications for Rulemaking Transparency and Participation*, by Curtis W. Copeland. The author of that report has retired from CRS; questions about its content can be directed to the authors of this report.

¹⁴ The ACA was enacted on March 23, 2010. The first edition of the Unified Agenda following enactment of the ACA was issued on December 20, 2010.

¹⁵ Memorandum from Dominic Mancini, Deputy 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,” March 28, 2013, at <http://www.whitehouse.gov/sites/default/files/omb/inforeg/for-agencies/spring-2013-agenda-data-call.pdf>. 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.

¹⁶ In addition to the RINs, CMS included an agency-specific number as part of the title of the rule (e.g., CMS-2327-F). Those numbers are included as part of the title in the table in the **Appendix**.

¹⁷ It should be emphasized that the proposed and final rules and long-term actions identified in the Unified Agenda and summarized in this report may not represent all the ACA-related rulemaking activity within HHS and other federal (continued...)

Upcoming ACA Proposed Rules

The July 3, 2013, edition of the Unified Agenda listed 20 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 Eleven of the 20 upcoming proposed rules were expected to be issued by components of the Department of Health and Human Services (HHS): CMS (nine actions); Health Resources and Services Administration (HRSA, one action); and the Office of Civil Rights (OCR, one action). The nine remaining proposed rules were expected to be issued by the Treasury Department’s Internal Revenue Service (TREAS/IRS, five actions) and the Office of Personnel Management (OPM, four actions).

Notable Proposed Rules

Rules agencies intend to issue pursuant to the ACA may be considered notable for a variety of reasons—for example, they may be considered notable if they are listed in the agency’s “regulatory plan,” which is described below, or if they meet a particular statutory or executive order definition. Some examples of notable rules are listed below.

Rules Included in the Regulatory Plan

As stated earlier, Executive Order 12866 requires that each agency prepare, as part of the fall edition of the Unified Agenda, a regulatory plan of the most important regulatory actions that the agency reasonably expects to issue in proposed or final form during the upcoming fiscal year. The Department of Health and Human Services considered one of the items in the proposed rule section of the Unified Agenda important enough to be included in its regulatory plan: an HHS/CMS rule that would establish a “Prospective Payment System for Federally Qualified Health Centers.” The rule was considered both “economically significant” and “major.”¹⁹

“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 five other actions that the agencies considered “economically significant” or “major” (one definition of “economically significant” or “major,” for example, is that the rule is

(...continued)

agencies. In particular, the 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, the Centers for Medicare & Medicaid Services (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, may not be discussed in this report if they were not included by agencies in the Unified Agenda.

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.

¹⁹ “Economically significant” and “major” proposed rules are discussed in the following section.

expected to have at least a \$100 million annual effect on the economy).²⁰ All five of the rules were expected to be issued by HHS/CMS. The “economically significant” or “major” proposed rules were

- an HHS/CMS rule on “Administrative Simplification: Compliance with Health Plan Certification,” which the agency expected to publish in September 2013 but had not yet published as of December 2, 2013;
- an HHS/CMS rule on “Disproportionate Share Hospital Payment Reduction,” which the agency published on May 15, 2013;²¹
- an HHS/CMS rule on “Changes to the End-Stage Renal Disease Prospective Payment System,” which the agency published on July 8, 2013;²²
- an HHS/CMS rule on “Notice of Benefit and Payment Parameters,” which the agency published on December 2, 2013;²³ and
- an HHS/CMS rule on “Establishment of the Basic Health Program,” which the agency published on September 25, 2013.²⁴

Other Significant Proposed Rules

In addition to the above-mentioned rules, the agencies characterized 4 of the 20 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 significant,” they were expected to be significant enough to be reviewed by OIRA under Executive Order 12866.²⁵ The “other significant” proposed rules were

- an HHS/CMS rule on “Requirements for Long-Term Care Facilities,” which the agency expects to publish in December 2013;

²⁰ For definitions and a more complete discussion of “economically significant” and “major” rules, see CRS Report R43056, *Counting Regulations: An Overview of Rulemaking, Types of Federal Regulations, and Pages in the Federal Register*, by Maeve P. Carey.

²¹ U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, “Medicaid Program; State Disproportionate Share Hospital Allotment Reductions,” 78 *Federal Register* 28551, May 15, 2013.

²² U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, “End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies,” 78 *Federal Register* 40836, July 8, 2013.

²³ Department of Health and Human Services, Centers for Medicare & Medicaid Services, “Notice of Benefit and Payment Parameters for 2015,” 78 *Federal Register* 72321, December 2, 2013.

²⁴ Department of Health and Human Services, Centers for Medicare & Medicaid Services, “Basic Health Program: State Administration of Basic Health Programs; Eligibility and Enrollment in Standard Health Plans; Essential Health Benefits in Standard Health Plans; Performance Standards for Basic Health Programs; Premium and Cost Sharing for Basic Health Programs; Federal Funding Process; Trust Fund and Financial Integrity,” 78 *Federal Register* 59122, September 25, 2013.

²⁵ 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*, coordinated by Maeve P. Carey.

- an HHS/CMS rule on “Exchanges: Additional Program Implementation,” which the agency published on June 19, 2013;²⁶
- an HHS/CMS rule on “Appeals Process for Medicare Part C and Part D Recovery Audit Contractor Determinations,” which the agency expects to publish in February 2014; and
- an HHS/OCR rule on “Nondiscrimination Under the Patient Protection and Affordable Care Act,” which the agency expects to publish sometime in December 2013.

Effects on Small Entities

The Regulatory Flexibility Act (RFA, 5 U.S.C. §601 *et seq.*) 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).²⁷ Two of the ACA-related rules listed in the proposed rule section triggered or were expected to trigger the requirements of the Regulatory Flexibility Act because of their effects on small entities:

- a proposed TREAS/IRS rule published on September 9, 2013, on “Reporting and Notice Requirements Under Section 6056” triggered the requirements of the RFA (5 U.S.C. §602) because of its effects on small businesses and small governments;²⁸ and
- a proposed HHS/CMS rule published on September 23, 2013, that would establish a “Prospective Payment System for Federally Qualified Health Centers (FQHCs)” is expected to trigger the requirements of the RFA because of its effect on small governments and small not-for-profit organizations.²⁹

In eight other upcoming proposed rules, the agencies indicated in the Agenda that they had yet to determine whether a regulatory flexibility analysis would be triggered. These rules were

- an HHS/CMS rule on “Administrative Simplification: Compliance with Health Plan Certification,” which the agency expected to publish in September 2013 but had not yet published as of December 2, 2013;
- an HHS/CMS rule on “Changes to the End-Stage Renal Disease Prospective Payment System,” which the agency published on July 8, 2013;³⁰

²⁶ U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, “Patient Protection and Affordable Care Act; Program Integrity: Exchange, SHOP, Premium Stabilization Programs, and Market Standards,” 78 *Federal Register* 37032, June 19, 2013.

²⁷ For more information, see CRS Report RL32240, *The Federal Rulemaking Process: An Overview*, coordinated by Maeve P. Carey.

²⁸ U.S. Department of the Treasury, Internal Revenue Service, “Information Reporting by Applicable Large Employers on Health Insurance Covered Offered Under Employer-Sponsored Plans,” 78 *Federal Register* 54996, September 9, 2013.

²⁹ U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, “Medicare Program; Prospective Payment System for Federally Qualified Health Centers; Changes to Contracting Policies for Rural Health Clinics; and Changes to Clinical Laboratory Improvement Amendments of 1988 Enforcement Actions for Proficiency Testing Referral,” 78 *Federal Register* 58386, September 23, 2013.

³⁰ U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, “End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, (continued...) ”

- an HHS/CMS rule on “Requirements for Long-Term Care Facilities,” which the agency expects to publish in December 2013;
- an HHS/CMS rule on “Exchanges: Additional Program Implementation,” which the agency published on June 19, 2013;³¹
- an HHS/CMS rule on “Notice of Benefit and Payment Parameters,” which the agency published on December 2, 2013;³²
- an HHS/OCR rule on “Nondiscrimination Under the Patient Protection and Affordable Care Act,” which the agency expects to publish sometime in December 2013;
- a TREAS/IRS rule on “Medical Loss Ratio for Section 833 Organizations,” which the agency published on May 13, 2013;³³ and
- a TREAS/IRS rule on “Tax Credit for Employee Health Insurance Expenses of Small Employer,” which the agency published on August 26, 2013.³⁴

Upcoming ACA Final Rules

The July 3, 2013, edition of the Unified Agenda listed 25 ACA-related actions in the proposed rule section (indicating that the agencies expected to issue these final rules within the next 12 months).³⁵ Thirteen of the 25 upcoming final actions are expected to be issued by components of HHS: the Food and Drug Administration (FDA, two actions); HRSA (two actions); CMS (eight actions); and the Office of the Secretary (OS, one action). Four of the 25 upcoming final rules are expected to be issued by TREAS/IRS. Five of the upcoming final rules are expected to be issued by the DOL: the Employee Benefits Security Administration (EBSA, three actions); Occupational Safety and Health Administration (OSHA, one action); and the Office of Workers’ Compensation Programs (OWCP, one action). Other final rules are expected to be issued by the Architectural and Transportation Barriers Compliance Board (ATBCB, one action); OPM (one action); and the Social Security Administration (SSA, one action).

(...continued)

Orthotics, and Supplies,” 78 *Federal Register* 40836, July 8, 2013.

³¹ U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, “Patient Protection and Affordable Care Act; Program Integrity: Exchange, SHOP, Premium Stabilization Programs, and Market Standards,” 78 *Federal Register* 37032, June 19, 2013.

³² Department of Health and Human Services, Centers for Medicare & Medicaid Services, “Notice of Benefit and Payment Parameters for 2015,” 78 *Federal Register* 72321, December 2, 2013.

³³ U.S. Department of the Treasury, Internal Revenue Service, “Computation of, and Rules Relating to, Medical Loss Ratio,” 78 *Federal Register* 27873, May 13, 2013.

³⁴ U.S. Department of the Treasury, Internal Revenue Service, “Tax Credit for Employee Health Insurance Expenses of Small Employers,” 78 *Federal Register* 52719, August 26, 2013.

³⁵ The number of actions listed in the Unified Agenda and the number of upcoming proposed rules reported here is not equivalent. For cases in which an agency is developing a rule to be issued jointly with another agency, each agency submits a separate entry to the Unified Agenda, which leads to duplicate search results. CRS attempted to eliminate these duplicate search results, and the number of final rules provided here is the number of rules expected, not the number of entries in the Unified Agenda. The joint rules are listed at the end of the **Appendix**.

Notable Final Rules

As mentioned above, rules may be notable for a variety of reasons; several examples of notable upcoming final rules are listed in the section below.

Rules Included in the Regulatory Plan

Three of the ACA regulations that were listed in the final rule section of the Unified Agenda were considered important enough to be included in the agencies' regulatory plans:³⁶

- an ATBCB rule on "Accessibility Standards for Medical Diagnostic Equipment," which the agency expects to issue as a final rule in March 2014;
- an HHS/FDA rule on "Food Labeling: Nutrition Labeling for Food Sold in Vending Machines," which the agency expected to issue as a final rule in September 2013 but had not been published as of December 2, 2013; and
- an upcoming HHS/FDA rule on "Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments," which the agency expected to issue as a final rule in September 2013 but had not been published as of December 2, 2013.

"Economically Significant" or "Major" Final Rules

In addition to the three final rules that were listed in the regulatory plan, the Unified Agenda listed six entries in the proposed 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). These six rules were

- an HHS/CMS rule on "Home and Community-Based State Plan Services Program and Provider Payment Reassignments," which the agency expected to issue as a final rule in November 2013 but had not been published as of December 2, 2013;
- an HHS/CMS rule on "Face-to-Face Requirements for Home Health Services; Policy Changes and Clarifications Related to Home Health," which the agency expected to issue as a final rule in October 2013 but had not been published as of December 2, 2013;
- an HHS/CMS rule on "Covered Outpatient Drugs," which the agency expected to issue as a final rule in January 2014;
- an HHS/CMS rule on "Medicaid, Exchanges, and Children's Health Insurance Programs," which the agency issued as a final rule on July 15, 2013;³⁷

³⁶ As stated earlier, Executive Order 12866 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.

³⁷ U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, "Medicaid and Children's Health Insurance Programs: Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes, and Premiums and Cost Sharing; Exchanges: Eligibility and Enrollment; Final Rule," 78 *Federal Register* 42159, July 15, 2013.

- an HHS/CMS rule on “Exchange Functions: Eligibility for Exemptions; Miscellaneous Minimum Essential Coverage Provisions,” which the agency issued as a final rule on July 1, 2013;³⁸ and
- a DOL/EBSA rule on “Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services,” which the agency issued as a final rule on July 2, 2013.³⁹

Other Significant Final Rules

In addition to the above-mentioned rules, 11 other entries in the proposed 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. The “other significant” final rules include

- an HHS/CMS, DOL/EBSA, and TREAS/IRS rule on “Certain Preventive Services Under the Affordable Care Act,” which the agencies issued as a final rule on July 2, 2013;⁴⁰
- an HHS/CMS rule on “Exchange Functions: Standards for Navigators and Non-Navigator Assistance Personnel,” which the agency issued as a final rule on July 17, 2013;⁴¹
- an HHS/OS rule on “Health and Human Services Acquisition Regulation (HHS’ Supplement to the Federal Acquisition Regulation),” which the agency expected to issue as an interim final rule by July 2013 but had not been published as of December 2, 2013;
- a DOL/OSHA rule on “Procedures for the Handling of Retaliation Complaints under Section 1558 of the Affordable Care Act of 2010,” which the agency expects to issue as a final rule in February 2014;
- 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 published as a final rule on September 25, 2013;⁴² and

³⁸ U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, “Patient Protection and Affordable Care Act; Exchange Functions: Eligibility for Exemptions; Miscellaneous Minimum Essential Coverage Provisions,” 78 *Federal Register* 39493, July 1, 2013.

³⁹ U.S. Department of Labor, Employee Benefits Security Administration, U.S. Department of the Treasury, Internal Revenue Service, and U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, “Coverage of Certain Preventive Services Under the Affordable Care Act,” 78 *Federal Register* 39870, July 2, 2013. The *Federal Register* publication of the final rule lists DOL/EBSA, USTREAS/IRS, and HHS/CMS as jointly issuing this rule. Within the Unified Agenda, however, only DOL/EBSA identified the rule as “major” or “economically significant.” HHS/CMS identified the rule as “other significant.”

⁴⁰ Ibid.

⁴¹ U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, “Patient Protection and Affordable Care Act; Exchange Functions: Standards for Navigators and Non-Navigator Assistance Personnel; Consumer Assistance Tools and Programs of an Exchange and Certified Application Counselors,” 78 *Federal Register* 42823, July 17, 2013.

⁴² U.S. Department of Labor, Office of Workers’ Compensation Programs, “Regulations Implementing the Byrd (continued...) ”

- an SSA rule on “Conforming Changes to Regulations Regarding Income-Related Monthly Adjustment Amounts to Medicare Part B Premiums,” which the agency issued as an interim final rule on September 18, 2013.⁴³

Effects on Small Entities

Four of the final rules listed in the Spring 2013 Unified Agenda are expected to trigger or triggered the requirements of the Regulatory Flexibility Act (5 U.S.C. §602) because of their effects on small businesses:

- an HHS/FDA rule on “Food Labeling: Nutrition Labeling for Food Sold in Vending Machines,” which the agency expected to issue as a final rule in September 2013 but had not been published as of December 2, 2013;
- an HHS/FDA rule on “Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments,” which the agency expected to issue as a final rule in September 2013 but had not been published as of December 2, 2013;
- an HHS/CMS rule on “Covered Outpatient Drugs,” which the agency expects to issue in January 2014; and
- a TREAS/IRS rule on “Special Rules Under the Additional Medicare Tax,” which was published as a final rule in November 2013.⁴⁴

Three of the rules listed above—the two FDA rules on “Food Labeling” and the TREAS/IRS rule on “Medicare Tax”—are also expected to have an effect on small governmental jurisdictions, another potential trigger for the Regulatory Flexibility Act’s analysis requirement. The TREAS/IRS rule on “Medicare Tax” is also expected to trigger the requirements of the Regulatory Flexibility Act because of its effect on small not-for-profit organizations.

In six other upcoming final rules, the agencies indicated that they had yet to determine whether a regulatory flexibility analysis would be triggered. These rules were

- an HHS/CMS, DOL/EBSA, and TREAS/IRS rule on “Certain Preventive Services Under the Affordable Care Act,” which was published as a final rule on July 2, 2013;⁴⁵

(...continued)

Amendments to the Black Lung Benefits Act: Determining Coal Miners’ and Survivors’ Entitlement to Benefits,” 78 *Federal Register* 59102, September 25, 2013.

⁴³ Social Security Administration, “Medicare Determinations and Income-Related Monthly Adjustment Amounts to Medicare Part B Premiums; Conforming Changes to Regulations,” 78 *Federal Register* 57257, September 18, 2013.

⁴⁴ U.S. Department of the Treasury, Internal Revenue Service, “Rules Relating to Additional Medicare Tax,” 78 *Federal Register* 71468, November 29, 2013.

⁴⁵ U.S. Department of Labor, Employee Benefits Security Administration, U.S. Department of the Treasury, Internal Revenue Service, and U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, “Coverage of Certain Preventive Services Under the Affordable Care Act,” 78 *Federal Register* 39870, July 2, 2013. The *Federal Register* publication of the final rule lists DOL/EBSA, USTREAS/IRS, and HHS/CMS as jointly issuing this rule. Within the Unified Agenda, however, only DOL/EBSA identified the rule as “major” or “economically significant.” HHS/CMS identified the rule as “other significant.”

- an HHS/OS rule on “Health and Human Services Acquisition Regulation (HHS’ Supplement to the Federal Acquisition Regulation),” which the agency expected to publish in July 2013 but had not yet published as of December 2, 2013;
- a DOL/EBSA rule on “Ninety-Day Waiting Period Limitation and Technical Amendments to Certain Health Coverage Requirements,” which the agency expects to issue jointly with HHS/CMS and TREAS/IRS in December 2013;
- a DOL/OWCP rule on “Regulations Implementing Amendments to the Black Lung Benefits Act,” which the agency published as a final rule on September 25, 2013;⁴⁶
- a TREAS/IRS rule on “Shared Responsibility for Employers Regarding Health Coverage,” which the agency expects to publish in December 2013; and
- an ATBCB rule on “Accessibility Standards for Medical Diagnostic Equipment,” which the agency expects to issue as a final rule in March 2014.

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 July 3, 2013, edition of the Unified Agenda listed 13 long-term actions related to ACA. In comparison to the proposed and final rules previously discussed, it is somewhat less clear when the ACA-related long-term actions are expected to occur. In 4 of the 13 long-term actions listed, the agencies said that the dates for the actions were “to be determined.”

Of the nine remaining long-term actions for which agencies provided an estimated date of publication, one is expected to be published as an ANPRM in 2014:

- a Department of Justice (DOJ)/Civil Rights Division (CRT) advance notice of proposed rulemaking (ANPRM) on “Nondiscrimination on the Basis of Disability by State and Local Governments and Public Accommodations: Accessibility of Medical Equipment and Furniture” (expected in 2014).

The remaining eight long-term actions are expected to have an NPRM, ANPRM, or an interim final rule published in the *Federal Register* in 2014 or 2015.

The rules with final action expected in 2014 include

- an HHS/CMS rule on “Medicare Shared Savings Program; Final Waivers” (expected in November 2014);
- a TREAS/IRS rule on “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 ” (expected in July 2014);

⁴⁶ U.S. Department of Labor, Office of Workers’ Compensation Programs, “Regulations Implementing the Byrd Amendments to the Black Lung Benefits Act: Determining Coal Miners’ and Survivors’ Entitlement to Benefits,” 78 *Federal Register* 59102, September 25, 2013.

- a TREAS/IRS rule on “Group Health Plans and Health Insurance Issuers Providing Dependent Coverage of Children to Age 26 Under the Patient Protection and Affordable Care Act” (expected in December 2014); and
- a TREAS/IRS rule on “Group Health Plans and Health Insurance Coverage Rules Relating to Status as a Grandfathered Health Plan Under the Patient Protection and Affordable Care Act” (expected in December 2014).

The regulatory action expected in 2015 is

- an HHS/CMS rule on “Reporting and Returning of Overpayments” (expected in 2015).

Notable Long-Term Actions

None of the ACA-related long-term actions were identified as “economically significant” or “major.”

The agencies considered 5 of the 13 long-term 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 were

- an HHS/HRSA rule on “340B Drug Pricing Program; Administrative Dispute Resolution Process”;
- an HHS/CMS rule on “Reporting and Returning of Overpayments”;
- an HHS/CMS rule on “Medicare Shared Savings Program; Final Waivers”;
- a DOJ/CRT rule on “Nondiscrimination on the Basis of Disability by State and Local Governments and Public Accommodations: Accessibility of Medical Equipment and Furniture”; and
- a DOL/EBSA rule on “Automatic Enrollment in Health Plans of Employees of Large Employers Under FLSA Section 18A.”

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, Congress often oversees the rules that agencies issue to ensure that they are consistent with congressional intent and various rulemaking requirements. In order for Congress to oversee the rules issued pursuant to ACA, Congress must first know that they are being issued—ideally as early as possible. The Unified Agenda is perhaps the best vehicle to provide that early information, describing not only what rules are expected to be issued, but also providing information regarding their significance and timing.

Congress has a range of tools available to oversee the rules that federal agencies are expected to issue to implement 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.⁴⁷ 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."⁴⁸ 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.⁴⁹ 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.⁵⁰ 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.⁵¹ 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 1 rule in the 17 years since it was enacted.⁵² 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 could be subject to presidential veto.

Finally, outside of the CRA, Congress has regularly included provisions in the text of agencies' appropriations bills in order to influence the regulatory process.⁵³ Such provisions include prohibitions on the finalization of particular proposed rules, restrictions on certain types of

⁴⁷ 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."

⁴⁸ Joint statement of House and Senate Sponsors, *Congressional Record*, daily edition, vol. 142 (April 19, 1996), p. E571, and *Congressional Record*, daily edition, vol. 142 (April 18, 1996), p. S3683.

⁴⁹ 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.

⁵⁰ For a detailed discussion of CRA procedures, see CRS Report RL31160, *Disapproval of Regulations by Congress: Procedure Under the Congressional Review Act*, by Richard S. Beth.

⁵¹ The CRA provides for three exceptions to the definition of the term "rule." Under 5 U.S.C. §804(3), the term "rule" does not include "(A) any rule of particular applicability, including a rule that approves or prescribes for the future rates, wages, prices, services, or allowances therefor, corporate or financial structures, reorganizations, mergers, or acquisitions thereof, or accounting practices or disclosures bearing on any of the foregoing; (B) any rule relating to agency management or personnel; or (C) any rule of agency organization, procedure, or practice that does not substantially affect the rights or obligations of non-agency parties."

⁵² 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.

⁵³ For more information on the use of appropriations restrictions, see CRS Report R41634, *Limitations in Appropriations Measures: An Overview of Procedural Issues*, by Jessica Tollestrup.

regulatory activity, and restrictions on implementation or enforcement of certain provisions. 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 usually considered "must pass" legislation. Congress's use of regulatory appropriations restrictions has fluctuated somewhat over time.⁵⁴

This report's **Appendix** lists the ACA proposed and final rules from the Spring 2013 Unified Agenda in a table. For each 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 is expected to be issued or was issued.⁵⁵ 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. The table includes only those Unified Agenda entries in which the Affordable Care Act was mentioned.

⁵⁴ 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.

⁵⁵ In addition to the RINs, CMS included an agency-specific number as part of the title of the rule (e.g., CMS-2327-F). Those numbers are included as part of the title in the table in the **Appendix**.

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

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Unified Agenda	Expected Publication Date
Proposed Rules			
HHS/HRSA	Teaching Health Center Graduate Medical Education Program (0906-AA98)	This proposed rule is required under the Affordable Care Act and would create regulations governing the eligibility, payment amount, reconciliation, and annual reporting for the Teaching Health Centers Graduate Medical Education Program.	06/2014
HHS/CMS	Administrative Simplification: Compliance: Health Plan Certification (CMS-0037-P) (0938-AQ85)	This proposed rule would 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.	09/2013 Note: Legal deadline for final rule is 12/31/2013. No NPRM had been published as of 12/02/2013.
HHS/CMS	Disproportionate Share Hospital Payment Reduction (CMS-2367-F) (0938-AR31)	This final rule would delineate the statutory aggregate reductions to State Medicaid Disproportionate Share Hospital (DSH) allotments from FYs 2014 through 2015. The annual reduction amounts will be implemented using a DSH Health Reform methodology determined by the Secretary.	NPRM was published on 05/15/2013 (78 F.R. 28551). Final rule was published on 09/18/2013 (78 F.R. 57293). Note: Legal deadline for final rule was 10/01/2013.
HHS/CMS	Changes to the End-Stage Renal Disease Prospective Payment System for CY 2014 (CMS-1526-P) (0938-AR55)	This annual proposed rule would update the bundled payment system for end stage renal disease (ESRD) facilities as required by MIPPA, the Affordable Care Act, and the American Taxpayer Relief Act of 2012. These changes would be applicable to services furnished on or after January 1 [2014].	NPRM was published on 07/08/2013 (78 F.R. 40836). Final rule was published 12/02/2013 (78 F.R. 72155). Note: Legal deadline for final rule was 11/01/2013.
HHS/CMS	Reform of Requirements for Long-Term Care Facilities and Quality Assurance and Performance Improvement (QAPI) Program (CMS-3260-P) (0938-AR61)	This proposed rule would reform the Medicare conditions of participation for long-term care facilities to reflect significant changes in the industry and remove obsolete or unnecessary provisions. In addition, under the Affordable Act, this rule would propose to expand the level and scope of required QAPI activities to ensure that facilities continuously identify and correct quality deficiencies as well as promote and sustain performance improvement.	12/2013 Note: No NPRM had been published as of 12/02/2013.

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Unified Agenda	Expected Publication Date
HHS/CMS	Prospective Payment System for Federally Qualified Health Centers (FQHCs) (CMS-1443-P) (0938-AR62)	The Affordable Care Act amends the current Medicare FQHC payment policy by requiring the establishment of a new payment system, effective with cost reporting periods beginning on or after October 1, 2014. This rule proposes the establishment of the new prospective payment system.	NPRM was published on 09/23/2013 (78 F.R. 58386). Note: Legal deadline for final rule was 10/01/2014.
HHS/CMS	Exchanges: Additional Program Implementation (CMS-9957-P) (0938-AR82)	Under the Affordable Care Act, this proposed rule sets forth standards for agents, brokers, and qualified health plan (QHP) issuers in Federally-facilitated Exchanges (FFE)s; State Exchanges; the Small Business Health Options Program (SHOP); risk adjustment, reinsurance, and risk corridors programs; advance payments of the premium tax credit (APTC); and cost-sharing reductions (CSRs). This proposed rule would also implement additional standards for enrollment in a QHP, the establishment and operation of the SHOP, cases related to QHPs and QHP issuers, the use of a standard health plan identifier for routing electronic enrollment and payment transactions, and standards for the use of HHS-approved survey vendors.	NPRM was published on 06/19/2013 (78 F.R. 37032). Note: Legal deadline for final rule is 01/01/2014. Final rules were published on 08/30/2013 (78 F.R. 54070) and 10/30/2013 (78 F.R. 65046).
HHS/CMS	Establishment of Appeals Process for Medicare Part C and Part D Recovery Audit Contractor (RAC) Determinations (CMS-6052-P) (0938-AR86)	This proposed rule would establish an appeals process for Parts C and D RAC determinations. The Medicare Parts C and D RAC program was authorized under the Affordable Care Act. No process currently exists for Parts C and D contractors to appeal the findings of RACs.	02/2014
HHS/CMS	CY 2015 Notice of Benefit and Payment Parameters (CMS-9954-P) (0938-AR89)	This proposed rule would establish the CY 2015 payment parameters for the cost-sharing reductions, advance premium tax credit, reinsurance, and risk adjustment programs as required by the Affordable Care Act.	NPRM was published on 12/02/2013 (78 F.R. 72321). Note: Legal deadline for final rule is 01/01/2014. Proposed and final rule must precede plan approval and open enrollment.
HHS/CMS	Establishment of the Basic Health Program (CMS-2380-P) (0938-AR93)	Under the Affordable Care Act, this proposed rule would establish the Basic Health Program. Under this program, States could offer public health insurance to individuals whose incomes are too high to qualify for Medicaid, but are also below 200% of the Federal poverty level.	NPRM was published on 09/25/2013 (78 F.R. 59122). Note: Legal deadline for final rule is 01/01/2014.
HHS/OCR	Nondiscrimination Under the Patient Protection and Affordable Care Act (0945-AA02)	This proposed rule would implement prohibitions against discrimination on the basis of race, color, national origin, sex, age, and disability, as provided in section 1557 of the Affordable Care Act. Section 1557 provides certain protections from discrimination by recipients of Federal financial assistance, federally conducted programs, and entities established under title I of the Affordable Care Act. This section also identifies additional forms of Federal financial assistance to which the section will apply.	12/2013 Note: No NPRM had been published as of 12/02/2013.

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Unified Agenda	Expected Publication Date
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.	12/2013 Note: Final rule was published on 12/06/2012 (77 F.R. 72721).
TREAS/IRS	Medical Loss Ratio for Section 833 Organizations (1545-BL05)	The proposed regulations will provide guidance under section 833(c)(5) of the Internal Revenue Code, as added by section 9016 of the Patient Protection and Affordable Care Act, on the 85 percent medical loss ratio requirement under section 833.	NPRM was published on 05/13/2013 (78 F.R. 27873).
TREAS/IRS	Reporting and Notice Requirements Under Section 6056 (1545-BL26)	Proposed regulations under section 6056 of the Internal Revenue Code, as enacted by the Affordable Care Act, to provide guidance on rules that require applicable large employers to file certain information with the Internal Revenue Service on coverage under an eligible employer-sponsored health plan and furnish to individuals statements that set forth the information required to be reported to the Internal Revenue Service.	NPRM was published on 09/09/2013 (78 F.R. 54996).
TREAS/IRS	Community Health Needs Assessments for Charitable Hospitals (1545-BL30)	The Notice of Proposed Rulemaking contains proposed regulations that provide guidance to charitable hospital organizations on the community health needs assessment requirements, and related excise tax and reporting obligations, enacted in the Patient Protection and Affordable Care Act of 2010. The proposed regulations also clarify the consequences for failing to meet these requirements, as well as additional requirements related to financial assistance, charges, and billing and collections. The proposed regulations will affect charitable hospital organizations.	NPRM was published on 04/05/2013 (78 F.R. 20523); corrections were subsequently published (see 78 F.R. 31454 and 78 F.R. 29628).
TREAS/IRS	Tax Credit for Employee Health Insurance Expenses of Small Employer (1545-BL55)	Proposed regulations under section 45R of the Internal Revenue Code, as enacted by the Affordable Care Act, that set forth the requirements for certain small employers to claim a tax credit when providing health insurance coverage to their employees through an Exchange.	NPRM was published on 08/26/2013 (78 F.R. 52719).
OPM	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 part 870 to include enrollments for eligible employees of tribes and tribal organizations under the provisions of the Affordable Care Act of 2010.	03/2014
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 part 890 to include enrollments for eligible employees of tribes and tribal organizations under the provisions of the Affordable Care Act of 2010.	02/2014

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Unified Agenda	Expected Publication Date
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 part 890 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.	12/2013 Note: No NPRM had been published as of 12/02/2013.
OPM	Federal Employees' Health Benefits Program: Miscellaneous Changes Proposed by the Affordable Care Act (3206-AM46)	The U.S. Office of Personnel Management (OPM) proposes to amend the Federal Employees Health Benefits (FEHB) regulations at 5 CFR part 890 to include changes under the provisions of the Affordable Care Act of 2010.	02/2014
Final Rules			
HHS/HRSA	Designation of Medically Underserved Populations and Health Professional Shortage Areas (0906-AA44)	The Affordable Care Act required the Secretary to establish a rulemaking committee to draft an interim final rule for designation of Medically Underserved Populations (MUPs) and Primary Care Health Professions Shortage Areas (HPSAs). The rulemaking committee was unable to reach the consensus required to produce an interim final rule for the Secretary's review and approval. However, the Affordable Care Act still requires the Secretary to issue an interim final rule at some point in the future.	03/2014 Note: On 2/29/2008, HRSA announced (73 F.R. 42743) its intention to publish an additional NPRM, following the second NPRM (73 F.R. 11232). The Spring 2013 Unified Agenda indicated the rule will be an interim final rule rather than another NPRM.
HHS/HRSA	National Practitioner Data Bank and Privacy Act; Exempt Records System; Technical Correction (0906-AA97)	This final rule updates the cross-reference cited in the Privacy Act regulations at 45 CFR 5b.11(b)(ii)(L), from section 60.16 to section 60.21. The National Practitioner Data Bank (NPDB) system of records (09-15-0054) is exempt from certain provisions of the Privacy Act at 45 CFR 5b.11(b)(2)(ii)(L), and the cross-reference cited in this section refers to the regulations that govern the NPDB. As a result of section 6403 of the Affordable Care Act, the regulations governing the NPDB were revised and certain section numbers in the NPDB regulations were changed, including the NPDB regulation cross-referenced at 45 CFR 5b.11(b)(2)(ii)(L). This change is technical in nature and does not significantly alter the current NPDB exemption at 45 CFR 5b.11(b)(2)(ii)(L).	Final rule was published on 08/05/2013 (78 F.R. 47210). Note: Legal deadline for final rule was 03/2011.

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Unified Agenda	Expected Publication Date
HHS/FDA	Food Labeling: Calorie Labeling of Articles of Food Sold in Vending Machines (0910-AG56)	FDA published a proposed rule 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 is issuing a final rule, and taking this action to carry out section 4205 of the Patient Protection and Affordable Care Act.	09/2013 Note: NPRM was published on 04/06/2011 (76 F.R. 19238). The final rule had not been published as of 12/02/2013.
HHS/FDA	Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments (0910-AG57)	FDA published a proposed rule in the Federal Register 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 is issuing a final rule, and taking this action to carry out section 4205 of the Patient Protection and Affordable Care Act.	09/2013 Note: NPRM was published on 04/06/2011 (76 F.R. 19192); comment period was extended on 05/24/2011 (76 F.R. 30051). The final rule had not been published as of 12/02/2013.
HHS/CMS	Home and Community-Based State Plan Services Program and Provider Payment Reassignments (CMS-2249-F) (0938-AO53)	This final rule amends the Medicaid regulations to define and describe State plan home and community-based services (HCBS) under the Affordable Care Act. This rule offers States flexibilities in providing necessary and appropriate services to elderly and disabled populations.	11/2013 Note: Original NPRM was published on 04/04/08 (73 F.R. 18676). Following enactment of ACA, a second NPRM was published on 05/03/2012 (77 F.R. 26362). Under the Deficit Reduction Act of 2005 (P.L. 109-171), the original legal deadline for final rule was 01/01/2007. The final rule had not been published as of 12/02/2013.
HHS/CMS	Face-to-Face Requirements for Home Health Services; Policy Changes and Clarifications Related to Home Health (CMS-2348-F) (0938-AQ36)	This final 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 tele-health) with the Medicaid eligible individual within reasonable timeframes. In addition, this rule amends home health services regulations 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.	10/2013 Note: NPRM was published on 07/12/2011 (76 F.R. 41032). The final rule had not been published as of 12/02/2013.

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Unified Agenda	Expected Publication Date
HHS/CMS	Covered Outpatient Drugs (CMS-2345-F) (0938-AQ41)	This final rule revises requirements pertaining to Medicaid reimbursement for covered outpatient drugs to implement provisions of the Affordable Care Act. This rule also revises other requirements related to covered outpatient drugs, including key aspects of Medicaid coverage, payment, and the drug rebate program.	01/2014 Note: NPRM was published on 02/02/2012 (77 F.R. 5318). Legal deadline for final rule was 01/01/2010.
HHS/CMS	Medicaid, Exchanges, and Children's Health Insurance Programs: Eligibility, Appeals, and Other Provisions Under the Affordable Care Act (CMS-2334-F) (0938-AR04)	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 rule continues CMS efforts to assist States in implementing Medicaid eligibility, appeals, enrollment changes, and other State health subsidy programs.	Final rules were published on 07/15/2013 (78 F.R. 42159) and 07/17/2013 (78 F.R. 42824). Note: Legal deadline for final rule is 01/2014. NPRM was published 01/22/2013 (78 F.R. 4593).
HHS/CMS	Exchange Functions: Eligibility for Exemptions; Miscellaneous Minimum Essential Coverage Provisions (CMS-9958-F) (0938-AR68)	This final rule implements provisions of the Affordable Care Act concerning verifications of employer-sponsored coverage eligibility for the purpose of determining an individual's eligibility for advanced premium tax credits (APTCs).	Final rule was published on 07/01/2013 (78 F.R. 39493). Note: Legal deadline for final rule is 01/01/2014. NPRM was published on 02/01/2013 (78 F.R. 7348).
HHS/CMS	Patient Protection and Affordable Care Act; Exchange Functions: Standards for Navigators and Non-Navigator Assistance Personnel (CMS-9955-F) (0938-AR75)	This final rule would establish standards for Navigators providing in-person assistance through an Exchange Navigator Program and non-Navigator assistance personnel in Federally Facilitated Exchanges (FEEs) and State Partnership Exchanges (SPEs) and non-Navigator assistance personnel in State-based Exchanges that are funded through federal Exchange Establishment grants. The Affordable Care Act requires each Exchange to develop and implement Navigator grant programs, which will help consumers understand new programs, avail themselves of new protections, and navigate the system to find the most affordable coverage that meets their needs.	Final rule was published on 07/17/2013 (78 F.R. 42823). Note: NPRM was published on 04/05/2013 (78 F.R. 20581).
HHS/OS	Health and Human Services Acquisition Regulation (HHS' Supplement to the Federal Acquisition Regulation) (0991-AB88)	HHS is amending its Federal Acquisition Regulation (FAR) supplement—the HHS Acquisition Regulation (HHSAR)—to add four new clauses, 352.203-70 Anti-Lobbying, 352.204-16 Prevention and Public Health Fund—Reporting Requirements, 352.231-70 Salary Rate Limitation, and 352.237-73 Nondiscrimination in Service Delivery, and their respective prescriptions at 303.808-70, 304.1602, 331.101-70, and 337.103-70(d) as well as amending related regulations at 303.808-70, 304.16, 304.1600, 304.1601, 304.1602, 305.8, 305.801, 305.802, 305.803, 305.804, 305.805, 331.101-70, 335.017-2, 337.103-70(d). This interim final rule amends the Department's FAR Supplement—the HHS Acquisition Regulation (HHSAR)—to provide implementation guidance for provisions in the HHS FY2012 Appropriations Acts and to establish HHS' nondiscrimination policy.	07/2013 Note: Legal deadline for interim final rule was 07/2013. The final rule had not been published as of 12/02/2013.

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Unified Agenda	Expected Publication Date
DOL/EBSA	Incentives for Nondiscriminatory Wellness Programs in Group Health Plans (1210-AB55)	The Patient Protection and Affordable Care Act of 2010 (the Affordable Care Act) amended title I of ERISA, by adding a new section 715 which encompasses various health reform provisions of the Public Health Service Act. These regulations provide guidance on wellness programs.	Final rule was published on 06/03/2013 (78 F.R. 33157). Note: NPRM was published on 11/26/2012 (77 F.R. 70619).
DOL/OSHA	Procedures for the Handling of Retaliation Complaints under Section 1558 of the Affordable Care Act of 2010 (1218-AC79)	OSHA is proposing to promulgate procedures for the handling and investigation of retaliation complaints pursuant to Section 1558 of the Patient Protection and Affordable Care Act of 2010 (the Affordable Care Act or ACA). This section established a new whistleblower protection statute to be administered by OSHA that provides protection from retaliation to employees in the health care industry who engage in protected activities under the ACA. Pursuant to the statute, the procedures will follow those enacted under the Consumer Product Safety Improvement Act, 15 U.S.C. 2087(b), including remedies and legal burdens of proof provisions. Promulgation of a regulation is necessary to govern whistleblower investigations conducted under the new statute.	02/2014 Interim final rule was published on 02/27/2013 (78 F.R. 13222).
DOL/OWCP	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. This final rule will define the class of claims affected by the amendments and set the criteria for establishing entitlement to benefits under the amendments.	Final rule was published on 09/25/2013 (78 F.R. 59102). Note: NPRM was published on 03/30/2012 (77 F.R. 19455).
TREAS/IRS	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.	06/2014 Note: NPRM was published on 08/18/2011 (76 F.R. 51310).
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.	Final rule was published on 11/29/2013 (78 F.R. 71468). Note: NPRM was published on 12/05/2012 (77 F.R. 72268).

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Unified Agenda	Expected Publication Date
TREAS/IRS	Health Insurance Provider Fees (1545-BL20)	The proposed regulations provide guidance on the annual fee imposed on covered entities engaged in the business of providing health insurance for United States health risks. This fee was enacted by section 9010 of the Patient Protection and Affordable Care Act (P.L. 111-148), as amended by section 10905 and further amended by section 1406 of Health Care and Education Reconciliation Act of 2010 (P.L. 111-152).	Final rule was published on 11/29/2013 (78 F.R. 71476). Note: NPRM was published on 03/04/2013 (78 F.R. 14034).
TREAS/IRS	Shared Responsibility for Employers Regarding Health Coverage (1545-BL33)	Proposed regulations under section 4980H of the Internal Revenue Code, as enacted by the Affordable Care Act, to provide guidance relating to the offering of health coverage by applicable large employers to their full-time employees.	12/2013 Note: NPRM was published on 01/02/2013 (78 F.R. 218). The final rule had not been published as of 12/02/2013.
ATBCB	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.	03/2014 Note: NPRM was published on 02/09/2012 (77 F.R. 6916), advisory committee was later established (see 77 F.R. 39656). Legal deadline for final rule was 03/22/2012.
OPM	Federal Employees Health Benefits Program and Federal Employees Dental and Vision Insurance Program: Coverage of Children Federal Flexible Benefits Plan: Pre-Tax Payment of Health Benefits Premiums (3206-AM55)	The U.S. Office of Personnel Management (OPM) plans to publish a final rule to amend the Federal Employees Health Benefits (FEHB) regulations at 5 CFR part 890 to include changes pertaining to the Affordable Care Act in regard to age 26 and children of same-sex partners.	Final rule was published on 10/30/2013 (78 F.R. 64873). Note: NPRM was published on 07/20/2012 (77 F.R. 42914).
SSA	Conforming Changes to Regulations Regarding Income-Related Monthly Adjustment Amounts to Medicare Part B Premiums (37341) (0960-AH47)	We [SSA] are modifying our regulations to the Medicare Part B income-related monthly adjustment amount (IRMAA) in order to conform to changes made to the Social Security Act (Act) by the Affordable Care Act. These rules remove the requirement that beneficiaries consent to the release of IRS information outside of SSA for appeals past the reconsideration level and freeze the income threshold and ranges from 2011 through 2019. We are also removing provisions that phased in the income-related monthly adjustment amount between 2007 and 2009. The regulation also updates an outdated provision to reflect the transfer of authority for hearing appeals under title XVIII of the Act from SSA to the Department of Health and Human Services, as prescribed by the Medicare Prescription Drug, and Modernization Act of 2003.	Interim final rule published on 09/18/2013 (78 F.R. 57257).

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Unified Agenda	Expected Publication Date
HHS/CMS, DOL/EBSA, TREAS/IRS, jointly	Certain Preventive Services Under the Affordable Care Act (CMS-9968-F) (0938-AR42), (1210-AB44), (1545-BJ60)	This final rule amends to regulations regarding certain preventive health services under provisions of the Affordable Care Act. The amendments establish alternative ways to fulfill the requirements of the Public Health Service Act and corresponding provisions under the Employee Retirement Income Security Act and the Internal Revenue Code.	Final rule published on 07/02/2013 (78 F.R. 39870). Note: Several earlier versions of this rule were published; see 78 F.R. 8456, 77 F.R. 16501, 77 F.R. 8725, 76 F.R. 46621, and 75 F.R. 41726.
HHS/CMS, DOL/EBSA, TREAS/IRS, jointly	Ninety-Day Waiting Period Limitation and Technical Amendments to Certain Health Coverage Requirements Under the Affordable Care Act (CMS-9952-F) (0938-AR77), (1210-AB56), (1545-BL50)	This final rule implements the 90-day waiting period limitation under section 2708 of the Public Health Service Act, as added by the Affordable Care Act, as amended, and incorporated into the Employee Retirement Income Security Act of 1974 and the Internal Revenue Code. It also amends regulations to conform to Affordable Care Act provisions already in effect as well as those that will become effective beginning 2014.	12/2013 Note: NPRM was published on 03/21/2013 (78 F.R. 17313). Legal deadline for final rule is 01/01/2014. The final rule had not been published as of 12/02/2013.

Source: Information in the first three columns is verbatim as reported in the Unified Agenda of Federal Regulatory and Deregulatory Actions, July 3, 2013, 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.

Author Contact Information

Maeve P. Carey
Analyst in Government Organization and
Management
mcarey@crs.loc.gov, 7-7775

Michelle D. Christensen
Analyst in Government Organization and
Management
mchristensen@crs.loc.gov, 7-0764