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Upcoming Rules Pursuant to the Patient Protection and Affordable Care Act: The Spring 2014 Unified Agenda

(name redacted)

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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 conduct 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, 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- “completed” actions (i.e., final rules or rules that have been withdrawn since the last edition of the Unified Agenda); and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 provide 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 most recent edition of the Unified Agenda, which was published on May 23, 2014, is the seventh edition of the agenda since enactment of the ACA. In this edition, agencies reported 14 proposed rules and 17 final rules that they expect to issue pursuant to the ACA within the next 12 months. Agencies also reported a total of four long-term regulatory actions.

The **Appendix** of this report lists the upcoming proposed and final rules published in the Spring 2014 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. 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) provides a notable example of congressional delegation of rulemaking authority to federal agencies.¹ 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 have issued, and will continue to issue, pursuant to the ACA have a major impact on how the law is implemented. For example, in an article 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 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.

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 (name redacted).

² CRS Report R41180, *Rulemaking Requirements and Authorities in the Patient Protection and Affordable Care Act (PPACA)*, by (name redacted). The author of that report has retired from CRS; questions about its content may be directed to the author 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, 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 contains 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.

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.⁶

Having an early sense of what rules agencies are going to issue, and when they are going to issue those rules, can help Congress conduct 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.⁷

The Unified Agenda

A potentially effective way for Congress to identify upcoming ACA rules is by reviewing the Unified Agenda of Federal Regulatory and Deregulatory Actions (hereafter Unified Agenda), which is usually published twice each year—in the spring and fall.⁸ The Unified Agenda is published by the Regulatory Information Service Center (RISC), a component of the General Services Administration (GSA), for the Office of Management and Budget’s (OMB’s) Office of Information and Regulatory Affairs (OIRA).⁹ The Unified Agenda helps agencies fulfill two current transparency requirements:

- The Regulatory Flexibility Act (5 U.S.C. §602) requires that all agencies publish semiannual regulatory agendas in the *Federal Register*, 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.¹⁰
- Section 4 of Executive Order 12866 on “Regulatory Planning and Review” requires that all executive branch agencies “prepare an agenda of all regulations under development or review.”¹¹ The stated purposes of this and other planning

⁵ David H. Rosenbloom, *Building a Legislative-Centered Public Administration: Congress and the Administrative State, 1946-1999* (Tuscaloosa, AL: University of Alabama Press, 2000), pp. 133-134.

⁶ For a discussion of Congress’s broad oversight authority, see CRS Report RL30240, *Congressional Oversight Manual*, by (name redacted) et al.

⁷ CRS Report R41180, *Rulemaking Requirements and Authorities in the Patient Protection and Affordable Care Act (PPACA)*, by (name redacted). The author of that report has retired from CRS; questions about its content may be directed to the author of this report.

⁸ 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.

⁹ The current edition of the Unified Agenda, which was published on November 26, 2013, is available at <http://www.reginfo.gov/public/do/eAgendaMain>.

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

¹¹ Executive Order 12866, “Regulatory Planning and Review,” 58 *Federal Register* 51735, October 4, 1993. Although most of the requirements in this executive order do not apply to independent regulatory agencies (e.g., the Securities (continued...))

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),¹² 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).¹³

There is no penalty for issuing a rule without a prior notice in the Unified Agenda, and some prospective rules listed in the Unified Agenda are never 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

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and Exchange Commission and Federal Reserve Board), this section of the order does include those agencies.

¹² 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.

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

most systematic, government-wide method to alert the public about their upcoming proposed rules.¹⁴

Scope and Methodology of This Report

The Spring 2014 edition of the Unified Agenda, published on May 23, 2014, is the seventh edition compiled and issued by RISC since enactment of the ACA.¹⁵ Federal agencies are usually required to submit data to RISC several weeks prior to publication, but some items may have been subsequently updated during the OIRA review process.¹⁶

This report examines the Spring 2014 edition of the Unified Agenda and identifies upcoming proposed and final rules and long-term regulatory actions expected to be issued pursuant to the 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.

In this edition, agencies reported 14 proposed rules and 17 final rules they expect to issue pursuant to the ACA within the next 12 months. Agencies also reported a total of four long-term regulatory 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 the proposed or final rule is 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.¹⁸

¹⁴ A previous CRS report found that of all the significant proposed rules published after having been reviewed by OIRA in 2008, about three-fourths had been listed in the proposed rule section of the Unified Agenda. See CRS Report R40713, *The Unified Agenda: Implications for Rulemaking Transparency and Participation*, by (name redacted). The author of that report has retired from CRS; questions about its content may be directed to the author of this report.

¹⁵ The Unified Agenda is published primarily online on OIRA’s website. The portion of the Agenda completed pursuant to the Regulatory Flexibility Act, in which agencies identify upcoming rules they expect to have a “significant economic effect on a substantial number of small entities,” is published in the *Federal Register*. The online version of the Unified Agenda includes that information and other information as well.

¹⁶ A previous email 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.

¹⁷ In addition to the RINs, the Centers for Medicare & Medicaid Services (CMS) include an agency-specific number as part of the title of its rules (e.g., CMS-2327-F). Those numbers are included as part of the title in the table in the **Appendix**.

¹⁸ 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 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, 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 agencies did not submit them as part of the Unified Agenda.

Upcoming ACA Proposed Rules

The Spring 2014 edition of the Unified Agenda listed 14 ACA-related rules 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).¹⁹ Ten of the 14 upcoming proposed rules were expected to be issued by components of the Department of Health and Human Services (HHS): Centers for Medicare & Medicaid Services (CMS, four rules); the Office of Inspector General (OIG, three rules); the Health Resources and Services Administration (HRSA, one rule); the Office for Civil Rights (OCR, one rule); and the Administration for Children and Families (ACF, one rule). Two other proposed rules were expected to be issued by the Equal Employment Opportunity Commission (EEOC). The final two proposed rules are to be issued jointly by CMS, the Department of Labor’s (DOL) Employee Benefits Security Administration (EBSA), and the Department of the Treasury’s (TREAS) Internal Revenue Service (IRS).

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 were listed in the agency’s “regulatory plan,” which is described below, or if they meet a particular statutory or executive order definition of significance. 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 detailing the most important regulatory actions the agency reasonably expects to issue in proposed or final form during the upcoming fiscal year. In the spring edition, agencies are asked to indicate whether their rules have appeared in the regulatory plan. However, of the proposed rules included in the Spring 2014 Unified Agenda, none had been included in the regulatory plan.

“Economically Significant” or “Major” Proposed Rules

Although none of the proposed rules were listed in the regulatory plan, the Unified Agenda listed three rules that were considered “economically significant” and/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).²⁰ All three rules are to be issued by CMS:

- a rule on “Reform of Requirements for Long-Term Care Facilities and Quality Assurance and Performance Improvement (QAPI) Program”;

¹⁹ The number of upcoming proposed rules listed in the Unified Agenda containing the phrase “Affordable Care Act” is actually 17, but three of the entries were duplicate entries from HHS/CMS, DOL/EBSA, and TREAS/IRS regarding two proposed rules that will be issued jointly by those agencies.

²⁰ For definitions and a more complete discussion of different types of rules, see CRS Report R43056, *Counting Regulations: An Overview of Rulemaking, Types of Federal Regulations, and Pages in the Federal Register*, by (name redacted).

- a rule on “CY 2016 Notice of Benefit and Payment Parameters”; and
- a rule on “Application of the Mental Health Parity and Addiction Equity Act to Medicaid Programs.”

“Other Significant” Proposed Rules

In addition to the above-mentioned rules, the agencies characterized 9 of the 14 upcoming proposed rules 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 12866.²¹

- an HHS/OIG rule on “Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Office of Inspector General’s Civil Monetary Penalty Rules”;
- an HHS/OIG rule on “Fraud and Abuse; Revisions to the Office of Inspector General’s Exclusion Authorities”;
- an HHS/CMS rule on “State Option To Provide Health Homes for Enrollees With Chronic Conditions”;
- an HHS/OCR rule on “Nondiscrimination Under the Patient Protection and Affordable Care Act”;
- an HHS/ACF rule on “Refugee Medical Assistance”;
- an EEOC rule on “Amendments to Regulations Under the Americans With Disabilities Act”;
- an EEOC rule on “Amendments to Regulations Under the Genetic Information Nondiscrimination Act of 2008”;
- an HHS/CMS, DOL/EBSA, and TREAS/IRS rule on “Ninety-Day Waiting Period Limitation”; and
- an HHS/CMS, DOL/EBSA, and TREAS/IRS rule on “Amendments to Excepted Benefits.”

Effects on Small Entities

The Regulatory Flexibility Act (RFA, 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, local governments, and small not-for-profit organizations).²² Six of the ACA-related rules listed in the proposed rule section expected that they may trigger the requirements of the Regulatory Flexibility Act because of their effects on small entities:

²¹ 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 (name redacted).

²² For more information, see CRS Report RL34355, *The Regulatory Flexibility Act: Implementation Issues and Proposed Reforms*, coordinated by (name redacted), and CRS Report RL32240, *The Federal Rulemaking Process: An Overview*, coordinated by (name redacted).

- an HHS/CMS rule on “Reform of Requirements for Long-Term Care Facilities and Quality Assurance and Performance Improvement (QAPI) Program”;
- an HHS/CMS rule on “Application of the Mental Health Parity and Addiction Equity Act to Medicaid Programs”;
- an EEOC rule on “Amendments to Regulations Under the Americans With Disabilities Act”;
- an EEOC rule on “Amendments to Regulations Under the Genetic Information Nondiscrimination Act of 2008”;
- an HHS/CMS, DOL/EBSA, and TREAS/IRS rule on “Amendments to Excepted Benefits”;²³ and
- an HHS/CMS, DOL/EBSA, and TREAS/IRS rule on “Ninety-Day Waiting Period Limitation.”²⁴

Timing of the Proposed Rules

As of June 19, 2014, four proposed rules listed in the Unified Agenda had been published in the *Federal Register*:

- an HHS/OIG rule on “Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Office of Inspector General’s Civil Monetary Penalty Rules”;²⁵
- an HHS/OIG rule on “Fraud and Abuse; Revisions to the Office of Inspector General’s Exclusion Authorities”;²⁶
- an HHS/CMS, DOL/EBSA, and TREAS/IRS rule on “Ninety-Day Waiting Period Limitation Under the Affordable Care Act”;²⁷ and
- an HHS/CMS, DOL/EBSA, and TREAS/IRS rule on “Amendments to Excepted Benefits.”²⁸

²³ Although this rule will be issued jointly with IRS and EBSA, CMS was the only one of the three agencies that indicated it could affect small entities under the RFA.

²⁴ Although this rule will be issued jointly with IRS and EBSA, CMS was the only one of the three agencies that indicated it could affect small entities under the RFA.

²⁵ Department of Health and Human Services, Office of Inspector General, “Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Office of Inspector General’s Civil Monetary Penalty Rules; Proposed Rule,” 79 *Federal Register* 27079, May 12, 2014.

²⁶ Department of Health and Human Services, Office of Inspector General, “Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Office of Inspector General’s Exclusion Authorities; Proposed Rule,” 79 *Federal Register* 26809, May 12, 2014.

²⁷ Department of the Treasury, Internal Revenue Service, Department of Labor, Employee Benefits Security Administration, and Department of Health and Human Services, Centers for Medicare & Medicaid Services, “Ninety-Day Waiting Period Limitation,” 79 *Federal Register* 10320, February 24, 2014.

²⁸ Department of the Treasury, Internal Revenue Service, Department of Labor, Employee Benefits Security Administration, and Department of Health and Human Services, Centers for Medicare & Medicaid Services, “Amendments to Excepted Benefits,” 78 *Federal Register* 77632, December 23, 2013.

An additional three upcoming proposed rules were expected to be issued in May or June 2014, but had not yet been issued as of June 19, 2014:

- an HHS/CMS rule on “Reform of Requirements for Long-Term Care Facilities and Quality Assurance and Performance Improvement (QAPI) Program”;
- an EEOC rule on “Amendments to Regulations Under the Americans With Disabilities Act”; and
- an EEOC rule on “Amendments to Regulations Under the Genetic Information Nondiscrimination Act of 2008.”

The remaining proposed rules listed in the Unified Agenda are expected to be issued sometime during the remaining months of 2014 or 2015.

Upcoming ACA Final Rules

The Spring 2014 edition of the Unified Agenda listed 17 upcoming rules in the final rule section (indicating that the agencies expected to issue these final rules within the next 12 months). Eleven of the 17 upcoming final rules are expected to be issued by components of HHS: the Health Resources and Services Administration (HRSA, one rule); the Food and Drug Administration (FDA, two rules); and CMS (eight rules). Three of the 17 upcoming final rules are expected to be issued by TREAS/IRS. Other final rules are expected to be issued by DOL’s Occupational Safety and Health Administration (OSHA, one rule); the Architectural and Transportation Barriers Compliance Board (ATBCB, one rule); and the Department of Veterans Affairs (VA, one rule).

Notable Final Rules

As discussed 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 had been considered important enough to be included in the agencies’ regulatory plans:²⁹

- two HHS/FDA rules on “Food Labeling: Calorie Labeling of Articles of Food Sold in Vending Machines” and “Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments,” both of which the agency expects to publish in June 2014;
- an ATBCB rule on “Accessibility Standards for Medical Diagnostic Equipment,” which the agency expects to publish in November 2014.

²⁹ 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. In the spring edition of the agenda, agencies are asked to indicate whether the rules had been published as part of the regulatory plan.

“Economically Significant” or “Major” Final Rules

The Unified Agenda listed seven entries in the final rule section that were considered “economically significant” and/or “major” (i.e., that were expected to have at least a \$100 million annual effect on the economy):

- two HHS/FDA rules on “Food Labeling: Calorie Labeling of Articles of Food Sold in Vending Machines” and “Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments,” both of which the agency expects to publish in June 2014;
- an HHS/CMS rule on “Face-to-Face Requirements for Home Health Services; Policy Changes and Clarifications Related to Home Health,” which the agency expects to publish in September 2014;
- an HHS/CMS rule on “Covered Outpatient Drugs,” which the agency expects to publish in June 2014;
- an HHS/CMS rule on “Prospective Payment System for Federally Qualified Health Centers; Changes to Contracting Policies for Rural Health Clinics and CLIA Enforcement Actions for Proficiency Testing Referral,” which the agency published as a final rule with comment period on May 2, 2014;³⁰
- an HHS/CMS rule on “Adoption of Operating Rules for HIPAA Transactions,” which the agency expects to publish as an interim final rule in March 2015; and
- an HHS/CMS rule on “Eligibility Notices, Fair Hearing and Appeal Processes for Medicaid and Exchange Eligibility Appeals, and Other Eligibility and Enrollment Provisions,” which the agency expects to publish in November 2014.

“Other Significant” Final Rules

In addition to the above-mentioned rules, six additional upcoming final rules listed in 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:

- an HHS/HRSA rule on “Designation of Medically Underserved Populations and Health Professional Shortage Areas,” which the agency expects to publish as an interim final rule in October 2014;
- an HHS/CMS rule on “Reporting and Returning of Overpayments,” which the agency expects to publish in February 2015;
- an HHS/CMS rule on “Medicare Shared Savings Program; Final Waivers,” which the agency expects to publish in November 2014;

³⁰ Department of Health and Human Services, Centers for Medicare & Medicaid Services, “Medicare Program; Prospective 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,” 79 *Federal Register* 25436, May 2, 2014.

- an HHS/CMS rule on “Patient Protection and Affordable Care Act; Third Party Payment of Qualified Health Plan (QHP) Premiums,” which the agency published as an interim final rule on March 19, 2014;³¹
- 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 publish in February 2015; and
- an ATBCB rule on “Accessibility Standards for Medical Diagnostic Equipment,” which the agency expects to publish in November 2014.

Effects on Small Entities

Four of the upcoming final rules indicated they are likely to have effects on small entities (businesses, governments, and/or not-for-profit organizations) as defined by the Regulatory Flexibility Act (RFA, 5 U.S.C. §602), possibly triggering the requirements of the RFA.³²

- an HHS/CMS rule on “Reporting and Returning of Overpayments”;
- an HHS/CMS rule on “Medicare Shared Savings Program; Final Waivers”;
- an HHS/CMS rule on “Eligibility Notices, Fair Hearing and Appeal Processes for Medicaid and Exchange Eligibility Appeals, and Other Eligibility and Enrollment Provisions”;
- an HHS/CMS rule on “Patient Protection and Affordable Care Act; Third Party Payment of Qualified Health Plan (QHP) Premiums.”

Timing of Final Rules

Two of the rules listed in the final rule section of the Unified Agenda had been published as of June 19, 2014:

- an HHS/CMS rule on “Prospective Payment System for Federally Qualified Health Centers; Changes to Contracting Policies for Rural Health Clinics and CLIA Enforcement Actions for Proficiency Testing Referral”;
- an HHS/CMS rule on “Patient Protection and Affordable Care Act; Third Party Payment of Qualified Health Plan (QHP) Premiums.”

An additional five upcoming final rules were expected to be issued in May or June 2014, but had not yet been issued as of June 19, 2014:

- an HHS/FDA rule on “Food Labeling: Calorie Labeling of Articles of Food Sold in Vending Machines”;

³¹ Department of Health and Human Services, Centers for Medicare & Medicaid Services, “Patient Protection and Affordable Care Act; Third Party Payment of Qualified Health Plan Premiums,” 79 *Federal Register* 15240, March 19, 2014.

³² See CRS Report RL34355, *The Regulatory Flexibility Act: Implementation Issues and Proposed Reforms*, coordinated by (name redacted), for an overview of these requirements.

- an HHS/FDA rule on “Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments”;
- an HHS/CMS rule on “Covered Outpatient Drugs”;
- a TREAS/IRS rule on “Branded Prescription Drug Fee”; and
- a TREAS/IRS rule on “Requirement of a Section 4959 Excise Tax Return and Time for Filing the Return.”

The remaining final rules listed in the Unified Agenda are expected to be issued sometime during 2014 or 2015.

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 that the agencies do not expect to take action on in the next 12 months). The Spring 2014 edition of the Unified Agenda listed four long-term actions related to the 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 each of the four long-term actions listed, the agencies said that the dates for the actions were “to be determined”:

- an HHS/HRSA proposed rule on “340B Civil Monetary Penalties for Manufacturers”;
- an HHS/HRSA proposed rule on “340B Drug Pricing Program; Administrative Dispute Resolution Process”;
- an HHS/HRSA proposed rule on “340B Ceiling Price Regulations”; and
- a DOL/EBSA “undetermined” action on “Automatic Enrollment in Health Plans of Employees of Large Employers Under FLSA Section 18A.”

Notable Long-Term Actions

None of the rules in the long-term actions section were considered “major” or “economically significant.” The agencies considered two of the four actions to be “other significant,” meaning that the agencies considered them significant enough to be reviewed by OIRA under Executive Order 12866, but they were not expected to be “economically significant”:

- an HHS/HRSA rule on “340B Drug Pricing Program; Administrative Dispute Resolution Process”; and
- a DOL/EBSA “undetermined” action on “Automatic Enrollment in Health Plans of Employees of Large Employers Under FLSA Section 18A.”

Effects on Small Entities

None of the long-term actions indicated they expected to have an effect on small entities. However, that could be because of the preliminary nature of the rules included in that section.

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 the ACA, Congress must first know what rules are being issued—ideally as early as possible. The Unified Agenda is perhaps the best vehicle to provide that early information, as it describes the rules that are expected to be issued and provides 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 the ACA. Congress may conduct 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.³³ 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.”³⁴ The CRA generally requires federal agencies to submit all of their covered final rules to both houses of Congress and GAO before they can take effect.³⁵ 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.³⁶ 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 makes binding on the affected public.³⁷ 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.

³³ 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.”

³⁴ 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.

³⁵ 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.

³⁶ For a detailed discussion of CRA procedures, see CRS Report RL31160, *Disapproval of Regulations by Congress: Procedure Under the Congressional Review Act*, by (name redacted).

³⁷ 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.”

For a variety of reasons, however, the CRA has been used to disapprove of only one rule in the 18 years since it was enacted.³⁸ 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 the CRA, Congress has regularly included provisions in the text of agencies' appropriations bills in order to influence the regulatory process.³⁹ 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. 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.⁴⁰

This report's **Appendix** contains a table listing the upcoming proposed and final rules published in the Spring 2014 Unified Agenda. 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.⁴¹ 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.

³⁸ 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.

³⁹ For more information on the use of appropriations restrictions, see CRS Report R41634, *Limitations in Appropriations Measures: An Overview of Procedural Issues*, by (name redacted).

⁴⁰ *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.

⁴¹ 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 Patient Protection and Affordable Care Act (ACA)

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Spring 2014 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 [ACA], and would create regulations governing the eligibility, payment amount, reconciliation, and annual reporting for the Teaching Health Centers Graduate Medical Education Program.	09/2014
HHS/OIG	Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Office of the Inspector General's Civil Monetary Penalty Rules (0936-AA04)	This rule makes changes to the Civil Monetary Penalties Law (CMPL) regulations at 42 CFR 1003 to implement authorities under the [ACA] and other statutes. ACA provides for CMPs, assessments, and exclusion for: Failure to grant timely access to OIG; Ordering or prescribing while excluded; Making false statements, omissions, or misrepresentations in an enrollment application; Failure to return an overpayment; and Making or using a false record or statement that is material to a false or fraudulent claim. These statutory changes are reflected in the proposed regulations. We also propose a reorganization of 42 CFR 1003 to make the regulations more accessible to the public, and to add clarity to the regulatory scheme. We propose an alternate methodology for calculating penalties and assessments for employing excluded individuals in positions in which the individuals do not directly bill the Federal health care programs for furnishing items or services. We also clarify the liability guidelines under OIG authorities, including the CMPL, the Emergency Medical Treatment and Labor Act; section 1140 of the Social Security Act for conduct involving electronic mail, Internet, and telemarketing solicitations; and section 1927 of the Social Security Act for late or incomplete reporting of drug-pricing information.	NPRM was published on 05/12/2014 (79 F.R. 27079).
HHS/OIG	Fraud and Abuse; Revisions to the Office of Inspector General's Exclusion Authorities (0936-AA05)	The [ACA] significantly expanded OIG's authority to protect Federal health care programs from fraud and abuse. OIG proposes to update its regulations to codify the changes made by ACA in the regulations. At the same time, OIG proposes updates pursuant to the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) and other statutory authorities, as well as technical changes to clarify and update the regulations.	NPRM was published on 05/09/2014 (79 F.R. 26809).

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Spring 2014 Unified Agenda	Expected Publication Date
HHS/OIG	Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements and Gainsharing (0936-AA06)	This proposed rule amends the safe harbors to the anti-kickback statute and the civil monetary penalty rules under the authority of the Office of Inspector General (OIG). The proposed rule would add new safe harbors, some of which codify statutory changes set forth in the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) and the [ACA], and all of which would protect certain payment practices and business arrangements from criminal prosecution and civil sanctions under the anti-kickback provisions of the statute. We also propose to codify ACA's revised definition of "remuneration" and add a gainsharing civil monetary penalty (CMP or penalty) provision in 42 CFR part 1003.	07/2014
HHS/CMS	State Option To Provide Health Homes for Enrollees With Chronic Conditions (CMS-2331-P) (0938-AQ48)	Under the [ACA], this proposed rule would provide guidance that authorizes a new Medicaid State Plan option to provide health homes for enrollees with chronic conditions.	10/2014
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 requirements for long-term care facilities to reflect significant changes in the industry and remove obsolete or unnecessary provisions. In addition, under the [ACA], 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.	05/2014 Note: NPRM had not been published as of 06/19/2014.
HHS/CMS	CY 2016 Notice of Benefit and Payment Parameters (CMS-9944-P) (0938-AS19)	This proposed rule would establish the CY 2016 payment parameters for the cost-sharing reductions, advance payments of the premium tax credit, reinsurance, and risk adjustment programs as required by the [ACA].	11/2014 Note: Legal deadline for final rule is 03/31/2015.
HHS/CMS	Application of the Mental Health Parity and Addiction Equity Act to Medicaid Programs (CMS-2333-P) (0938-AS24)	Under the [ACA], this proposed rule would implement Mental Health Parity in Medicaid, managed care, CHIP, and alternative benefit plans.	12/2014
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 [ACA]. Section 1557 provides protection from discrimination in health programs and activities of covered entities. This section also identifies additional forms of Federal financial assistance to which the section will apply.	08/2014

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Spring 2014 Unified Agenda	Expected Publication Date
HHS/ACF	Refugee Medical Assistance (0970-AC64)	The Office of Refugee Resettlement proposes to update the refugee medical assistance (RMA) regulations to conform to changes to Medicaid resulting from the implementation of the [ACA]. This update will harmonize RMA and Medicaid income methodologies and reduce the burden on States by eliminating the current need for a separate income determination process for Medicaid and RMA.	02/2015
EEOC	Amendments to Regulations Under the Americans With Disabilities Act (3046-AB01)	This proposed rule would amend 29 CFR section 1630.14(d) to address whether, and to what extent, title I of the Americans with Disabilities Act (ADA) allows employers to offer financial inducements and/or impose financial penalties as part of wellness programs offered through their health plans, and to address other aspects of wellness programs that may be subject to the ADA's nondiscrimination provisions.	06/2014 Note: NPRM had not been published as of 06/19/2014.
EEOC	Amendments to Regulations Under the Genetic Information Nondiscrimination Act of 2008 (3046-AB02)	This proposed rule would amend 29 CFR sections 1635.8(b)(2) and 1635.8(c)(2) to resolve the frequently-asked question of whether employers may offer inducements to employees' spouses or other family members who answer questions about their current medical conditions on a health risk assessment (HRA). Additionally, some technical amendments would correct a typographical error in the rule's discussion of wellness programs and would add references to the [ACA], where appropriate.	06/2014 Note: NPRM had not been published as of 06/19/2014.
DOL/EBSA, HHS/CMS, TREAS/IRS	Ninety-Day Waiting Period Limitation Under the Affordable Care Act (1210-AB61), (0938-AS22), (1545-BL97)	The [ACA] amended title I of the Employment Retirement Income Security Act (ERISA), by adding a new section 715 which encompasses various health reform provisions of the Public Health Service (PHS) Act. These regulations provide guidance on a discrete issue related to the 90-day waiting period limitation under section 2708 of the PHS Act.	NPRM was published on 02/24/2014 (79 F.R. 10320). Note: Legal deadline for final rule was 01/01/2014. EBSA expected to finish analyzing comments by 05/2014. CMS included what appeared to be this rule under a different RIN than what is listed in the actual rule (0938-AR77). IRS did not include this rule in the Agenda.
HHS/CMS, DOL/EBSA, TREAS/IRS	Amendments to Excepted Benefits (CMS-9946-F) (0938-AS16), (1210-AB60), (1545-BL90)	This final rule implements limited excepted benefits under the Employee Retirement Income Security Act of 1974, the Internal Revenue Code, and the Public Health Service Act, as amended by the [ACA]. Excepted benefits are generally exempt from the health reform requirements of those laws. The types of limited excepted benefits addressed by the rule include limited scope vision or dental benefits, and benefits for long-term care, nursing home care, home health care, or community based care. The rule would be effective for plan years starting in 2015 and describes the circumstances under which employers would be permitted to provide wraparound coverage in the form of excepted benefits (limited wraparound coverage) without disqualifying an employee from eligibility for premium tax credits and cost-sharing reductions.	NPRM was published on 12/24/2013 (78 F.R. 77632). Note: CMS, EBSA, and IRS expect to have completed analyzing comments received by 05/2014.

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Spring 2014 Unified Agenda	Expected Publication Date
Final Rules			
HHS/HRSA	Designation of Medically Underserved Populations and Health Professional Shortage Areas (0906-AA44)	The [ACA] 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 [ACA] still requires the Secretary to issue an interim final rule.	10/2014 Note: Original NPRM was published on 09/01/1998 (63 F.R. 46538). Second NPRM was published on 07/23/2008 (73 F.R. 42743).
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 [ACA].	06/2014 Note: NPRM was published on 04/06/2011 (76 F.R. 19238). Final rule had not been published as of 06/19/2014.
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 [ACA].	06/2014 Note: NPRM was published on 04/06/2011 (76 F.R. 19192). Final rule had not been published as of 06/19/2014.
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 [ACA] 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. 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.	09/2014 Note: NPRM was published on 07/12/2011 (76 F.R. 41032).
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 [ACA]. This rule also revises other requirements related to covered outpatient drugs, including key aspects of Medicaid coverage, payment, and the drug rebate program.	06/2014 Note: NPRM was published on 02/02/2012 (77 F.R. 5318). Legal deadline for final rule was 01/01/2010. Final rule had not been published as of 06/19/2014.

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Spring 2014 Unified Agenda	Expected Publication Date
HHS/CMS	Reporting and Returning of Overpayments (CMS-6037-F) (0938-AQ58)	This final rule implements provisions of the [ACA], which require the Secretary to establish a process for a provider or supplier to return an overpayment to the Medicare program, as well as establish a process for CMS and its contractors to receive and apply the overpayment.	02/2015 Note: NPRM was published on 02/16/2012 (77 F.R. 9179). Legal deadline for final rule is 02/16/2015.
HHS/CMS	Medicare Shared Savings Program; Final Waivers (CMS-1439-F) (0938-AR30)	This 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 [ACA] 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).	11/2014 Note: Original interim final rule was published on 11/02/2011 (76 F.R. 67992). Legal deadline for final rule is 11/02/2014.
HHS/CMS	Prospective Payment System for Federally Qualified Health Centers; Changes to Contracting Policies for Rural Health Clinics and CLIA Enforcement Actions for Proficiency Testing Referral (CMS-1443-FC) (0938-AR62)	This final rule establishes methodology and payment rates for a prospective payment system (PPS) for Federally qualified health center (FQHC) services under Medicare Part B beginning on October 1, 2014, in compliance with the statutory requirement of the [ACA]. This rule also establishes a policy which would allow rural health clinics (RHCs) to contract with nonphysician practitioners when statutory requirements for employment of nurse practitioners and physician assistants are met, and makes other technical and conforming changes to the RHC and FQHC regulations. Finally, this rule makes changes to the Clinical Laboratory Improvement Amendments (CLIA) regulations regarding enforcement actions for proficiency testing referral.	Final rule was published on 05/02/2014 (79 F.R. 25436). Note: NPRM was published on 09/23/2013 (78 F.R. 58386). Legal deadline for final rule is 10/01/2014.
HHS/CMS	Adoption of Operating Rules for HIPAA Transactions (CMS-0036-IFC) (0938-AS01)	Under the [ACA], this interim final rule adopts operating rules for HIPAA transactions for health care claims or equivalent encounter information, enrollment and disenrollment of a health plan, health plan premium payments, and referral certification and authorization.	03/2015 Note: Expected to be issued as interim final rule. Statute requires operating rules be effective January 1, 2016.
HHS/CMS	Eligibility Notices, Fair Hearing and Appeal Processes for Medicaid and Exchange Eligibility Appeals, and Other Eligibility and Enrollment Provisions (CMS-2334-F2) (0938-AS27)	The [ACA] expands access to health insurance through improvements in Medicaid; the establishment of Affordable Insurance Exchanges; and coordination between Medicaid, CHIP, and Exchanges. This rule finalizes the remaining provisions proposed in the January 19, 2013, proposed rule, but not finalized in the July 15, 2013, final rule to continue our efforts to assist states in implementing Medicaid eligibility, appeals, and enrollment changes, and other state health subsidy programs.	11/2014 Note: NPRM referred to appears to have been proposed on 02/22/2013 (78 F.R. 4594).

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Spring 2014 Unified Agenda	Expected Publication Date
HHS/CMS	Patient Protection and Affordable Care Act; Third Party Payment of Qualified Health Plan (QHP) Premiums (CMS-9943-IFC) (0938-AS28)	This interim final rule is intended to ensure that QHP issuers accept third party payments from State and Federal Government programs. Some QHP issuers are refusing to accept third party payments, including payments from the Ryan White HIV/AIDS Program, for premiums for Marketplace plans causing clients to lose coverage.	Interim final rule published on 03/19/2014 (79 F.R. 15240).
DOL/OSHA	Procedures for the Handling of Retaliation Complaints Under Section 1558 of the Affordable Care Act of 2010 (1218-AC79)	OSHA is promulgating procedures for the handling and investigation of retaliation complaints pursuant to Section 1558 of the [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 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.	02/2015 Note: Original interim final rule published on 02/27/2013 (78 F.R. 13222).
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 [ACA].	06/2014 Note: NPRM was published on 08/18/2011 (76 F.R. 51310). Final rule had not been published as of 06/19/2014.
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 [ACA], 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.	12/2014 Note: NPRM was published on 08/26/2013 (78 F.R. 52719).
TREAS/IRS	Requirement of a Section 4959 Excise Tax Return and Time for Filing the Return (1545-BL57)	The regulations provide guidance to charitable hospital organizations that are liable for the excise tax, enacted as part of the [ACA], for failing to satisfy the community health needs assessment (CHNA) requirements. The regulations specify the return to accompany payment of the excise tax and the time for filing that return.	06/2014 Note: NPRM was published on 08/15/2013 (78 F.R. 49700). Final rule had not been published as of 06/19/2014.

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Spring 2014 Unified Agenda	Expected Publication Date
VA	Enrollment and Disenrollment Procedures in the Veterans' Health Care Program, CHAMPVA, and the Spina Bifida Health Care Benefits Program (2900-AO97)	The Department of Veterans Affairs (VA) amends its regulations to clarify and establish enrollment and disenrollment procedures for three VA programs that provide comprehensive health care to veteran and non-veteran VA beneficiaries. These amendments are necessary so that VA is compliant with reporting requirements issued by the Internal Revenue Service to implement portions of the [ACA]. These amendments do not affect the provision of VA health care benefits to VA beneficiaries.	08/2014 Note: Expected to be interim final rule.
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.	11/2014 Note: NPRM was published on 02/09/2012 (77 FR 6916). Legal deadline was 03/22/2012.

Source: Information in the first three columns is verbatim as reported in the Unified Agenda of Federal Regulatory and Deregulatory Actions, May 23, 2014, at <http://www.reginfo.gov/public/do/eAgendaMain>. Expected publications dates and information about legal deadlines listed in the fourth column are from the Unified Agenda. Publication information on the rules that have been published is from the *Federal Register* itself, accessed through the Government Printing Office's Federal Digital System.

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

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