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

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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 (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- "completed" actions (i.e., final rules or rules that have been withdrawn since the last edition of the Unified Agenda); and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 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 November 26, 2013, is the sixth edition of the agenda since enactment of ACA. In this edition, agencies reported 19 proposed rules and 20 final rules that they expect to issue pursuant to ACA within the next 12 months. Agencies also reported a total of 12 long-term regulatory actions.

The **Appendix** of this report lists the upcoming proposed and final rules published in the Fall 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. 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 entitled "The War Isn't Over," 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.

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[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 may 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, 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 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 law does not, however, 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.[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 Todd Garvey et al.

[7] 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 may be directed to the authors 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

(...continued)

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 Fall 2013 edition of the Unified Agenda, published on November 26, 2013, is the sixth edition compiled and issued by RISC since enactment of the ACA.[15] Federal agencies were required to submit data to RISC for the Unified Agenda by August 29, 2013, but some items may have been subsequently updated during the OIRA review process.[16]

This report examines the Fall 2013 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 19 proposed rules and 20 final rules they expect to issue pursuant to the ACA within the next 12 months. Agencies also reported a total of 12 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]

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[14] 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 may be directed to the authors of this report.

[15] Following the ACA's enactment in March 2010, the first edition of the Unified Agenda containing regulations that were to be issued pursuant to the ACA was issued on December 20, 2010.

[16] Memorandum from Howard Shelanski, Administrator of the Office of Information and Regulatory Affairs, "Memorandum for Regulatory Policy Officers at Executive Departments and Agencies & Managing and Executive Directors of Certain Agencies and Commissions," August 7, 2013, at http://www.whitehouse.gov/sites/default/files/omb/inforeg/memos/fall-2013-regulatory-plan-and-agenda.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.

[17] 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**.

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

Upcoming ACA Proposed Rules

The Fall 2013 edition of the Unified Agenda listed 19 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] Twelve of the 19 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, seven rules), the Office of Inspector General (OIG, three rules), the Health Resources and Services Administration (HRSA, one rule), and the Office for Civil Rights (OCR, one rule). Other proposed rules were expected to be issued by the Treasury Department's Internal Revenue Service (TREAS/IRS, four rules) and the Office of Personnel Management (OPM, two rules). The final upcoming proposed rule is expected to be issued by the Department of Labor's Employee Benefits Security Administration (DOL/EBSA).

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 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. HHS considered one of the items in the proposed rule section of the Unified Agenda important enough to be included in its regulatory plan: a rule pertaining to "Eligibility, Enrollment, and Appeals Updates" (expected to be issued in February 2014).

"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 three other rules that CMS considered "economically significant" and "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] The three CMS rules are

- a rule on "Prospective Payment System for Federally Qualified Health Centers; Changes to Contracting Policies for Rural Health Clinics and CLIA Enforcement

[19] 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 they would each report it separately to the Unified Agenda, and such a rule would appear as two actions. None of the rules listed in the Unified Agenda indicated that they are joint rules, however, so that is unlikely in this case. (As explained below, two of the rules listed in the "final rule stage" are actually a single joint rule.)

[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 Maeve P. Carey.

Actions for Proficiency Testing Referral," which CMS published as a proposed rule on September 23, 2013, and expects to publish as a final rule in August 2014;[21]

- a rule on "CY 2015 Notice of Benefit and Payment Parameters," which CMS published as a proposed rule on December 2, 2013;[22] and
- a rule on "Establishment of the Basic Health Program," which the agency published as a proposed rule on September 25, 2013, and expects to publish as a final rule in March 2014.[23]

"Other Significant" Proposed Rules

In addition to the above-mentioned rules, the agencies characterized 6 of the 19 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.[24] The "other significant" proposed rules are

- an HHS/CMS rule on "Administrative Simplification: Compliance: Health Plan Certification," which CMS published as a proposed rule on January 2, 2014;[25]
- an HHS/CMS rule on "Reform of Requirements for Long-Term Care Facilities and Quality Assurance and Performance Improvement (QAPI) Program," which the agency expects to publish sometime in March 2014;
- an HHS/CMS rule on "Establishment of Quality Standards for Exchanges and Qualified Health Plans (QHPs)," which the agency expects to publish sometime in March 2014;
- an HHS/CMS rule on "Eligibility, Enrollment, and Appeals Updates," which the agency expects to publish sometime in February 2014;

[21] 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.

[22] U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2015," 78 *Federal Register* 72322, December 2, 2013.

[23] U.S. 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.

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

[25] U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, "Administrative Simplification: Certification of Compliance for Health Plans; Proposed Rule," 79 *Federal Register* 297, January 2, 2014.

- an HHS/OCR rule on "Nondiscrimination Under the Patient Protection and Affordable Care Act," which the agency expects to publish sometime in August 2014; and
- a DOL/EBSA rule on "Amendments to Excepted Benefits," which the agency published as a proposed rule on December 24, 2013.[26]

Effects on Small Entities

The Regulatory Flexibility Act (5 U.S.C. §602) 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).[27] Five of the ACA-related rules listed in the proposed rule section were expected to trigger the requirements of the Regulatory Flexibility Act because of their effects on small entities.

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

- an HHS/CMS rule on "Administrative Simplification: Compliance: Health Plan Certification"; and
- an HHS/CMS rule on "Reform of Requirements for Long-Term Care Facilities and Quality Assurance and Performance Improvement (QAPI) Program."

Two of the upcoming proposed rules were expected to trigger the requirements of the Regulatory Flexibility Act because of their effects on small businesses and local governments:

- an HHS/CMS rule on "CY 2015 Notice of Benefit and Payment Parameters"; and
- an HHS/CMS rule on "Eligibility, Enrollment, and Appeals Updates."

The HHS/CMS rule on "Establishment of Quality Standards for Exchanges and Qualified Health Plans (QHPs)" is also expected to have an effect on small businesses, local governments, and not-for-profit organizations, another potential trigger for the Regulatory Flexibility Act's analysis requirement.

Timing of the Proposed Rules

As of January 23, 2014, nine items in the proposed rule section of the Unified Agenda had been published in the *Federal Register* as a proposed rule. The rules for which proposed rules have been published are

[26] U.S. Department of the Treasury, Internal Revenue Service; U.S. Department of Labor, Employee Benefits Security Administration; and U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, "Amendments to Excepted Benefits," 79 *Federal Register* 77632. Although this proposed rule was published jointly by TREAS/IRS, DOL/EBSA, and HHS/CMS, only DOL/EBSA listed it in the Unified Agenda.

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

- 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";[28]
- an HHS/CMS rule on "CY 2015 Notice of Benefit and Payment Parameters";[29]
- an HHS/CMS rule on "Establishment of the Basic Health Program";[30]
- an HHS/CMS rule on "Administrative Simplification: Compliance: Health Plan Certification";[31]
- a DOL/EBSA rule on "Amendments to Excepted Benefits";[32]
- a TREAS/IRS rule on "Fees on Health Insurance and Self-Insured Plans";[33]
- a TREAS/IRS rule on "Reporting and Notice Requirements Under Section 6056";[34]
- a TREAS/IRS rule on "Tax Credit for Employee Health Insurance Expenses of Small Employers";[35] and
- a TREAS/IRS rule on "Requirement of a Section 4959 Excise Tax Return and Time for Filing the Return."[36]

[28] 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.

[29] U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2015," 78 *Federal Register* 72322, December 2, 2013.

[30] U.S. 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.

[31] U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, "Administrative Simplification: Certification of Compliance for Health Plans; Proposed Rule," 79 *Federal Register* 297, January 2, 2014.

[32] U.S. Department of the Treasury, Internal Revenue Service; U.S. Department of Labor, Employee Benefits Security Administration; and U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, "Amendments to Excepted Benefits," 79 *Federal Register* 77632.

[33] TREAS/IRS published this rule as an NPRM on April 17, 2012, and a final rule on December 6, 2012. It is unclear why the rule is listed in the proposed rule section of the Fall 2013 Unified Agenda. See U.S. Department of the Treasury, Internal Revenue Service, "Fees on Health Insurance Policies and Self-Insured Plans for the Patient-Centered Outcomes Research Trust Fund," 77 *Federal Register* 22691, April 17, 2012 (proposed rule); and U.S. Department of the Treasury, Internal Revenue Service, "Fees on Health Insurance Policies and Self-Insured Plans for the Patient-Centered Outcomes Research Trust Fund," 77 *Federal Register* 72721, December 6, 2012 (final rule).

[34] U.S. Department of the Treasury, Internal Revenue Service, "Information Reporting by Applicable Large Employers on Health Insurance Coverage Offered Under Employer-Sponsored Plans," 78 *Federal Register* 54996, September 9, 2013.

[35] U.S. Department of the Treasury, Internal Revenue Service, "Tax Credit for Employee Health Insurance Expenses of Small Employers," 78 *Federal Register* 57219, August 26, 2013.

[36] U.S. Department of the Treasury, Internal Revenue Service, "Requirement of a Section 4959 Excise Tax Return and Time for Filing the Return," 78 *Federal Register* 49700, August 15, 2013.

One proposed rule was expected to be published sometime during December 2013, but had not been published as of January 23, 1014. That rule is an OPM rule on "Federal Employees' Health Benefits Program; Disputed Claims and External Review Requirements."

Upcoming ACA Final Rules

The Fall 2013 edition of the Unified Agenda listed 20 upcoming rules in the final rule section (indicating that the agencies expected to issue these final rules within the next 12 months).[37] Eight of the 20 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); CMS (four rules); and the Office of the Secretary (OS, one rule). Seven of the 20 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); the Office of Personnel Management (OPM, one rule); and the Social Security Administration (SSA, one rule). Finally, one rule will be issued jointly by DOL/EBSA, HHS/CMS, and TREAS/IRS.

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

Four 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:[38]

- 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 February 2014;
- an ATBCB rule on "Accessibility Standards for Medical Diagnostic Equipment," which the agency expects to publish in September 2014; and
- an SSA rule on "Conforming Changes to Regulations Regarding Income-Related Monthly Adjustment Amounts to Medicare Part B Premiums," which the agency

[37] The Unified Agenda reported 21 actions in the final rule category, but the 21 actions actually represent 20 rules. One of the rules is a joint rule, and joint rules are listed once in the Unified Agenda by each participating agency. Both HHS/CMS and DOL/EBSA submitted an entry for the joint rule on "Ninety-Day Waiting Period Limitation and Technical Amendments to Certain Health Coverage Requirements Under the Affordable Care Act," and therefore it is listed twice in the final rules section of the Unified Agenda database. In this report, it is counted as only one rule. The joint rule is listed at the end of the **Appendix**.

[38] 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.

published as an interim final rule with request for comments on September 18, 2013.[39]

"Economically Significant" or "Major" Final Rules

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

- 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 February 2014;
- an HHS/CMS rule on "Home and Community-Based State Plan Services Program, Waivers, and Provider Payment Reassignments," which the agency published as a final rule on January 16, 2014;[40]
- 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 May 2014; and
- an HHS/CMS rule on "Adoption of Operating Rules for HIPAA Transactions," which the agency expects to publish in June 2014.

"Other Significant" Final Rules

In addition to the above-mentioned rules, seven other 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. These seven rules are

- 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 September 2014;
- an HHS/OS rule on "Health and Human Services Acquisition Regulation (HHS' Supplement to the Federal Acquisition Regulation)," which the agency expects to publish as an interim final rule in April 2014;

[39] 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.

[40] U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, "Medicaid Program; State Plan Home and Community-Based Services, 5-Year Period for Waivers, Provider Payment Reassignment, and Home and Community-Based Setting Requirements for Community First Choice and Home and Community-Based Services (HCBS) Waivers; Final Rule," 79 *Federal Register* 2947, January 16, 2014.

- 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 July 2014;
- an ATBCB rule on "Accessibility Standards for Medical Diagnostic Equipment," which the agency expects to publish in September 2014;
- an OPM rule on "Federal Employees' Health Benefits Program: Members of Congress and Congressional Staff," which the agency expects to publish as a final rule in 2014;
- an SSA rule on "Conforming Changes to Regulations Regarding Income-Related Monthly Adjustment Amounts to Medicare Part B Premiums," which the agency published as an interim final rule with request for comments on September 18, 2013;[41] and
- an HHS/CMS and DOL/EBSA joint rule on "Ninety-Day Waiting Period Limitation and Technical Amendments to Certain Health Coverage Requirements Under the Affordable Care Act," which HHS indicated would be published in December 2013 and DOL/EBSA indicated would be published in February 2014 (the rule had not been published as of January 23, 2014).[42]

Effects on Small Entities

Two of the upcoming final rules were expected to trigger the requirements of the Regulatory Flexibility Act (5 U.S.C. §602) because of their effects on small businesses:

- an HHS/CMS rule on "Home and Community-Based State Plan Services Program, Waivers, and Provider Payment Reassignments"; and
- an HHS/CMS rule on "Ninety-Day Waiting Period Limitation and Technical Amendments to Certain Health Coverage Requirements Under the Affordable Care Act." Although this rule will be issued jointly with DOL/EBSA, DOL/EBSA did not indicate in its Unified Agenda entry that the requirements of the Regulatory Flexibility Act would be triggered.

Timing of Final Rules

Five of the rules listed in the final rule section of the Unified Agenda had been published as of January 23, 2014:

- an HHS/CMS rule on "Home and Community-Based State Plan Services Program, Waivers, and Provider Payment Reassignments";[43]

[41] 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.

[42] This rule will also be issued jointly with TREAS/IRS, though TREAS/IRS included it in the "Long-Term Actions" portion of the Unified Agenda and estimated it would be published in December 2014.

[43] U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, "Medicaid Program; State Plan Home and Community-Based Services, 5-Year Period for Waivers, Provider Payment Reassignment, and Home and Community-Based Setting Requirements for Community First Choice and Home and Community-Based Services (HCBS) Waivers; Final Rule," 79 *Federal Register* 2947, January 16, 2014.

- a TREAS/IRS rule on "Medical Loss Ratio for Section 833 Organizations";[44]
- a TREAS/IRS rule on "Rules Relating to the Additional Medicare Tax";[45]
- a TREAS/IRS rule on "Health Insurance Provider Fees";[46] and
- an SSA rule on "Conforming Changes to Regulations Regarding Income-Related Monthly Adjustment Amounts to Medicare Part B Premiums."[47]

An additional two upcoming final rules were expected to be issued in December 2013, but had not yet been issued as of January 23, 2014:

- a TREAS/IRS rule on "Community Health Needs Assessments for Charitable Hospitals"; and
- an HHS/CMS and DOL/EBSA joint rule on "Ninety-Day Waiting Period Limitation and Technical Amendments to Certain Health Coverage Requirements Under the Affordable Care Act."[48]

The remaining final rules listed in the Unified Agenda are expected to be issued sometime during 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 Fall 2013 edition of the Unified Agenda listed 12 long-term actions related to ACA. In comparison to the proposed and final rules previously discussed, it is much less clear when the ACA-related long-term actions are expected to occur. In 4 of the 12 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."

[44] U.S. Department of the Treasury, Internal Revenue Service, "Computation of, and Rules Relating to, Medical Loss Ratio," 79 *Federal Register* 755, January 7, 2014.

[45] U.S. Department of the Treasury, Internal Revenue Service, "Rules Relating to Additional Medicare Tax," 78 *Federal Register* 71468, November 29, 2013.

[46] U.S. Department of the Treasury, Internal Revenue Service, "Health Insurance Providers Fee," 78 *Federal Register* 71476, November 29, 2013.

[47] 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.

[48] This rule will also be issued jointly with TREAS/IRS, although TREAS/IRS included it in the long-term actions portion of the Unified Agenda and estimated it would be published in December 2014.

Of the eight remaining long-term actions for which agencies provided an estimated date of publication, two are expected to be published in November 2014:

- an HHS/CMS final rule on "Medicare Shared Savings Program; Final Waivers"; and
- a Department of Justice/Civil Rights Division (CRT) advance notice of proposed rulemaking on "Nondiscrimination on the Basis of Disability by State and Local Governments and Public Accommodations: Accessibility of Medical Equipment and Furniture."

Four rules are estimated to be published in December 2014, all of which are TREAS/IRS final rules:

- "Group Health Plans and Health Insurance Issuers Providing Dependent Coverage of Children to Age 26 Under the Patient Protection and Affordable Care Act";
- "Group Health Plans and Health Insurance Coverage Rules Relating to Status as a Grandfathered Health Plan Under the Patient Protection and Affordable Care Act";
- "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"; and
- "Requirements for Group Health Plans and Health Insurance Issuers Relating to Internal Claims and Appeals and External Review Processes Under the Patient Protection and Affordable Care Act."

One additional item indicating that its estimated publication would be December 2014 was a TREAS/IRS rule referenced earlier in this report that will be issued jointly with HHS/CMS and DOL/EBSA entitled "Ninety-Day Waiting Period Limitation and Technical Amendments to Certain Health Coverage Requirements Under the Affordable Care Act." HHS/CMS indicated in the Unified Agenda that they expected the rule to be issued in December 2013, while DOL/EBSA estimated that the rule would be issued in February 2014.

Finally, one regulatory action is expected in 2015: an HHS/CMS final rule on "Reporting and Returning of Overpayments," which the agency estimates it will publish in February 2015.

Notable Long-Term Actions

None of the rules in the long-term actions section were considered "major." In 8 of the 12 actions listed, agencies indicated that they did not expect the rules to be "major," and in the remaining 4, agencies had not yet determined whether any of the rules would be "major."

The agencies considered 5 of the 12 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":

- 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 the 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, as it describes not only what rules 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, 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.[49] 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."[50] 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.[51] 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.[52] 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)

[49] 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."

[50] 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.

[51] 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.

[52] 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.

that the agency wishes to make binding on the affected public.[53] After these rules are submitted, Congress can use the expedited procedures specified in the CRA to disapprove any of the rules. CRA resolutions of disapproval must be presented to the President for signature or veto.

For a variety of reasons, however, the CRA has been used to disapprove of only one rule in the 18 years since it was enacted.[54] 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.[55] 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.[56]

This report's **Appendix** contains a table listing the upcoming proposed and final rules published in the Fall 2013 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.[57] 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.

[53] 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."

[54] 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.

[55] 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.

[56] 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.

[57] 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

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Fall 2013 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 (ACA) 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/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.	04/2014
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.	04/2014

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Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Fall 2013 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 [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	Administrative Simplification: Compliance: Health Plan Certification (CMS-0037-P) (0938-AQ85)	This proposed rule would implement provisions of the [ACA] 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.	NPRM was published on 01/02/2014 (79 F.R. 297). Note: Legal deadline was 12/31/2013.
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 [ACA], this rule would propose to expand the level and scope of required [Quality Assurance & Performance Improvement] activities to ensure that facilities continuously identify and correct quality deficiencies as well as promote and sustain performance improvement.	03/2014
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-F) (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.	NPRM was published on 09/23/2013 (78 F.R. 58386). Note: Legal deadline is 10/01/2014. Final rule expected 08/2014.

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Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Fall 2013 Unified Agenda	Expected Publication Date
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 [ACA].	NPRM was published on 12/02/2013 (78 F.R. 72322). Note: Proposed and subsequent final rule must precede plan approval and open enrollment (must be complete by 01/01/2014).
HHS/CMS	Establishment of the Basic Health Program (CMS-2380-F) (0938-AR93)	This final rule establishes the Basic Health Program as required by the [ACA]. The Basic Health Program provides States the flexibility to establish an alternative coverage program for low-income individuals who would otherwise be eligible to purchase coverage through the exchange. This final rule addresses eligibility and enrollment, benefits, delivery of health care services, transfer of funds to participating states, and secretarial oversight relating to the Basic Health Program.	NPRM was published on 09/25/2013 (78 F.R. 58786). Note: Legal deadline was 01/01/2014. Final rule expected 03/2014.
HHS/CMS	Establishment of Quality Standards for Exchanges and Qualified Health Plans (QHPs) (CMS-3288-P) (0938-AS00)	This proposed rule would establish requirements for exchanges and for qualified health plans to implement specific quality related provisions of the [ACA]. In addition, this rule would establish an appeals process for enrollee satisfaction survey vendors.	03/2014
HHS/CMS	Eligibility, Enrollment, and Appeals Updates (CMS-9949-P) (0938-AS02)	This proposed rule would update policy based on experience with initial open enrollment.	02/2014
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
DOL/EBSA	Amendments to Excepted Benefits (1210-AB60)	This document contains proposed rules that would amend the regulations regarding 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 Health Insurance Portability and Accountability Act (HIPAA) and the [ACA].	NPRM was published on 12/24/2013 (78 F.R. 77632).

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Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Fall 2013 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 [ACA], on fees imposed on health insurance and self-insured health plans.	12/2013 Note: TREAS/IRS published this rule as an NPRM on 04/17/2012 (77 F.R. 22691) and a final rule on 12/06/2012 (77 F.R. 72721). It is unclear why the rule is listed in the proposed rule section of the Unified Agenda.
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 [ACA], 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	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.	NPRM was published on 08/23/2013 (78 F.R. 52719). Note: Final rule listed as expected 12/2013; had not been published as of 01/23/2014.
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.	NPRM was published 08/15/2013 (78 F.R. 49700).
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 [ACA].	12/2013 Note: NPRM had not been published as of 01/23/2014.

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Fall 2013 Unified Agenda	Expected Publication Date
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 [ACA].	02/2014
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 at some point in the future.	09/2014 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].	02/2014 Note: NPRM was published on 04/06/2011 (76 F.R. 19238).
HHS/FDA	Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments (0910-AG57)	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].	02/2014 Note: NPRM was published on 04/06/2011 (76 F.R. 19192).

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Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Fall 2013 Unified Agenda	Expected Publication Date
HHS/CMS	Home and Community-Based State Plan Services Program, Waivers, and Provider Payment Reassignments (CMS-2249-F) (0938-AO53)	This final rule defines and describes state plan home and community-based services (HCBS) under the [ACA]. It describes Medicaid coverage of an optional state plan benefit to furnish HCBS and draw federal matching funds. Also, this rule makes several changes to the regulations implementing Medicaid HCBS waivers.	Final rule was published on 01/16/2014 (79 F.R. 2947). Note: NPRM was published on 04/04/2008 (73 F.R. 18676); second NPRM was published on 05/03/2012 (77 F.R. 26362).
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.	05/2014 Note: NPRM was published on 02/02/2012. Legal deadline was 01/01/2010.
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.	06/2014 Note: Statute requires operating rules be adopted by 07/01/2014 and effective 01/01/2016.

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Fall 2013 Unified Agenda	Expected Publication Date
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 FY 2012 Appropriations Acts and to establish HHS' nondiscrimination policy.	04/2014
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 [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. The ACA interim final rule was published February 27, 2013.	07/2014 Note: Interim final rule was 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.	06/2014 Note: NPRM was published on 08/18/2011 (76 F.R. 51310).
TREAS/IRS	Requirements for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act (1545-BJ58)	These proposed regulations provide guidance requiring coverage of certain preventive health services without cost-sharing under section 2713 of the Public Health Service Act, incorporated into section 9815 of the Internal Revenue Code by section 1563(f) of the [ACA].	07/2014 Note: NPRM was published on 07/19/2010; second NPRM was published on 03/03/2011.

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Fall 2013 Unified Agenda	Expected Publication Date
TREAS/IRS	Rules Relating to the Additional Medicare Tax (1545-BK54)	Proposed amendments of sections 31.3101, 31.3102, 31.3202, 31.1401, 31.6205, 31.6011, 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 [ACA], 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).
TREAS/IRS	Medical Loss Ratio for Section 833 Organizations (1545-BL05)	The final regulations will provide guidance under section 833(c)(5) of the Internal Revenue Code, as added by section 9016 of the [ACA], on the 85 percent medical loss ratio requirement under section 833.	Final rule was published on 01/07/2014 (79 F.R. 755). Note: NPRM was published on 05/13/2013 (78 F.R. 27873).
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	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 [ACA]. 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.	12/2013 Note: NPRM was published on 04/02/2013 (78 F.R. 20523). Final rule had not been published as of 01/23/2014.

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Fall 2013 Unified Agenda	Expected Publication Date
TREAS/IRS	Shared Responsibility for Employers Regarding Health Coverage (1545-BL33)	Final regulations under section 4980H of the Internal Revenue Code, as enacted by the [ACA], 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). Final rule had not been published as of 01/23/2014.
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.	09/2014 Note: NPRM was published on 02/09/2012 (77 F.R. 6916). Legal deadline was 03/22/2012.
OPM	Federal Employees' Health Benefits Program: Members of Congress and Congressional Staff (3206-AM85)	The United States Office of Personnel Management (OPM) plans to issue a final rule to amend the Federal Employees' Health Benefits (FEHB) Program regulations regarding coverage for Members of Congress and congressional staff, in light of the new requirement in section 1312 of the [ACA].	03/2014 Note: NPRM was published on 08/08/2013 (78 F.R. 48337).
SSA	Conforming Changes to Regulations Regarding Income-Related Monthly Adjustment Amounts to Medicare Part B Premiums (3734I) (0960-AH47)	We 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 [ACA]. 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 was published 09/18/2013 (78 F.R. 57257).

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Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Fall 2013 Unified Agenda	Expected Publication Date
HHS/CMS, DOL/EBSA, TREAS/IRS	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 [ACA], 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 [ACA] provisions already in effect as well as those that will become effective beginning 2014.	12/2013 Note: CMS and EBSA listed this joint rule separately in the Unified Agenda; CMS estimated the final rule to be completed in 12/2013 and EBSA estimated it to be completed in 02/2014. IRS listed the rule in the long-term actions section of the Agenda and estimated it would be published in 12/2014. NPRM was published 03/21/2013 (78 F.R. 17313). Legal deadline was 01/01/2014. Final rule had not been published as of 01/23/2014.

Source: Information in the first three columns is verbatim as reported in the Unified Agenda of Federal Regulatory and Deregulatory Actions, November 26, 2013, 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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