Upcoming Rules Pursuant to the Patient Protection and Affordable Care Act: The 2012 Unified Agenda

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February 1, 2013

Congressional Research Service
7-5700
www.crs.gov
R42946

CRS Report for Congress
Prepared for Members and Committees of Congress

Summary

The Patient Protection and Affordable Care Act (ACA, as amended) was signed into law by President Barack Obama on March 23, 2010. ACA is a comprehensive overhaul of the health care system that includes such provisions as the expansion of eligibility for Medicaid, amendments to Medicare that are intended to reduce its growth, an individual mandate for the purchase of health insurance, and the establishment of insurance exchanges through which individuals and families can receive federal subsidies to help them purchase insurance. As is the case with many laws that Congress passes, ACA contains many instances of delegation of rulemaking authority to federal agencies.

One way in which Congress can identify upcoming rules and regulations that will be issued pursuant to ACA is by reviewing the Unified Agenda of Federal Regulatory and Deregulatory Actions (hereafter, 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) Office of Information and Regulatory Affairs (OIRA). The Unified Agenda lists upcoming activities, by agency, in three separate categories:

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- "completed" actions (i.e., final rules or rules that have been withdrawn since the last edition of the Unified Agenda); and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

All entries in the Unified Agenda have uniform data elements, including the department and agency issuing the rule, the title of the rule, 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 December 21, 2012, is the fourth edition of the Unified Agenda since enactment of ACA. In this edition, agencies reported 23 proposed rules and 18 final rules that they expect to issue pursuant to ACA within the next 12 months. Agencies also reported a total of 22 long-term regulatory actions and 20 completed actions.

The Appendix of this report lists the upcoming proposed and final rules published in the 2012 Unified Agenda in a table.

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Introduction

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

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

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

Mandatory and Discretionary Rulemaking Provisions

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

[1] ACA was signed into law on March 23, 2010 (P.L. 111-148, 124 Stat. 119). On March 30, 2010, the President signed the Health Care and Education Reconciliation Act (HCERA; P.L. 111-152, 124 Stat. 1029), which amended multiple health care and revenue provisions in ACA. Note that previous CRS reports on the Patient Protection and Affordable Care Act used the acronym PPACA to refer to the law. CRS is now using the more common acronym ACA. For more information on ACA, see CRS Report R41664, *ACA: A Brief Overview of the Law, Implementation, and Legal Challenges*, 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 is no longer at CRS; questions about its content can be directed to the authors of this report.

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

[4] Although the law contains a number of deadlines for the issuance of rules, rulemaking deadlines are generally somewhat difficult to enforce, unless the statute itself contains an enforcement mechanism. None of the provisions in ACA contain a legislative enforcement mechanism. One potential option for enforcement is civil litigation, although (continued...)

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

Congressional Oversight and the Unified Agenda

In his book *Building a Legislative-Centered Public Administration*, David H. Rosenbloom noted that rulemaking and lawmaking are functionally equivalent (the results of both processes have the force of law), and that when agencies issue rules they, in effect, legislate. He went on to say that the "Constitution's grant of legislative power to Congress encompasses a responsibility to ensure that delegated authority is exercised according to appropriate procedures."[5] Congressional oversight of rulemaking can deal with a variety of issues, including the substance of the rules issued pursuant to congressional delegations of authority and the process by which those rules are issued.

Having an early sense of what rules the agencies are going to issue and when can help Congress to provide 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.[6] However, the law does not indicate when some of the mandatory rules should be issued.

The Unified Agenda

A potentially effective way for Congress to identify upcoming ACA rules is by reviewing the Unified Agenda, which is usually published twice each year (in the spring and fall).[7] The Unified Agenda is published by the Regulatory Information Service Center (RISC), a component of the U.S. General Services Administration (GSA), for the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA).[8] The Unified Agenda helps agencies fulfill two current transparency requirements:

- The Regulatory Flexibility Act (5 U.S.C. §602) requires that all agencies publish semiannual regulatory agendas in the *Federal Register*, in April and October of

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courts often defer to agencies' judgment on the timing of their issuance of a rule.

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

[6] CRS Report R41180, *Rulemaking Requirements and Authorities in the Patient Protection and Affordable Care Act (PPACA)*, by Curtis W. Copeland. The author of that report is no longer at CRS; questions about its content can be directed to the authors of this report.

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

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

each year, describing regulatory actions that they are developing that may have a significant economic impact on a substantial number of small entities.[9]

- Section 4 of Executive Order 12866 on "Regulatory Planning and Review" requires that all executive branch agencies "prepare an agenda of all regulations under development or review."[10] The stated purposes of this and other planning requirements in the order are, among other things, to "maximize consultation and the resolution of potential conflicts at an early stage" and to "involve the public and its State, local, and tribal officials in regulatory planning." The executive order also requires that each agency prepare, as part of the fall edition of the Unified Agenda, a "regulatory plan" of the most important significant regulatory actions that the agency reasonably expects to issue in proposed or final form during the upcoming fiscal year.

The Unified Agenda lists upcoming activities, by agency, in three separate categories:

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

All entries in the Unified Agenda have uniform data elements, including the department and agency issuing the rule, the title of the rule, the Regulation Identifier Number (RIN),[11] an abstract describing the nature of action being taken, and a timetable showing the dates of past actions and a projected date (sometimes just the projected month and year) for the next regulatory action. Each entry also contains an element indicating the priority of the regulation (e.g., whether it is considered "economically significant" under Executive Order 12866, or whether it is considered a "major" rule under the Congressional Review Act).[12]

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

[10] Executive Order 12866, "Regulatory Planning and Review," 58 *Federal Register* 51735, October 4, 1993. Although most of the requirements in this executive order do not apply to independent regulatory agencies (e.g., the Securities and Exchange Commission and Federal Reserve Board), this section of the order does include those agencies.

[11] RINs are assigned by RISC, and the Office of Management and Budget has asked agencies to include RINs in the headings of their rulemaking documents when they are published in the *Federal Register* to make it easier for the public and agency officials to track the publication history of regulatory actions. For a copy of this memorandum, see http://www.whitehouse.gov/sites/default/files/omb/assets/inforeg/IncreasingOpenness_04072010.pdf.

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

There is no penalty for issuing a rule without a prior notice in the Unified Agenda, and some prospective rules listed in the Unified Agenda never get issued, reflecting the fluid nature of the rulemaking process. Nevertheless, the Unified Agenda can help Congress and the public know what regulatory actions are about to occur, and it arguably provides federal agencies with the most systematic, government-wide method to alert the public about their upcoming proposed rules.[13]

This Report

The December 21, 2012, edition of the Unified Agenda is the fourth edition that RISC has compiled and issued since the enactment of ACA.[14] Federal agencies were required to submit data to RISC for the Unified Agenda by September 7, 2012, but some items may have been subsequently updated during the OIRA review process.[15]

This report examines the December 21, 2012, edition of the Unified Agenda and identifies upcoming proposed and final rules and long-term regulatory actions that are expected to be issued pursuant to ACA in the next 12 months. To identify those upcoming rules and actions, CRS searched all fields of the Unified Agenda (all agencies) using the term "Affordable Care Act," focusing on the proposed rule and final rule stages of rulemaking, as well as the "long-term actions" category.

In this edition, agencies reported 23 proposed rules and 18 final rules that they expect to issue pursuant to ACA within the next 12 months. Agencies also reported a total of 22 long-term regulatory actions and 20 completed actions.

The results of the search for proposed and final rules are provided in the **Appendix** to this report. For each upcoming proposed and final rule listed, the table identifies the department and agency expected to issue the rule, the title of the rule and its RIN, an abstract describing the nature of the rulemaking action, and the date that the proposed or final rule is expected to be issued.[16] The abstracts presented in the table were taken verbatim from the Unified Agenda entries. Within the proposed and final rule sections of the table, the entries are organized by agency.

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Congressional Review Act (5 U.S.C. §§801-808) is similar to the definition of "economically significant," since both definitions are triggered if a rule has, among other things, a $100 million effect on the economy.

[13] 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 is no longer at CRS; questions about its content can be directed to the authors of this report.

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

[15] Memorandum from Cass R. Sunstein, Administrator of the Office of Information and Regulatory Affairs, "Memorandum for Regulatory Policy Officers at Executive Departments and Agencies and Managing and Executive Directors of Certain Agencies and Commissions," June 13, 2012, at http://www.whitehouse.gov/sites/default/files/omb/inforeg/for-agencies/fall-2012-regulatory-plan-and-unified-agenda-of-federal-regulatory-and-deregulatory-actions.pdf. A previous e-mail from John C. Thomas, RISC Executive Director, August 3, 2011, to CRS indicated that Unified Agenda items are sometimes updated during the OIRA review process.

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

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, ACA made numerous changes to existing Medicare payment systems, either permanently or on a temporary basis, and required coverage of new Medicare benefits. In most cases, CMS has opted to address these changes in its annual rulemaking updates for the various Medicare payment systems. For example, the annual final rules updating Medicare payment policies and rates for physician services and for hospital inpatient services both include multiple sets of provisions to incorporate and implement ACA mandates. These rules, and similar annual updates, are not discussed in this report.

Upcoming ACA Proposed Rules

The December 21, 2012, edition of the Unified Agenda listed 23 ACA-related actions in the "proposed rule stage" (indicating that the agencies expected to issue proposed rules on the topics within the next 12 months, or for which the closing dates of the comment periods are the next step).[17] Ten of the 23 upcoming proposed rules were expected to be issued by components of the Department of Health and Human Services (HHS): Centers for Medicare and Medicaid Services (CMS, nine actions) and the Office of Civil Rights (OCR, one action). Other proposed rules were expected to be issued by the Treasury Department's Internal Revenue Service (TREAS/IRS, six actions); and the Office of Personnel Management (OPM, five actions). The remaining two upcoming proposed rules were expected to be issued by the Department of Labor's Employee Benefits Security Administration (DOL/EBSA) jointly with HHS/CMS and TREAS/IRS.

Notable Proposed Rules

The Department of Health and Human Services considered three of the items in the "proposed rule" section of the Unified Agenda important enough to be included in its regulatory plan. All three rules were from HHS/CMS, and all three were considered "economically significant" or "major."[18] The three rules HHS included in its regulatory plan are:

- a rule on "Standards Related to Essential Health Benefits";[19]
- a rule on "Benefit and Payment Parameters," which would provide additional guidance for several programs including risk adjustment, reinsurance, and risk corridors;[20] and
- a rule that would establish a "Prospective Payment System for Federally Qualified Health Centers."

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

[18] 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. Economically significant and major proposed rules are discussed in the following section.

[19] Department of Health and Human Services, "Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation," 77 *Federal Register* 70644, November 26, 2012.

[20] Department of Health and Human Services, "Notice of Benefit and Payment Parameters," 77 *Federal Register* 73118, December 7, 2012.

Economically Significant or Major Proposed Rules

In addition to the three ACA-related proposed rules that were listed in the regulatory plan, the Unified Agenda listed six other actions that the agencies considered "economically significant" or "major" (one definition of "economically significant" or "major," for example, is that the rule is expected to have at least a $100 million annual effect on the economy). Four of the rules were expected to be issued by HHS/CMS, one was to be issued by OPM, and one was expected to be issued jointly by TREAS/IRS, DOL/EBSA, and HHS/CMS. The economically significant or major proposed rules are

- an HHS/CMS rule on "Medicaid, Exchanges, and Children's Health Insurance Programs," which was expected to be published sometime during December 2012, but had not been published as of January 14, 2013;
- an HHS/CMS rule on "Medicare Advantage (MA) and Prescription Drug Benefit Programs," which was expected to be published sometime during December 2012, but had not been published as of January 14, 2013;
- an HHS/CMS rule on "Health Insurance Market: Rate Review," which the agency published on November 26, 2012;[21]
- an HHS/CMS rule on "Administrative Simplification: Compliance with Health Plan Certification," which the agency expects to publish in March 2013;
- an OPM rule on "Multi-State Exchanges," which the agency published on December 5, 2012;[22] and
- a rule on "Preventive Services," which was published as an ANPRM by TREAS/IRS, DOL/EBSA, and HHS/CMS jointly on March 21, 2012;[23]

"Other Significant" Proposed Rules

In addition to the above-mentioned rules, the agencies characterized 4 of the 23 actions that were listed in the "proposed rule" section of the Unified Agenda as "other significant," indicating that although they were not listed in the regulatory plan or expected to be "economically significant," they were expected to be significant enough to be reviewed by OIRA under Executive Order 12866.[24] The "other significant" proposed rules are

[21] U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, "Patient Protection and Affordable Care Act; Health Insurance Market: Rate Review," 77 *Federal Register* 70584, November 26, 2012.

[22] U.S. Office of Personnel Management, "Patient Protection and Affordable Care Act; Establishment of the Multi-State Plan Program for the Affordable Insurance Exchanges," 77 *Federal Register* 72581, December 5, 2012.

[23] 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, "Certain Preventive Services Under the Affordable Care Act," 77 *Federal Register* 16501, March 21, 2012. In the Unified Agenda, DOL classified this action as both "major" and "economically significant." HHS, however, classified this action as "other significant" only. This action was not listed in the Unified Agenda by IRS.

[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.

- an HHS/CMS rule on "Minimum Essential Coverage Exemptions," which the agency expects to publish in January 2013, but had not yet published as of January 14, 2013;
- an HHS/CMS rule on "Disproportionate Share Hospital Payment Reduction," which the agency expects to publish sometime in March 2013;
- an HHS/OCR rule on "Nondiscrimination Under the Patient Protection and Affordable Care Act," which the agency expects to publish sometime in March 2013; and
- a rule on "Incentives for Nondiscriminatory Wellness Programs," which was published as an NPRM by TREAS/IRS, DOL/EBSA, and HHS/CMS jointly on November 26, 2012.[25]

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, small governments, and small not-for-profit organizations).[26] Three 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:

- a TREAS/IRS rule on "Special Rules Under the Additional Medicare Tax";[27] and
- a TREAS/IRS rule on "Reporting and Notice Requirements Under Section 6056 of the Internal Revenue Code."

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

- an HHS/CMS rule that would establish a "Prospective Payment System for Federally Qualified Health Centers (FQHCs)"; and
- the two TREAS/IRS rules listed above on "Special Rules Under the Additional Medicare Tax" and "Reporting and Notice Requirements Under Section 6056."

The TREAS/IRS rule on "Special Rules Under the Additional Medicare Tax" and the HHS/CMS rule on "Prospective Payment System for FQHCs" were also expected to have an effect on small

[25] 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, "Incentives for Nondiscriminatory Wellness Programs in Group Health Plans," 77 *Federal Register* 70620, November 26, 2012.

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

[27] U.S. Department of the Treasury, Internal Revenue Service, "Rules Relating to Additional Medicare Tax," 77 *Federal Register* 72268, December 5, 2012.

not-for-profit organizations, another potential trigger for the Regulatory Flexibility Act's analysis requirement.

In 11 other upcoming final rules, the agencies indicated that they had yet to determine whether a regulatory flexibility analysis would be triggered. These rules included

- an HHS/CMS rule on "Medicaid, Exchanges, and Children's Health Insurance Programs: Eligibility";
- an HHS/CMS rule on "Minimum Essential Coverage Exemptions"; and
- a TREAS/IRS rule on "Medical Loss Ratio for Section 833 Organizations."

Timing of the Proposed Rules

The agencies indicated that 14 of the 23 items in the "proposed rule" section of the Unified Agenda had either been published in the *Federal Register* or would be published in the *Federal Register* by the end of December 2012.[28] As of January 14, 2013, seven items in the "proposed rule" section had been published in the *Federal Register* as a notice of proposed rulemaking (NPRM). The rules for which NPRMs have been published are

- an HHS/CMS rule on "Standards Related to Essential Health Benefits";[29]
- an HHS/CMS rule on "Health Insurance Market: Rate Review";[30]
- an HHS/CMS rule on "Notice of Benefit and Payment Parameters";[31]
- a TREAS/IRS rule on "Special Rules Under the Additional Medicare Tax";[32]
- a TREAS/IRS rule on "Fees on Health Insurance and Self-Insured Plans";[33]
- an OPM rule on "Multi-State Exchanges";[34] and
- an HHS/CMS, DOL, TREAS/IRS rule on "Wellness Programs."[35]

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

[29] U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, "Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation," 77 *Federal Register* 70644, November 26, 2012.

[30] U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, "Patient Protection and Affordable Care Act; Health Insurance Market: Rate Review," 77 *Federal Register* 70584, November 26, 2012.

[31] Department of Health and Human Services, "Notice of Benefit and Payment Parameters," 77 *Federal Register* 73118, December 7, 2012.

[32] U.S. Department of the Treasury, Internal Revenue Service, "Rules Relating to Additional Medicare Tax," 77 *Federal Register* 72268, December 5, 2012.

[33] 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.

[34] U.S. Office of Personnel Management, "Patient Protection and Affordable Care Act; Establishment of the Multi-State Plan Program for the Affordable Insurance Exchanges," 77 *Federal Register* 72581, December 5, 2012.

[35] 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, "Incentives for Nondiscriminatory Wellness Programs in Group Health Plans," 77 *Federal Register* 70620, November 26, 2012.

The seven proposed rules that were expected to be published by the end of December 2012, but that had not been published as of January 14, 2013, are

- an HHS/CMS rule on "Children's Health Insurance Programs";
- an HHS/CMS rule on "Medicare Advantage (MA) and Prescription Drug Benefit Programs";
- a TREAS/IRS rule on "Medical Loss Ratio for Section 833 Organizations";
- a TREAS/IRS rule on "Health Insurance Provider Fees";
- a TREAS/IRS rule on "Reporting and Notice Requirements Under Section 6056 of the Internal Revenue Code";
- a TREAS/IRS rule on "Community Health Needs Assessments for Charitable Hospitals"; and
- an HHS/CMS, DOL, TREAS/IRS rule on "Preventive Services."[36]

Several other proposed rules were expected to be issued in 2013, including

- an HHS/CMS rule on "Administrative Simplification: Compliance: Health Plan Certification" (expected to be published in March 2013);
- an HHS/CMS rule on "Disproportionate Share Hospital Payment Reduction" (expected to be published in March 2013);
- an HHS/CMS rule on "Prospective Payment System for Federally Qualified Health Centers (FQHCs)(expected to be published in June 2013)"; and
- an OPM rule on "Federal Employees Health Benefits Program; Disputed Claims and External Review Requirements" (expected to be published in March 2013).

Upcoming ACA Final Rules

The December 21, 2012, edition of the Unified Agenda listed 18 ACA-related actions in the "final rule" section (indicating that the agencies expected to issue these final rules within the next 12 months).[37] Nine of the 18 upcoming final actions are expected to be issued by components of HHS: the Health Resources and Services Administration (HRSA, two actions); the Food and Drug Administration (FDA, two actions); CMS (four actions); and the Office of the Secretary (OS, one action). Three of the 18 upcoming final rules are expected to be issued by TREAS/IRS. Two of the upcoming final rules are expected to be issued by the DOL—one each by the Occupational Safety and Health Administration (OSHA) and the Office of Workers'

[36] An advanced notice of proposed rulemaking (ANPRM), however, has been published for this rule. 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, "Certain Preventive Services Under the Affordable Care Act," 77 *Federal Register* 16501, March 21, 2012.

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

Compensation Programs (OWCP). Other final rules are expected to be issued by the Department of Defense's (DOD's) Office of the Secretary (OS, one action); the Architectural and Transportation Barriers Compliance Board (ATBCB, one action); OPM (one action); and the Social Security Administration (SSA, one action).

Notable Final Rules

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:

- a DOD/OS rule on "Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), TRICARE Young Adult";
- two HHS/FDA rules on "Food Labeling: Nutrition Labeling for Food Sold in Vending Machines" and "Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments"; and
- an ATBCB rule on "Accessibility Standards for Medical Diagnostic Equipment."

Economically Significant or Major Final Rules

The Unified Agenda listed five 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 fives rules are

- two HHS/FDA rules on "Food Labeling: Nutrition Labeling for Food Sold in Vending Machines" and "Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments";
- an HHS/CMS rule on "Home and Community-Based State Plan Services Program and Provider Payment Reassignments";
- an HHS/CMS rule on "Face-to-Face Requirements for Home Health Services; Policy Changes and Clarifications Related to Home Health"; and
- an HHS/CMS rule on "Covered Outpatient Drugs."

"Other Significant" Final Rules

In addition to the above-mentioned rules, nine other entries in the "final rule" section of the Unified Agenda were characterized as "other significant," indicating that although they were not listed in the regulatory plan or expected to be "economically significant," they were expected to be significant enough to be reviewed by OIRA under Executive Order 12866. These nine rules are

- a DOD/OS rule on "Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); TRICARE Young Adult";
- an HHS/HRSA rule on "Elimination of Duplication Between the Healthcare Integrity and Protection Data Bank and the National Practitioner Data Bank";
- an HHS/HRSA rule on "Privacy Act Exemption for the National Practitioner Data Bank";

- an HHS/CMS rule on "Federal Medicaid Assistance Percentages—Methodologies for Calculation of Enhanced Rate";
- an HHS/OS rule on "Health and Human Services Acquisition Regulation (HHS' Supplement to the Federal Acquisition Regulation)";
- a DOL/OSHA rule on "Procedures for the Handling of Retaliation Complaints under Section 1558 of the Affordable Care Act of 2010";
- a DOL/OWCP rule on "Regulations Implementing Amendments to the Black Lung Benefits Act: Determining Coal Miners and Survivors Entitlement to Benefits";
- an ATBCB rule on "Accessibility Standards for Medical Diagnostic Equipment"; and
- an SSA rule on "Conforming Changes to Regulations Regarding Income-Related Monthly Adjustment Amounts to Medicare Part B Premiums."

Effects on Small Entities

Four 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:

- two HHS/FDA rules on "Food Labeling: Nutrition Labeling for Food Sold in Vending Machines" and "Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments";
- an HHS/CMS rule on "Covered Outpatient Drugs"; and
- a TREAS/IRS rule on "Indoor Tanning Services; Cosmetic Services Excise Taxes."

The two FDA rules listed above on "Food Labeling" were also expected to have an effect on small governmental jurisdictions, another potential trigger for the Regulatory Flexibility Act's analysis requirement.

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

- an HHS/HRSA rule on "Elimination of Duplication Between the Healthcare Integrity and Protection Data Bank and the National Practitioner Data Bank";
- an HHS/OS rule on "Health and Human Services Acquisition Regulation (HHS' Supplement to the Federal Acquisition Regulation)";
- a DOL/OWCP rule on "Regulations Implementing Amendments to the Black Lung Benefits Act: Determining Coal Miners and Survivors Entitlement to Benefits"; and
- an ATBCB rule on "Accessibility Standards for Medical Diagnostic Equipment."

Timing of Final Rules

The agencies indicated that 2 of the 18 items in the "final rule" section of the Unified Agenda would be issued by the end of February 2013. These are

- a DOD/OS rule on "Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), TRICARE Young Adult"; and
- an HHS/CMS rule on "Federal Medicaid Assistance Percentages—Methodologies for Calculation of Enhanced Rate."

An additional 12 upcoming final rules are expected to be issued in the first half of 2013. The remaining 4 rules are expected to be issued in the second half of 2013.

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 December 21, 2012, edition of the Unified Agenda listed 22 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 15 of the 22 long-term actions listed, the agencies said that the dates for the actions were "to be determined." Of the seven remaining long-term actions for which agencies provided an estimated date of publication, four are expected in December 2013, two are expected in 2014, and one is expected in 2015. The four rules that are expected in December 2013 are all TREAS/IRS 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."

The regulatory actions expected in 2014 and 2015 are

- an HHS/CMS rule on "Medicare Shared Savings Program; Final Waivers" (expected in 2014);
- an HHS/CMS rule on "Reporting and Returning of Overpayments" (expected in 2015); and
- a Department of Justice (DOJ)/Civil Rights Division (CRT) advance notice of proposed rulemaking (ANPRM) on "Nondiscrimination on the Basis of

Disability by State and Local Governments and Public Accommodations: Accessibility of Medical Equipment and Furniture" (expected in 2014).

Notable Long-Term Actions

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

- a DOL/EBSA action entitled "Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan Under the Patient Protection and Affordable Care Act."

The agencies considered 14 of the 22 actions to be "other significant," meaning that the agencies considered them significant enough to be reviewed by OIRA under Executive Order 12866, but not "economically significant." These actions include

- an HHS/HRSA rule on "Designation of Medically Underserved Populations and Health Professional Shortage Areas";
- an HHS/HRSA rule on "340B Drug Pricing Program; Administrative Dispute Resolution Process"; and
- 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."

Congressional Oversight Options

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

Congress has a range of tools available to oversee the rules that federal agencies are expected to issue to implement ACA, including oversight hearings and confirmation hearings for the heads of regulatory agencies. Individual Members of Congress may also participate in the rulemaking process by, among other things, meeting with agency officials and filing public comments.[38] Congress, committees, and individual Members can also request that the Government Accountability Office (GAO) evaluate the agencies' rulemaking activities.

[38] 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."

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."[39] 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.[40] 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.[41] The definition of a covered rule in the CRA is quite broad, arguably including any type of document (e.g., legislative rules, policy statements, guidance, manuals, and memoranda) that the agency wishes to make binding on the affected public.[42] 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 1 rule in the 17 years since it was enacted.[43] Perhaps most notably, it is likely that a President would veto a resolution of disapproval to protect rules developed under his own Administration, and it may be difficult for Congress to muster the two-thirds vote in both houses needed to overturn the veto. Congress can also use regular (i.e., non-CRA) legislative procedures to disapprove agencies' rules, but such legislation may prove even more difficult to enact than a CRA resolution of disapproval (primarily because of the lack of expedited procedures in the Senate), and if enacted could be subject to presidential veto.

Finally, outside of the CRA, Congress has regularly included provisions in the text of agencies' appropriations bills in order to influence the regulatory process.[44] 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.[45]

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

[40] 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.

[41] 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.

[42] 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."

[43] 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.

[44] 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.

[45] 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 (continued...)

The **Appendix** lists the upcoming proposed and final rules published in the 2012 Unified Agenda in a table. 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.[46] 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.

(...continued)

restrictions appeared to be intended to stop particular rules issued at the end of presidential administrations.

[46] 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 Unified Agenda	Expected Publication Date
Proposed Rules			
HHS/CMS	Administrative Simplification: Compliance: Health Plan Certification (CMS-0037-P) (0938-AQ85)	This proposed rule would implement provisions of the Affordable Care Act of 2010 under Administrative Simplification to certify that data and information systems are in compliance with any applicable standards and associated operating rules for electronic funds transfers, eligibility for a health plan, health claim status, and health care payment and remittance advice.	03/2013 Note: Legal deadline is 12/31/2013 for first phase of compliance; second phase to occur by 12/31/2015.
HHS/CMS	Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation (CMS-9980-F) (0938-AR03)	This final rule details standards for health insurance consistent with title I of the Affordable Care Act. Specifically, this rule outlines Exchange and issuer standards related to coverage of essential health benefits (EHB) and actuarial value (AV). This rule also proposes a timeline for qualified health plans to be accredited in Federally-facilitated Exchanges and an amendment that provides an application process for the recognition of additional accrediting entities for purposes of certification of qualified health plans.	NPRM was published on 11/26/2012 (77 F.R. 70644). Note: Legal deadline for final rule is 01/01/2014.
HHS/CMS	Medicaid, Exchanges, and Children's Health Insurance Programs: Eligibility, Appeals, and Other Provisions Under the Affordable Care Act (0938-AR04)	The Affordable Care Act expands access to health insurance through improvements in Medicaid, the establishment of Affordable Insurance Exchanges (Exchanges), and coordination between Medicaid, the Children's Health Insurance Program (CHIP), and Exchanges. This proposed rule would continue our efforts to assist States in implementing Medicaid eligibility, appeals, enrollment changes, and other State health subsidy programs.	12/2012 Note: Legal deadline for final rule is 01/01/2014. No NPRM had been published as of 01/14/2013.
HHS/CMS	Disproportionate Share Hospital Payment Reduction (CMS-2367-P) (0938-AR31)	This proposed rule would delineate the statutory aggregate reductions to State Medicaid Disproportionate Share Hospital (DSH) allotments from FYs 2014 through 2020. The annual reduction amounts would be implemented using a DSH Health Reform methodology determined by the Secretary.	03/2013 Note: Legal deadline for final rule is 10/01/2013.

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Unified Agenda	Expected Publication Date
HHS/CMS	Patient Protection and Affordable Care Act; Health Insurance Market: Rate Review (CMS-9972-F) (0938-AR40)	This final rule implements the Affordable Care Act's policies related to fair health insurance premiums, guaranteed availability, guaranteed renewability, risk pools, and catastrophic plans. The rule clarifies the approach used to enforce the applicable requirements of the Affordable Care Act with respect to health insurance issuers and group health plans that are non-federal governmental plans. The rule also revises the timing of the submission of requests for State-specific thresholds; revises the standards for health insurance issuers and States regarding reporting, utilization, and collection of data, and amends the requirements for a State to have an Effective Rate Review Program.	NPRM was published on 11/26/2012 (77 F.R. 70584). Note: Legal deadline for final rule is 01/01/2014.
HHS/CMS	Notice of Benefit and Payment Parameters (CMS-9964-P) (0938-AR51)	Under the Affordable Care Act, this proposed rule would establish parameters of the risk adjustment, reinsurance, risk corridors, advanced premium tax credit, and cost-sharing reduction programs.	NPRM was published on 12/07/2012 (77 F.R. 73118). Note: Legal deadline for final rule is 01/01/2014.
HHS/CMS	Prospective Payment System for Federally Qualified Health Centers (FQHCs) (CMS-1443-P) (Section 610 Review) (0938-AR62)	The Affordable Care Act amends the current Medicare FQHC payment policy by requiring the establishment of a new payment system, effective with cost reporting periods beginning on or after October 1, 2014. This rule proposes the establishment of the new prospective payment system.	06/2013 Note: Legal deadline for final rule is 10/01/2014.
HHS/CMS	Minimum Essential Coverage Exemptions (CMS-9958-P) (0938-AR68)	This proposed rule would implement provisions of the Affordable Care Act concerning verifications of employer-sponsored coverage eligibility for the purpose of determining an individual's eligibility for advanced premium tax credits (APTCs).	01/2013 Note: Legal deadline for final rule is 01/01/2014. No NPRM had been published as of 01/14/2013.
HHS/CMS	Medicare Advantage (MA) and Prescription Drug Benefit Programs: Medical Loss Ratio Requirements (CMS-4173-P) (0938-AR69)	Under the Affordable Care Act, this proposed rule would implement medical loss ratio requirements for the Medicare Advantage (MA) and prescription drug benefit programs.	12/2012 Note: Legal deadline for final rule is 01/01/2014. No NPRM had been published as of 01/14/2013.

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Unified Agenda	Expected Publication Date
HHS/OCR	Nondiscrimination Under the Patient Protection and Affordable Care Act (0945-AA02)	This proposed rule would implement prohibitions against discrimination on the basis of race, color, national origin, sex, age, and disability, as provided in Section 1557 of the Affordable Care Act. Section 1557 provides certain protections from discrimination by recipients of Federal financial assistance, federally conducted programs, and entities established under Title I of the Affordable Care Act. This section also identifies additional forms of Federal financial assistance to which the section will apply.	03/2013
TREAS/IRS	Special Rules Under the Additional Medicare Tax (1545-BK54)	Proposed amendments of Sections 31.3101, 31.3102, 31.3111, 31.3121, 1.1401, 31.6205, 31.6011, 31.6205, 31.6402, and 31.6413 of the Employment Tax Regulations provide guidance for employers and employees relating to the implementation of the Additional Medicare Tax, as enacted by the Affordable Care Act, and correction procedures for errors related to the Additional Medicare Tax.	NPRM and notice of public hearing published on 12/05/2012 (77 F.R. 72268).
TREAS/IRS	Fees on Health Insurance and Self-Insured Plans (1545-BK59)	The proposed regulations provide guidance under Sections 4375 to 4377 of the Internal Revenue Code, as added by Section 6301 of the Patient Protection and Affordable Care Act, on fees imposed on health insurance and self-insured health plans.	NPRM was published on 12/06/2012 (77 F.R. 72721). Note: Original NPRM and notice of public hearing for this rule were published on 04/17/2012 (77 F.R. 22691). The public hearing was cancelled on 08/09/2012 (77 F.R. 47573).
TREAS/IRS	Medical Loss Ratio for Section 833 Organizations (1545-BL05)	The proposed regulations will provide guidance under Section 833(c)(5) of the Internal Revenue Code, as added by Section 9016 of the Patient Protection and Affordable Care Act, on the 85% medical loss ratio requirement under Section 833.	12/2012 Note: No NPRM had been published as of 01/14/2013.
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).	12/2012 Note: No NPRM had been published as of 01/14/2013.
TREAS/IRS	Reporting and Notice Requirements Under Section 6056 (1545-BL26)	Proposed regulations under Section 6056 of the Internal Revenue Code, as enacted by the Affordable Care Act, to provide guidance on rules that require applicable large employers to file certain information with the Internal Revenue Service on coverage under an eligible employer-sponsored health plan and furnish to individuals statements that set forth the information required to be reported to the Internal Revenue Service.	12/2012 Note: No NPRM had been published as of 01/14/2013.

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Unified Agenda	Expected Publication Date
TREAS/IRS	Community Health Needs Assessments for Charitable Hospitals (1545-BL30)	The Notice of Proposed Rulemaking contains proposed regulations that provide guidance to charitable hospital organizations on the community health needs assessment requirements, and related excise tax and reporting obligations, enacted in the Patient Protection and Affordable Care Act of 2010. The proposed regulations also clarify the consequences for failing to meet these requirements, as well as additional requirements related to financial assistance, charges, and billing and collections. The proposed regulations will affect charitable hospital organizations.	12/2012 Note: No NPRM had been published as of 01/14/2013.
OPM	Federal Employees Group Life Insurance Program; Tribes and Tribal Organizations (3206-AM41)	The U.S. Office of Personnel Management (OPM) proposes to amend the Federal Employees Group Life Insurance regulations at 5 CFR part 870 to include enrollments for eligible employees of tribes and tribal organizations under the provisions of the Affordable Care Act of 2010.	03/2013
OPM	Federal Employees Health Benefits Program; Tribes and Tribal Organizations (3206-AM40)	The U.S. Office of Personnel Management (OPM) proposes to amend the Federal Employees Health Benefits (FEHB) regulations at 5 CFR part 890 to include enrollments for eligible employees of tribes and tribal organizations under the provisions of the Affordable Care Act of 2010.	03/2013
OPM	Federal Employees Health Benefits Program; Disputed Claims and External Review Requirements (3206-AM42)	The U.S. Office of Personnel Management (OPM) proposes to amend the Federal Employees Health Benefits (FEHB) regulations at 5 CFR part 890 to include changes to resolution of disputed health claims and to provide for external review under the provisions of the Affordable Care Act of 2010.	03/2013
OPM	Federal Employees Health Benefits Program: Miscellaneous Changes Proposed by the Affordable Care Act (3206-AM46)	The U.S. Office of Personnel Management (OPM) proposes to amend the Federal Employees Health Benefits (FEHB) regulations at 5 CFR part 890 to include changes under the provisions of the Affordable Care Act of 2010.	05/2013
OPM	Multi-State Exchanges; Implementations for Affordable Care Act Provisions (3206-AM47)	The U.S. Office of Personnel Management (OPM) is proposing regulations for the implementation of provisions of the Affordable Care Act of 2010 that will enable OPM to contract with at least two multi-State plans for the Affordable Insurance Exchanges to be offered in 2014.	NPRM was published on 12/05/2012 (77 F.R. 72581).

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Unified Agenda	Expected Publication Date
TREAS/IRS, DOL/EBSA, HHS/CMS, jointly	Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act (CMS-9968-P) (1210-AB44), (0938-AR42)	The Patient Protection and Affordable Care Act of 2010 (the Affordable Care Act) amended Title I of the Employee Retirement Income Security Act (ERISA), by adding a new Section 715 which encompasses various health reform provisions of the Public Health Service Act. These regulations provide guidance on the rules relating to coverage of preventive services without cost sharing under the Affordable Care Act. As mentioned in previous requests, RIN 1210-AB41 was split into additional RINs due to the breadth of issues covered, and this is the fourth request in a series relating to the Affordable Care Act.	12/2012, 02/2013 Note: ANPRM was published on 03/21/2012 (77 F.R. 16501). DOL/EBSA listed an expected publication date of 12/2012. HHS/CMS's expected publication date was 02/2013.
TREAS/IRS, DOL/EBSA, HHS/CMS, jointly	Incentives for Nondiscriminatory Wellness Programs in Group Health Plans (CMS-9979-F) (1210-AB55), (0938-AR48)	The Patient Protection and Affordable Care Act of 2010 (the Affordable Care Act) amended Title I of ERISA, by adding a new Section 715 which encompasses various health reform provisions of the Public Health Service Act. These regulations provide guidance on wellness programs.	NPRM was published on 11/26/2012 (77 F.R. 70620).
Final Rules			
DOD/OS	Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); TRICARE Young Adult (0720-AB48)	This interim final rule implements Section 702 of the Ike Skelton National Defense Authorization Act for Fiscal Year 2011 (NDAA for FY2011). It establishes the TRICARE Young Adult (TYA) program to provide an extended medical coverage opportunity to most unmarried children under the age of 26 of uniformed services sponsors. The TRICARE Young Adult program is a premium-based program.	02/2013 Note: Originally published as an interim final rule on 04/27/2011 (76 F.R. 23479). Legal deadline for final rule was 01/01/2011.
HHS/HRSA	Elimination of Duplication Between the Healthcare Integrity and Protection Data Bank and the National Practitioner Data Bank (0906-AA87)	This final rule, required by the Affordable Care Act, eliminates the redundant reporting requirements for two closely related national health care data banks. It terminates the Healthcare Integrity and Protection Data Bank (HIPDB) and transfers all data collected in the HIPDB to the National Practitioner Data Bank (NPDB). It also provides for the disclosure of information, fee collection, and establishment of dispute procedures.	03/2013 Note: NPRM was published on 02/15/2012 (77 F.R. 9138). The Unified Agenda indicated that there is a statutory deadline, but did not specify what the deadline is.

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Unified Agenda	Expected Publication Date
HHS/HRSA	Privacy Act Exemption for the National Practitioner Data Bank (0906-AA97)	This interim final rule will exempt the system of records for the National Practitioner Data Bank (NPDB) from certain provisions of the Privacy Act (5 U.S.C. 552a). The exemption will be necessary when the two data banks, the Healthcare Integrity and Protection Data Bank (HIPDB) and the NPDB, merge as required by Section 6403 of the Affordable Care Act. As a result, the NPDB will include the investigative materials compiled for law enforcement purposes reported to the HIPDB. The system of records for the HIPDB has an exemption (45 CFR 5b.11(b)(2)(ii)(F)) from certain provisions of the Privacy Act. In order to maintain the exemption for the investigative materials, it is necessary to amend the regulatory language to expand the same privacy act exemptions for the HIPDB to the NPDB.	09/2013
HHS/FDA	Food Labeling: Nutrition Labeling for Food Sold in Vending Machines (0910-AG56)	The Food and Drug Administration (FDA) published a proposed rule in the Federal Register of April 6, 2011 (72 FR 19238) to establish requirements for nutrition labeling of certain food items sold in certain vending machines. FDA also proposed the terms and conditions for vending machine operators registering to voluntarily be subject to the requirements. FDA took this action to carry out Section 4205 of the Patient Protection and Affordable Care Act (Affordable Care Act or ACA), which was signed into law on March 23, 2010.	04/2013 Note: NPRM was published on 04/06/2011 (76 F.R. 19238).
HHS/FDA	Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments (0910-AG57)	The Food and Drug Administration (FDA) published a proposed rule in the Federal Register of April 6, 2011 (72 FR 19192), to establish requirements for nutrition labeling of standard menu items in chain restaurants and similar retail food establishments. FDA also proposed the terms and conditions for restaurants and similar retail food establishments registering to voluntarily be subject to the Federal requirements. FDA took this action to carry out Section 4205 of the Patient Protection and Affordable Care Act (Affordable Care Act or ACA), which was signed into law on March 23, 2010.	04/2013 Note: NPRM was published on 04/06/2011 (76 F.R. 19192).
HHS/CMS	Home and Community-Based State Plan Services Program and Provider Payment Reassignments (CMS-2249-F) (0938-AO53)	This final rule amends the Medicaid regulations to define and describe State plan home and community-based services (HCBS) under the Affordable Care Act. This rule offers States flexibilities in providing necessary and appropriate services to elderly and disabled populations.	05/2013 Note: Original NPRM was published on 04/04/08 (73 F.R. 18676). Following enactment of ACA, a second NPRM was published on 05/03/2012 (77 F.R. 26362). Under the Deficit Reduction Act of 2005 (P.L. 109-71), the original legal deadline for final rule was 01/01/2007.

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Unified Agenda	Expected Publication Date
HHS/CMS	Face-to-Face Requirements for Home Health Services; Policy Changes and Clarifications Related to Home Health (CMS-2348-F) (0938-AQ36)	This final rule revises the Medicaid home health service definition as required by Section 6407 of the Affordable Care Act of 2010 to add a requirement that physicians document the existence of a face-to-face encounter (including through the use of 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.	05/2013 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 Affordable Care Act. This rule also revises other requirements related to covered outpatient drugs, including key aspects of Medicaid coverage, payment, and the drug rebate program.	08/2013 Note: NPRM was published on 02/02/2012 (77 F.R. 5318).
HHS/CMS	Federal Medicaid Assistance Percentages—Methodologies for Calculation of Enhanced Rate (CMS-2327-F) (0938-AR38)	The Affordable Care Act authorizes enhanced Federal Medical Assistance Percentages (FMAP) for newly eligible individuals as defined by the act. This rule finalizes a section of the proposed rule published on August 17, 2011, that set forth methodologies for FMAP calculations.	02/2013 Note: This final rule will finalize only a section of the NPRM that was published on 08/17/2011 (76 F.R. 51148). Legal deadline for final rule is 01/01/2014.
HHS/OS	Health and Human Services Acquisition Regulation (HHS' Supplement to the Federal Acquisition Regulation) (0991-AB88)	This interim final rule amends the Department's Federal Acquisition Regulation (FAR) Supplement—the HHS Acquisition Regulation (HHSAR)—to provide implementation guidance for provisions in the HHS FY2012 Appropriations Acts and to establish HHS' non-discrimination policy.	03/2013

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Unified Agenda	Expected Publication Date
DOL/OSHA	Procedures for the Handling of Retaliation Complaints under Section 1558 of the Affordable Care Act of 2010 (1218-AC79)	OSHA is proposing to promulgate procedures for the handling and investigation of retaliation complaints pursuant to Section 1558 of the Patient Protection and Affordable Care Act of 2010 (the Affordable Care Act or ACA). This section established a new whistleblower protection statute to be administered by OSHA that provides protection from retaliation to employees in the health care industry who engage in protected activities under the ACA. Pursuant to the statute, the procedures will follow those enacted under the Consumer Product Safety Improvement Act, 15 U.S.C. 2087(b), including remedies and legal burdens of proof provisions. Promulgation of a regulation is necessary to govern whistleblower investigations conducted under the new statute.	03/2013
DOL/OWCP	Regulations Implementing Amendments to the Black Lung Benefits Act: Determining Coal Miners and Survivors Entitlement to Benefits (1240-AA04)	The Patient Protection and Affordable Care Act (PPACA) of 2010 amended the Black Lung Benefits Act, 30 U.S.C. 901 to 944, to reinstate two methods of establishing entitlement that were repealed with respect to claims filed after 1981. Specifically, the PPACA reinstated 30 U.S.C. 921(c)(4)(presumption of total disability or death due to pneumoconiosis arising out of coal mine employment where the miner had 15 years of coal mine employment and proof of total disability) and 30 U.S.C. 932(l) (automatic entitlement to benefits for eligible survivors of miners who were awarded benefits based on lifetime claims). The newly amended statutory provisions apply to claims filed after January 1, 2005, that are pending on or after PPACA's March 23, 2010, enactment date, and to all claims filed on or after March 23, 2010. This final rule will define the class of claims affected by the amendments and set the criteria for establishing entitlement to benefits under the amendments.	09/2013 Note: NPRM was published on 03/30/2012 (77 F.R. 19456).
TREAS/IRS	Branded Prescription Drug Fee (1545-BJ39)	Implementation of Section 9008 applies to imposition of annual fee on branded prescription pharmaceutical manufacturers and importers, of the Patient Protection and Affordable Care Act of 2010, P.L. 111-148.	04/2013 Note: NPRM was published on 08/18/2011 (76 F.R. 51310).
TREAS/IRS	Indoor Tanning Services; Cosmetic Services Excise Taxes (1545-BJ40)	Proposed regulations provide guidance on the indoor tanning services tax made by the Patient Protection and Affordable Care Act of 2010, affecting users and providers of indoor tanning services.	06/2013 Note: NPRM was published on 06/15/2012 (75 F.R. 33740). IRS held a public hearing on 10/11/2011 (notice of the hearing was published on 08/03/2011; see 76 F.R. 46677).

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Unified Agenda	Expected Publication Date
TREAS/IRS	Requirements for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act (1545-BJ58)	These proposed regulations provide guidance requiring coverage of certain preventive health services without cost-sharing under Section 2713 of the Public Health Service Act, incorporated into Section 9815 of the Internal Revenue Code by Section 1563(f) of the Patient Protection and Affordable Care Act, P.L. 111-148.	04/2013 Note: NPRM was published on 07/19/2010 (75 F.R. 41787). A second NPRM was published on 08/03/2011 (76 F.R. 46677).
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.	11/2013 Note: Public information meeting was held on 07/29/2010 (see notice published 75 F.R. 35439); NPRM published on 02/09/2012 (77 F.R. 6916); notice of intent to form advisory committee published on 03/13/2012 (77 F.R. 14706).
OPM	Federal Employees Health Benefits Program: Miscellaneous Changes (3206-AM55)	The U.S. Office of Personnel Management (OPM) will publish a final rule to amend the Federal Employees Health Benefits (FEHB) regulations at 5 CFR Part 890 to include changes pertaining to the Affordable Care Act in regards to age 26 and children of same-sex partners.	03/2013 Note: NPRM was published on 07/20/2012 (77 F.R. 42914).

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Unified Agenda	Expected Publication Date
SSA	Conforming Changes to Regulations Regarding Income-Related Monthly Adjustment Amounts to Medicare Part B Premiums (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 Affordable Care Act. These rules remove the requirement that beneficiaries consent to the release of IRS information outside of SSA for appeals past the reconsideration level and freeze the income threshold and ranges from 2011 through 2019. We are also removing provisions that phased in the income-related monthly adjustment amount between 2007 and 2009. The regulation also updates an outdated provision to reflect the transfer of authority for hearing appeals under Title XVIII of the act from SSA to the Department of Health and Human Services, as prescribed by the Medicare Prescription Drug, and Modernization Act of 2003.	06/2013

Source: Information in the first three columns is verbatim as reported in the Unified Agenda of Federal Regulatory and Deregulatory Actions, December 21, 2012, available at http://www.reginfo.gov/public/do/eAgendaMain. Information in the fourth column is from the Unified Agenda and the *Federal Register*.

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

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