



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

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August 18, 2011

Congressional Research Service

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[www.crs.gov](http://www.crs.gov)

R41963

## Summary

Congress delegates rulemaking authority to agencies for a variety of reasons and in a variety of ways. The Patient Protection and Affordable Care Act (PPACA; P.L. 111-148) is a particularly noteworthy example of congressional delegation of rulemaking authority to federal agencies. A previous CRS report identified more than 40 provisions in PPACA that require or permit the issuance of rules to implement the legislation.

One way for Congress to identify upcoming PPACA rules is by reviewing the Unified Agenda of Federal Regulatory and Deregulatory Actions, which is published twice each year (spring and fall) by the Regulatory Information Service Center (RISC), a component of the U.S. General Services Administration, for the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA). The Unified Agenda lists upcoming activities, by agency, in five separate categories or stages of the rulemaking process: the prerule stage, the proposed rule stage, the final rule stage, long-term actions, and completed actions. All entries in the Unified Agenda have uniform data elements, including the department and agency issuing the rule, the title of the rule, its Regulation Identifier Number (RIN), an abstract describing the nature of action being taken, and a timetable showing the dates of past actions and a projected date 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).

This report examines the most recent edition of the Unified Agenda, published on July 7, 2011 (the second edition that RISC compiled and issued after the enactment of PPACA). The report identifies upcoming proposed and final rules listed in the July 7, 2011, Unified Agenda that are expected to be issued pursuant to PPACA. (A previous CRS report identified the rulemaking actions that were listed in the December 2010 version of the Unified Agenda.) The **Appendix** lists these upcoming proposed and final rules in a table. The report also briefly discusses the long-term actions listed in the Unified Agenda, as well as some options for congressional oversight over the PPACA rules.

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## Introduction

Federal regulations generally result from an act of Congress and are the 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 (PPACA; P.L. 111-148, as amended) is a particularly noteworthy example of congressional delegation of rulemaking authority to federal agencies.<sup>1</sup> PPACA 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 PPACA that require or permit the issuance of rules to implement the legislation.<sup>2</sup>

The rules that agencies issue pursuant to PPACA are expected to have a major impact on how the legislation is implemented. For example, in an article entitled “The War Isn’t Over” that was posted on the *New England Journal of Medicine’s* Health Care Reform Center shortly after PPACA 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.<sup>3</sup>

## 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 PPACA 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.<sup>4</sup> Other provisions

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<sup>1</sup> For more information on PPACA, see CRS Report R40942, *Private Health Insurance Provisions in the Patient Protection and Affordable Care Act (PPACA)*, by (name redacted), (name redacted), and (name redacted); CRS Report R41278, *Public Health, Workforce, Quality, and Related Provisions in PPACA: Summary and Timeline*, coordinated by (name redacted) and (name redacted); CRS Report R41196, *Medicare Provisions in the Patient Protection and Affordable Care Act (PPACA): Summary and Timeline*, coordinated by (name redacted); and CRS Report R41210, *Medicaid and the State Children’s Health Insurance Program (CHIP) Provisions in PPACA: Summary and Timeline*, by (name redacted) et al.

<sup>2</sup> CRS Report R41180, *Rulemaking Requirements and Authorities in the Patient Protection and Affordable Care Act (PPACA)*, by (name redacted).

<sup>3</sup> 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>.

<sup>4</sup> 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 PPACA contain a legislative enforcement mechanism, so the remaining options for enforcement include political (continued...)

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

By December 2010, federal agencies had already issued at least 18 final rules implementing sections of PPACA.<sup>5</sup> Although the legislation specifically required or permitted some of the rules to be published, other rules implemented PPACA provisions that did not specifically mention rulemaking. The use of rulemaking in these cases does not appear to be either improper or unusual; if the requirements in those rules were intended to be binding on the public, rulemaking may have been the agencies only viable option to implement the related statutory provisions.<sup>6</sup>

## 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.”<sup>7</sup> 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.

For Congress to oversee the regulations being issued to implement PPACA, it would help to have an early sense of what rules the agencies are going to issue, and when. The previously mentioned CRS report identifying the provisions in the act that require or permit rulemaking can be useful in this regard.<sup>8</sup> However, the legislation did not indicate when some of the mandatory rules should be issued, some of the rules that the agencies are permitted (but not required) to issue may never be developed, and many of the rules that the agencies have already issued to implement PPACA were not specifically mentioned in the act.

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pressure on the agencies or civil litigation, although courts often defer to agencies’ judgment on the timing of their issuance of a rule.

<sup>5</sup> CRS Report R41346, *Initial Final Rules Implementing the Patient Protection and Affordable Care Act*, by (name redacted).

<sup>6</sup> Case law and guidance from OMB indicate that agencies should not attempt to bind affected parties through policy statements and other non-rule documents. See, for example, *Appalachian Power Co. v. Environmental Protection Agency*, 208 F.3d 1015 (D.C. Cir. 2000); and Office of Management and Budget, “Final Bulletin for Agency Good Guidance Practices,” 72 *Federal Register* 3432, January 25, 2007, which states (on p. 3433) that “The courts, Congress, and other authorities have emphasized that rules which do not merely interpret existing law or announce tentative policy positions but which establish new policy positions that the agency treats as binding must comply with the (Administrative Procedure Act’s) notice-and-comment requirements, regardless of how they initially are labeled.”

<sup>7</sup> 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.

<sup>8</sup> CRS Report R41180, *Rulemaking Requirements and Authorities in the Patient Protection and Affordable Care Act (PPACA)*, by (name redacted).

## **The Unified Agenda**

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

- The Regulatory Flexibility Act (5 U.S.C. § 602) requires that all agencies publish semiannual regulatory agendas in the *Federal Register* describing regulatory actions that they are developing that may have a significant economic impact on a substantial number of small entities.<sup>10</sup>
- 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."<sup>11</sup> 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 five separate categories or stages of the rulemaking process:

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

All entries in the Unified Agenda have uniform data elements, including the department and agency issuing the rule, the title of the rule, its Regulation Identifier Number (RIN),<sup>12</sup> an abstract

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<sup>9</sup> The current edition of the Unified Agenda is available at <http://www.reginfo.gov/public/do/eAgendaMain>.

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

<sup>11</sup> Executive Order 12866, "Regulatory Planning and Review," 58 *Federal Register* 51735, Oct. 4, 1993. Although most of the requirements in this executive order do not apply to independent regulatory agencies (e.g., the Securities and Exchange Commission), this section includes these agencies.

<sup>12</sup> RINs are assigned by RISC, and the Office of Management and Budget has asked agencies to include RINs in the (continued...)

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).<sup>13</sup>

There is no penalty for issuing a rule without a prior notice in the Unified Agenda, and some prospective rules listed in the Unified Agenda never get issued, reflecting the fluid nature of the rulemaking process. Nevertheless, the Unified Agenda can help Congress and the public know what regulatory actions are about to occur, and it arguably provides federal agencies with the most systematic, government-wide method to alert the public about their upcoming proposed rules. A previously issued CRS report indicated that about three-fourths of the significant proposed rules published after having been reviewed by OIRA in 2008 were previously listed in the “proposed rule” section of the Unified Agenda.<sup>14</sup>

## **This Report**

The July 7, 2011, edition of the Unified Agenda and Regulatory Plan is the second edition that RISC has compiled and issued after the enactment of PPACA.<sup>15</sup> Federal agencies were required to submit data to RISC for the Unified Agenda by February 25, 2011,<sup>16</sup> but some items were subsequently updated during the OIRA review process.<sup>17</sup>

This report examines the July 7, 2011, edition of the Unified Agenda and identifies upcoming proposed and final rules and long-term actions that were expected to be issued pursuant to PPACA 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

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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](http://www.whitehouse.gov/sites/default/files/omb/assets/inforeg/IncreasingOpenness_04072010.pdf).

<sup>13</sup> 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 essentially the same as “economically significant.”

<sup>14</sup> CRS Report R40713, *The Unified Agenda: Implications for Rulemaking Transparency and Participation*, by (name redacted).

<sup>15</sup> PPACA was enacted on March 23, 2010. The first edition of the Unified Agenda following enactment of PPACA was issued on December 20, 2010. For a similar CRS report listing the rules pursuant to PPACA that were listed as upcoming in the December 20, 2010 edition of the Unified Agenda, see CRS Report R41586, *Upcoming Rules Pursuant to the Patient Protection and Affordable Care Act: Fall 2010 Unified Agenda*, by (name redacted) and (name redacted).

<sup>16</sup> Letter from Cass R. Sunstein, Administrator of the Office of Information and Regulatory Affairs, “Regulatory Policy Officers at Executive Departments and Agencies and Managing and Executive Directors of Certain Agencies and Commissions,” January 21, 2011.

<sup>17</sup> E-mail from John C. Thomas, RISC Executive Director, August 3, 2011.

proposed rule and final rule stages of rulemaking, and also including the “long-term actions” category.

The results of the search for proposed and final rules are provided in the **Appendix** to this report. For each upcoming proposed and final rule listed, the table identifies the department and agency expected to issue the rule, the title of the rule and its RIN, an abstract describing the nature of the rulemaking action, and the date that the proposed or final rule was expected to be issued.<sup>18</sup> The abstracts presented in the table were taken verbatim from the Unified Agenda entries. Within the proposed and final rule sections of the table, the entries are organized by agency.

Because agencies were compiling the information early in the year, their estimates for when upcoming proposed and final rules would be issued may have been out of date by the time the Unified Agenda was published. To provide the most up-to-date information, on August 3, 2011, CRS electronically searched the *Federal Register* to see whether the proposed and final rules listed in the Unified Agenda had been published. This information is provided in the table. If the proposed or final rule was published as of August 3, the *Federal Register* citation is also provided.

## Upcoming PPACA Proposed Rules

The July 7, 2011, edition of the Unified Agenda listed 41 PPACA-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). Thirty-three of the 41 upcoming proposed rules were expected to be issued by components of the Department of Health and Human Services (HHS): the Health Resources and Services Administration (HRSA, four actions); the Food and Drug Administration (FDA, two actions); Indian Health Service (IHS, two actions); the Centers for Medicare and Medicaid Policy (CMS, 21 actions); the Administration on Aging (AOA, one action); and the Office of the Secretary (OS, three actions). Other proposed rules were expected to be issued by the Department of Labor’s (DOL) Employee Benefits Security Administration (EBSA, one action); the DOL’s Office of Workers’ Compensation Programs (OWCP, one action); the Treasury Department’s Departmental Offices (DO, one action); the Internal Revenue Service (IRS, two actions); and the Office of Personnel Management (OPM, three actions).

## Timing of the Proposed Rules

The agencies indicated that 17 of the 41 items in the “proposed rule” section of the Unified Agenda would be issued by the end of July 2011.<sup>19</sup> As of August 3, 2011, 9 of these 17 anticipated notices of proposed rulemaking (NPRMs) had been published, and 8 had not yet been published. Some of the rules for which NPRMs have been published include

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<sup>18</sup> In addition to the RINs, CMS included an agency-specific number as part of the title of the rule (e.g., CMS-1345-P). Those numbers are included as part of the title in the table in the **Appendix**.

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



- an HHS/HRSA rule on “340B Orphan Drug Exclusion,”<sup>20</sup>
- an HHS/FDA rule on “Food Labeling: Nutrition Labeling for Food Sold in Vending Machines,”<sup>21</sup>
- an HHS/CMS rule on “Availability of Medicare Data for Performance Measurement,”<sup>22</sup> and
- an HHS/CMS rule on “Establishment of the Consumer Operated and Oriented Plan Program.”<sup>23</sup>

Some of the eight proposed rules that were expected to be published by the end of July 2011, but that had not been published as of August 3, 2011, include

- an HHS/HRSA rule on “Elimination of Duplication Between the Healthcare Integrity and Protection Data Bank and the National Practitioner Data Bank;”
- an HHS/CMS rule on “Administrative Simplification: Standard Unique Identifier for Health Plans;”
- an HHS/CMS rule on “Medicaid Eligibility Expansion Under the Affordable Care Act of 2010;” and
- a Treasury/IRS rule on “Development and Utilization of Uniform Explanation of Coverage Documents, Definitions, and Requirements To Provide Information Under the Patient Protection and Affordable Care Act.”

Several other proposed rules were expected to be issued later in 2011, including

- an HHS/IHS rule on “Standards for the Planning, Design, Construction and Operation of Health Care and Sanitation Facilities” (expected to be published in December 2011);
- an HHS/CMS rule on “Implementing Regulations for Reauthorization of the Children’s Health Insurance Program (CHIP)” (expected to be published in December 2011);
- an HHS/OS rule on “Nondiscrimination Under the Affordable Care Act” (expected to be published in September 2011); and
- an OPM rule on “Federal Employees Health Benefits Program; Disputed Claims and External Review Requirements” (expected to be published in September 2011).

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<sup>20</sup> U.S. Department of Health and Human Services, Health Resources and Services Administration, “Exclusion of Orphan Drugs for Certain Covered Entities Under 340B Program,” *76 Federal Register* 29183, May 20, 2011.

<sup>21</sup> U.S. Department of Health and Human Services, Food and Drug Administration, “Food Labeling: Calorie Labeling of Articles of Food in Vending Machines,” *76 Federal Register* 19238, April 6, 2011.

<sup>22</sup> U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, “Medicare Program; Availability of Medicare Data for Performance Measurement,” *76 Federal Register* 33566, June 8, 2011.

<sup>23</sup> U.S. Department of Health and Human Services, “Patient Protection and Affordable Care Act; Establishment of Consumer Operated and Oriented Plan (CO-OP) Program,” *76 Federal Register* 43237, July 20, 2011.

## **Notable Proposed Rules**

HHS agencies considered 4 of the 41 items in the “proposed rule” section of the Unified Agenda important enough to be included in the regulatory plan:

- Two HHS/FDA rules on “Food Labeling: Nutrition Labeling for Food Sold in Vending Machines,” which the agency published as an NPRM on April 6, 2011;<sup>24</sup> and “Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments,” which the agency published as an NPRM on April 6, 2011;<sup>25</sup>
- An HHS/CMS rule on “Medicare Shared Savings Program: Accountable Care Organizations,” which the agency published as an NPRM on April 7, 2011;<sup>26</sup> and
- An HHS/AOA rule on “Community Living Assistance Services and Supports (CLASS) Program—Designation of the CLASS Independence Benefit Plan and Enrollment Rules,” which the agency expects to publish as an NPRM in October 2011.

## **Economically Significant or Major Proposed Rules**

In addition to the PPACA-related “proposed rule” actions that were listed in the regulatory plan, the Unified Agenda listed eight 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). Examples include

- an HHS/CMS rule on “Medicaid Eligibility Expansion Under the Affordable Care Act of 2010,” which was expected to be published as an NPRM sometime during June 2011, but had not been published as of August 3, 2011;
- an HHS/CMS rule on “Requirements To Implement American Health Benefit Exchanges and Other Provisions of the Affordable Care Act,” which was published as an NPRM on July 15, 2011;<sup>27</sup> and
- an HHS/OCIIO rule on “Public Use Files of Health Plan Data,” which is expected to be issued sometime during December 2011.

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<sup>24</sup> U.S. Department of Health and Human Services, Food and Drug Administration, “Food Labeling: Calorie Labeling of Articles of Food in Vending Machines,” 76 *Federal Register* 19238, April 6, 2011.

<sup>25</sup> U.S. Department of Health and Human Services, Food and Drug Administration, “Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments,” 76 *Federal Register* 19192, April 6, 2011.

<sup>26</sup> U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, “Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations,” 76 *Federal Register* 68583, April 7, 2011.

<sup>27</sup> U.S. Department of Health and Human Services, “Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans,” 76 *Federal Register* 41866, July 15, 2011.

## **“Other Significant” Proposed Rules**

In addition to the above-mentioned rules, the agencies characterized 27 of the 41 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.<sup>28</sup> These proposed rules included

- an HHS/IHS rule on “Confidentiality of Medical Quality Assurance Records; Qualified Immunity for Participants,” which the agency expects to publish in February 2012;
- an HHS/CMS rule on “Face-to-Face Requirements for Home Health Services; Policy Changes and Clarifications Related to Home Health,” which the agency published on July 12, 2011;<sup>29</sup>
- an HHS/AOA rule on “Community Living Assistance Services and Supports (CLASS) Program—Designation of the CLASS Independence Benefit Plan and Enrollment Rules,” which the agency expects to issue in October 2011; and
- a DOL/OWCP rule on “Regulations Implementing Amendments to the Black Lung Benefits Act: Determining Coal Miners and Survivors Entitlement to Benefits,” which the agency expects to issue in March 2012.

## **Effects on Small Entities**

The Regulatory Flexibility Act (5 U.S.C. §§ 601-612) generally requires federal agencies to assess the impact of their forthcoming regulations on “small entities” (i.e., small businesses, small governments, and small not-for-profit organizations).<sup>30</sup> Three of the previously-mentioned PPACA-related rules listed in the “proposed rule” section were expected to affect small businesses, small governments, or both, and were expected to require a regulatory flexibility analysis:

- 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 Chain Restaurants;” and
- An HHS/CMS rule on “Medicaid Eligibility Expansion Under the Affordable Care Act of 2010.”

In addition to these rules, eight other actions listed in the “proposed rule” section were expected to have an effect on small businesses, small governments, or small not-for-profits, but the

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<sup>28</sup> 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*, by (name redacted).

<sup>29</sup> U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, “Medicaid Program; Face-to-Face Requirements for Home Health Services; Policy Changes and Clarifications Related to Home Health,” 76 *Federal Register* 41032, July 12, 2011.

<sup>30</sup> For more information, see CRS Report RL34355, *The Regulatory Flexibility Act: Implementation Issues and Proposed Reforms*, by (name redacted).

agencies either did not expect to the rules to trigger the requirements of the Regulatory Flexibility Act, or were undecided as to whether they would do so. These actions included

- an HHS/CMS rule on “Administrative Simplification: Standard Unique Identifier for Health Plans;”
- an HHS/CMS rule on “Durable Medical Equipment (DME) Face to Face Encounters and Written Orders Prior to Delivery;” and
- a DOL/EBSA rule on “Ex Parte Cease and Desist and Summary Seizure Orders Under ERISA Section 521.”

## Upcoming PPACA Final Rules

The July 7, 2011, edition of the Unified Agenda listed 13 PPACA-related actions in the “final rule stage” section (indicating that the agencies expected to issue final rules on the subjects within the next 12 months). Eight of the upcoming final rules were expected to be issued by CMS; two by the IRS; and one each by HRSA, the Occupational Safety and Health Administration (OSHA) within DOL, and the Social Security Administration.

### Timing of Final Rules

The agencies indicated that 6 of the 13 items in the “final rule” section of the Unified Agenda would be issued by the end of July 2011. As of August 3, 2011, four of these rules had been issued:

- An HHS/CMS rule on “Administrative Simplification: Adoption of Authoring Organizations for Operating Rules and Adoption of Operating Rules for Eligibility and Claims Status;” which was published as an interim final rule on July 8, 2011;<sup>31</sup>
- An HHS/CMS rule on “Payment Adjustment for Provider—Preventable Conditions Including Health Care-Acquired Conditions,” which was published as a final rule on June 6, 2011;<sup>32</sup>
- An HHS/CMS rule on “Enhanced Federal Funding for Medicaid Eligibility Determination and Enrollment Activities,” which was published as a final rule on April 19, 2011;<sup>33</sup> and
- An HHS/CMS rule on “Internal Claims, Appeals, and External Review Processes Under the Affordable Care Act,” which was originally published as an interim

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<sup>31</sup> U.S. Department of Health and Human Services, Centers for Medicare and Medicaid, “Administrative Simplification: Adoption of Operating Rules for Eligibility for a Health Plan and Health Care Claim Status Transactions,” 75 *Federal Register* 40457, July 8, 2011.

<sup>32</sup> U.S. Department of Health and Human Services, Centers for Medicare and Medicaid, “Medicaid Program; Payment Adjustment for Provider-Preventable Conditions Including Health Care-Acquired Conditions,” 76 *Federal Register* 32186, June 6, 2011.

<sup>33</sup> U.S. Department of Health and Human Services, Centers for Medicare and Medicaid, “Medicaid Program; Federal Funding for Medicaid Eligibility Determination and Enrollment Activities,” 76 *Federal Register* 21950, April 19, 2011.

final rule on July 23, 2010, followed by a second interim final rule on June 24, 2011.<sup>34</sup>

As of August 3, 2011, the remaining two final rules that the agencies indicated would be published by the end of July 2011 had not been published:

- An HHS/CMS rule on “Changes to the Demonstration Review and Approval Process,” and
- An IRS rule on “Development and Utilization of Uniform Explanation of Coverage Documents, Definitions, and Requirements To Provide Information Under the Patient Protection and Affordable Care Act.”

The agencies indicated that six other final rules would be published sometime in 2011:

- An HHS/HRSA rule on “Designation of Medically Underserved Populations and Health Professional Shortage Areas,” which was expected to be issued in November 2011;
- An HHS/CMS rule on “Administrative Simplification: Adoption of Standard and Operating Rule for Electronic Funds Transfer (EFT) and Operating Rule for Remittance Advice,” which was expected to be issued in December 2011;
- An HHS/CMS rule on “Medicaid Recovery Audit Contractors,” which was expected to be issued in August 2011;
- An HHS/CMS rule on “Community First Choice Option,” which was expected to be issued in August 2011;
- A DOL/OSHA rule on “Procedures for the Handling of Retaliation Complaints Under Section 1558 of the Affordable Care Act,” which was expected to be issued in September 2011; and
- An IRS rule on “Indoor Tanning Services,” which was expected to be issued in December 2011.

## **Notable Final Rules**

None of the rules that were listed in the “final rule” section of the Unified Agenda were considered important enough to be included in the agencies’ regulatory plans.

## **Economically Significant or Major Final Rules**

The Unified Agenda listed three entries in the “final rule” section that were considered “economically significant” or “major” (e.g., that were expected to have at least a \$100 million annual effect on the economy). All three rules were CMS rules: (1) “Medicaid Recovery Audit Contractors;” (2) “Community First Choice Option;” and (3) “Enhanced Federal Funding for Medicaid Eligibility Determination and Enrollment Activities.”

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<sup>34</sup> This interim final rule was a joint 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 and Medicaid, “Group Health Plans and Health Insurance Issuers: Rules Relating to Internal Claims and Appeals and External Review Processes,” 76 *Federal Register* 37208, June 24, 2011.

## **“Other Significant” Final Rules**

In addition to the above-mentioned rules, eight 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 final rules included

- an HHS/HRSA rule on “Designation of Medically Underserved Populations and Health Professional Shortage Areas;”
- an HHS/CMS rule on “Administrative Simplification: Adoption of Standard and Operating Rule for Electronic Funds Transfer (EFT) and Operating Rule for Remittance Advice;”
- a DOL/OSHA rule on “Procedures for the Handling of Retaliation Complaints Under Section 1558 of the Affordable Care Act of 2010;” and
- a Social Security Administration rule on “Regulations Regarding Income-Related Monthly Adjustment Amounts to Medicare Beneficiaries’ Prescription Drug Premiums.”

## **Effects on Small Entities**

Two of the upcoming final rules were expected to trigger the requirements of the Regulatory Flexibility Act because of their effects on small businesses: the CMS rule on “Enhanced Federal Funding for Medicaid Eligibility Determination and Enrollment Activities,” and the IRS rule on “Indoor Tanning Services.”

Three other CMS rules were expected to have an effect on small businesses, governments, or other organizations, but were not expected to require a regulatory flexibility analysis: (1) “Administrative Simplification: Adoption of Standard and Operating Rule for Electronic Funds Transfer (EFT) and Operating Rule for Remittance Advice;” (2) “Administrative Simplification: Adoption of Authoring Organizations for Operating Rules and Adoption of Operating Rules for Eligibility and Claims Status;” and (3) “Medicaid Recovery Audit Contractors.”

## **PPACA Long-Term Actions**

As noted earlier in this report, the Unified Agenda also identifies “long-term actions”—that is, regulatory actions that are under development in the agencies that the agencies do not expect to take action on in the next 12 months. The July 7, 2011 edition of the Unified Agenda listed 27 long-term actions related to PPACA. In comparison with the proposed and final rules previously discussed, it is much less clear when the PPACA-related long-term actions are expected to occur; in 17 of the 27 cases, the agencies said that the dates for the actions were “to be determined.” Of the remaining ten long-term actions, six were expected in June 2012, one in August 2012, one in calendar year 2013, and two in calendar year 2014.

## **Nature of the Long-Term Actions**

Of the 27 long-term actions, 15 were upcoming final rules that were expected to be issued once the agency had considered the comments received in response to previously issued interim final rules.<sup>35</sup> These actions included

- an HHS/CMS rule on “Requirements for Long-Term Care Facilities: Notification of Facility Closure;” with the final rule expected to be published in February 2014;<sup>36</sup> and
- a DOL/EBSA rule on “Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions and Patient Protections Under the Affordable Care Act,” with the date of the final rule “to be determined.”<sup>37</sup>

The eight other long-term actions were upcoming final rules that the agency expected to issue after considering the comments received in response to a previously issued notice of proposed rulemaking. These actions included

- an HHS/CMS rule on “Affordable Care Act Waiver for State Innovation; Review and Approval Process;”<sup>38</sup> and
- an IRS rule on “Requirements Applicable to Group Health Plans and Health Insurance Issuers Under the Patient Protection and Affordable Care Act, I.”<sup>39</sup>

The four other PPACA-related long-term actions included

- an HHS/CMS NPRM on “Long-Term Care Facility Quality Assessment and Performance Improvement Dementia Management and Abuse Prevention Training,” and
- a DOL/EBSA unspecified rulemaking action on “Automatic Enrollment in Health Plans of Employees of Large Employers Under FLSA Section 18A;”

## **Notable Long-Term Actions**

The agencies identified 10 of the 27 PPACA-related long-term actions as “economically significant,” “major,” or both. Nine of these actions were cases in which the agencies had issued interim final rules and were reviewing the comments received. These included

- two HHS/CMS actions on such topics as “Preexisting Condition Exclusions, Lifetime and Annual Limits, Prohibition on Discrimination and Patient Protections;” “Preventive Services Under the Affordable Care Act;” “Affordable Care Act Waiver for State Innovation; Review and Approval Process;” and

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<sup>35</sup> Interim final rules are a particular application of the “good cause” exception to notice-and comment rulemaking (5 U.S.C. § 553), in which the agency issues a final rule without a prior notice of proposed rulemaking, but with a post-promulgation opportunity for the public to comment. Interim final rules often take effect immediately, but the effective dates may also be delayed.

<sup>36</sup> The associated interim final rule was published on February 18, 2011 (76 *Federal Register* 9503).

<sup>37</sup> The associated interim final rule was published on June 28, 2010 (75 *Federal Register* 37188).

<sup>38</sup> The associated notice of proposed rulemaking was published on March 14, 2011 (76 F.R. 13553).

<sup>39</sup> The associated notice of proposed rulemaking was published on May 13, 2010 (75 F.R. 27141).

- 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.”

One other long-term action that was identified as major was a CMS rule on “Affordable Care Act Waiver for State Innovation; Review and Approval Process.” The agency published an NPRM on March 14 and will be taking final action at a later date “to be determined.”

The agencies considered 12 of the 27 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 included

- an HHS/IHS rule on “Catastrophic Health Emergency Fund (CHEF);”
- two HHS/CMS actions entitled “Health Care Reform Insurance Web Portal Requirements” and “Student Health Insurance Coverage;” and
- a DOL/EBSA action 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, it is appropriate for Congress to oversee the rules that agencies issue to ensure that they are consistent with congressional intent and the rulemaking requirements established in various statutes and executive orders. For Congress to oversee the rules being issued pursuant to PPACA, it must first know that they are being issued—ideally as early as possible. The Unified Agenda is perhaps the best vehicle to provide that early information, describing not only what rules are expected to be issued, but also providing information regarding their significance and timing.

Congress has a range of tools available to oversee the rules that federal agencies are expected to issue to implement PPACA, 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.<sup>40</sup> 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.”<sup>41</sup> The act generally requires federal agencies to submit all of their covered final rules to both houses of Congress and GAO

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<sup>40</sup> 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.”

<sup>41</sup> 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).



before they can take effect.<sup>42</sup> 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.<sup>43</sup> 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.<sup>44</sup> 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 only one rule in the 14 years since it was enacted.<sup>45</sup> Perhaps most notably, it is likely that a President would veto a resolution of disapproval to protect rules developed under his own administration, and it may be difficult for Congress to muster the two-thirds vote in both houses needed to overturn the veto. Congress can also use regular (i.e., non-CRA) legislative procedures to disapprove agencies' rules, but such legislation may prove even more difficult to enact than a CRA resolution of disapproval (primarily because of the lack of expedited procedures in the Senate), and if enacted may also be vetoed by the President.

Although the CRA has been used only once to overturn an agency rule, Congress has regularly included provisions in the text of agencies' appropriations bills directing or preventing the development of particular regulations. Such provisions include prohibitions on the finalization of particular proposed rules, restrictions on certain types of regulatory activity, and restrictions on implementation or enforcement of certain provisions.<sup>46</sup> Appropriations provisions can also be used to prompt agencies to issue certain regulations, or to require that certain procedures be followed before or after their issuance. The inclusion of regulatory provisions in appropriations legislation as a matter of legislative strategy appears to arise from two factors: (1) Congress's ability via its "power of the purse" to control agency action, and (2) the fact that appropriations bills are considered "must pass" legislation. Congress's use of regulatory appropriations restrictions has fluctuated somewhat over time, and previous experience suggests such use they may be somewhat less frequent when Congress and the President are of the same party.<sup>47</sup>

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<sup>42</sup> 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.

<sup>43</sup> For a detailed discussion of CRA procedures, see CRS Report RL31160, *Disapproval of Regulations by Congress: Procedure Under the Congressional Review Act*, by (name redacted).

<sup>44</sup> For more on the potential scope of the definition of a "rule" under the CRA, see CRS Report RL30116, *Congressional Review of Agency Rulemaking: An Update and Assessment of The Congressional Review Act after a Decade*, by (name redacted).

<sup>45</sup> The rule overturned in March 2001 was the Occupational Safety and Health Administration's ergonomics standard. This reversal was the result of a unique set of circumstances in which the incoming President (George W. Bush) did not veto the resolution disapproving the outgoing President's (William J. Clinton's) rule. See CRS Report RL30116, *Congressional Review of Agency Rulemaking: An Update and Assessment of The Congressional Review Act after a Decade*, by (name redacted), for a description of several possible factors affecting the CRA's use, and for other effects that the act may have on agency rulemaking.

<sup>46</sup> See CRS Report RL34354, *Congressional Influence on Rulemaking and Regulation Through Appropriations Restrictions*, by (name redacted).

<sup>47</sup> *Ibid.*, p. 35. This report indicated that some appropriations restrictions were repeated every year for 10 years, some were repeated several years in a row but then stopped, and some appeared in only one appropriations bill. Some restrictions appeared to be intended to stop particular rules issued at the end of presidential administrations.

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

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Unified Agenda	Expected Publication Date
<b>Proposed Rules</b>			
HHS/HRSA	Elimination of Duplication Between the Healthcare Integrity and Protection Data Bank and the National Practitioner Data Bank (0906-AA87)	This rule is required under the Affordable Care Act. The purpose is to eliminate the redundant reporting requirements for two closely related national health care data banks. This rule terminates the Healthcare Integrity and Protection Databank (HIPDB) and transfers all data collected in the HIPDB to the National Practitioner Data Bank (NPDB) established pursuant to the Health Care Quality Improvement Act of 1986. This rule will also provide for the disclosure of information, fee collection, establishment of dispute procedures, and an effective date of no later than one year after enactment or when regulations are published.	07/2011  Note: Although the Agenda indicates that there is a statutory deadline for this rule, it does not specify what the deadline is. No NPRM had been published as of 08/03/2011.
HHS/HRSA	340B Drug Pricing Program; Manufacturer Civil Monetary Penalties (0906-AA89)	This rulemaking is required under the Affordable Care Act. The purpose is to implement an enhancement to the 340B Program. It amends section 340B of the Public Health Service Act to impose monetary sanctions (not to exceed \$5,000 per instance) on drug manufacturers who intentionally charge a covered entity (aka "safety net provider") a price above the ceiling price established under the procedures of the 340B Program.	07/2011  Note: An advance notice of proposed rulemaking (ANPRM) was published on 09/20/2010 (75 F.R. 57230). Legal deadline for ANPRM was 09/20/2010. No NPRM had been published as of 08/03/2011.
HHS/HRSA	340B Ceiling Price Regulations (0906-AA92)	The purpose of this rulemaking is to implement a new statutory requirement in the Affordable Care Act to develop and publish through an appropriate policy or regulation issuance, precisely defined standards and methodology for the calculation of ceiling prices for purposes of 340B.	11/2011
HHS/HRSA	340B Orphan Drug Exclusion (0906-AA94)	Under the changes made by section 2302 Health Care and Education Reconciliation Act (P.L. 111-152), orphan drugs, when used for the rare condition or disease for which that orphan drug was designated under section 526 of the Federal Food, Drug, and Cosmetic Act (FFDCA), are excluded from the definition of covered outpatient drug for the specified newly-eligible covered entity types for purposes of the 340B [Drug Pricing] Program. This regulatory action details how these exclusions will be implemented under the 340B [Drug Pricing] Program. The purpose of issuing this proposed rule is to clarify HHS's stated effort in: (1) Providing clarity in the marketplace, (2) maintaining the 340B savings and interests to the newly-eligible covered entities; and (3) protecting the financial incentives for manufacturing orphan drugs designated for a rare disease or condition as indicated in the Affordable Care Act as intended by Congress.	05/20/2011  Note: NPRM was published on 05/20/2011 (76 F.R. 29183).

<b>Department/ Agency</b>	<b>Title of Rule (RIN)</b>	<b>Abstract, as Provided in the Unified Agenda</b>	<b>Expected Publication Date</b>
HHS/FDA	Food Labeling: Nutrition Labeling for Food Sold in Vending Machines (0910-AG56)	The Food and Drug Administration (FDA) is proposing regulations to establish requirements for nutrition labeling of certain food sold in certain vending machines. FDA is also proposing the terms and conditions for vending machine operators registering to voluntarily be subject to the requirements of section 4205. FDA is taking 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.	04/06/2011  Note: NPRM was published on 04/06/2011 (76 F.R. 19238). Legal deadline for the proposed rule was 03/23/2010.
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) is proposing regulations to establish requirements for nutrition labeling of standard menu items in chain restaurants and similar retail food establishments. FDA is also proposing the terms and conditions for restaurants and similar retail food establishments registering to voluntarily be subject to the requirements of section 4205. FDA is taking 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.	04/06/2011  Note: NPRM was published on 04/06/2011 (76 F.R. 19192). Legal deadline for the proposed rule was 03/23/2011.
HHS/IHS	Standards for the Planning, Design, Construction and Operation of Health Care and Sanitation Facilities (0917- AA08)	Section 311(c)(1) of the Indian Health Care Improvement Act, P.L. 94-437 (1976), as amended by the Patient Protection and Affordable Care Act, P.L. 111-148, section 10221 (2010) requires the Secretary, acting through the Indian Health Service (IHS), to establish, by regulation, standards for the planning, design, construction, and operation of health care and sanitation facilities serving Indians under the Indian Health Care Improvement Act. Additionally, these regulations would stipulate which departmental regulations would be applicable to these activities.	12/2011
HHS/IHS	Confidentiality of Medical Quality Assurance Records; Qualified Immunity for Participants (0917-AA09)	Section 805(j) of the Indian Health Care Improvement Act, P.L. 94-437 (1976), as amended by the Patient Protection and Affordable Care Act, P.L. 111-148, section 10221 (2010) requires the Secretary of the Department of Health and Human Services, acting through the Indian Health Service (IHS), to promulgate regulations to implement section 805. Section 805 makes confidential and privileged the medical quality assurance records of Indian health programs and urban Indian organizations, with very limited exceptions. It also prohibits the testimony of individuals that review or create medical quality assurance records, with very limited exceptions. Although section 805 is immediately executable, the Secretary is required to issue regulations which could substantively affect the implementation of this provision.	02/2012
HHS/CMS	Home and Community-Based Services (HCBS) State Plan Services Program and 5-Year Approvals and Renewals for Waivers and Demonstration Projects(CMS- 2249-P2) (0938- AO53)	In 2008, CMS issued a proposed rule that would define and describe State plan home and community-based services (HCBS) under the Deficit Reduction Act. This rule would allow States, at their option, to provide home and community-based services (HCBS) under their regular State Medicaid plans. This proposed rule revises the 2008 proposed rule to implement provisions of the Affordable Care Act that require oversight and assessment of the administration of home and community based services. In addition, this rule would respond to public comments received on the previous proposed rule pertaining to the HCBS benefit under the Medicaid State plan. Finally, this proposed rule would clarify that Medicaid waivers that provide services for individuals dually eligible for Medicare and Medicaid could be authorized for as long as 5 years. Any waiver that provides medical assistance for dual eligible individuals (including any waivers under which non-dual eligible individuals may be enrolled) may be conducted for a period of 5 years and, upon request by the State, may be extended for additional 5-year periods.	09/2011 (second NPRM)  Note: Original NPRM was published on 04/04/2008 (73 F.R. 18676). HHS is revising that earlier NPRM in light of the Affordable Care Act.

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Unified Agenda	Expected Publication Date
HHS/CMS	Establishing Additional Medicare Provider and Supplier Enrollment Safeguards and Surety Bonds for DMEPOS (CMS-6045-P) (0938-AP01)	This proposed rule would expand existing provider and supplier enrollment requirements to obtain or maintain Medicare billing privileges. Under the Affordable Care Act, this rule would also require surety bonds for DMEPOS [Durable Medical Equipment, Prosthetics, Orthotics, and Supplies]. This proposed rule would also specify the qualification standards and the type of prosthetic and orthotic devices billable to the Medicare program. It also proposes the accreditation deadline for the entities billing orthotics and prosthetics and identifies the DMEPOS product categories exempt from accreditation requirements.	04/2012
HHS/CMS	Implementing Regulations for Reauthorization of the Children's Health Insurance Program (CHIP) (CMS-2301-P) (0938-AP68)	This proposed rule would introduce several new features as a result of the passage of the Children's Health Insurance Program Reauthorization Act (CHIPRA) including a CHIP performance bonus payment system through 2013. For example, the rule would define and provide more guidance on the parameters of the new Express Lane Eligibility option for States including what it means to be an Express Lane agency. It would also define the parameters for the new state option to cover pregnant women in CHIP and provide further guidance regarding the newly required dental benefit package. In addition, it would codify the definition of individuals who are lawfully residing in the US but who are not citizens who can be enrolled in Medicaid and CHIP. Under section 2102 of the Affordable Care Act, this rule would also make technical corrections to selected provisions in CHIPRA and the American Recovery and Reinvestment Act of 2009 (ARRA).	09/2011
HHS/CMS	Administrative Simplification: Standard Unique Identifier for Health Plans (CMS-0040-P) (0938-AQ13)	This rule would implement provisions of the Affordable Care Act of 2010 under Administrative Simplification that establish a unique health plan identifier. This health plan identifier will be used to identify health plans in HIPAA [Health Insurance Portability and Accountability Act of 1996] standard transactions.	07/2011  Note: Legal deadline for the final rule is 10/01/2012. No NPRM had been published as of 08/03/2011.
HHS/CMS	Availability of Medicare Data for Performance Measurement (CMS-5059-P) (0938-AQ17)	Under the Affordable Care Act of 2010, this rule would authorize the release and use of standardized extracts of Medicare claims data to measure the performance of providers and suppliers in ways that protect patient privacy and in accordance with other requirements.	06/2011  Note: Legal deadline for the final rule is 01/01/2012. NPRM was published on 06/08/2011 (76 F.R. 33566).
HHS/CMS	Durable Medical Equipment (DME) Face to Face Encounters and Written Orders Prior to Delivery (CMS-6033-P) (0938-AQ21)	This proposed rule would implement section 1834(a)(1)(B) of the Social Security Act, which was recently amended by the Affordable Care Act. We propose establishing a face-to-face encounter as a condition of payment for certain durable medical equipment (DME) items. When this face-to-face encounter is performed by a physician assistant, a nurse practitioner or a clinical nurse specialist, a physician must document that the face-to-face has occurred pursuant to the order being written. The complete list of covered items of DME that require a face-to-face encounter will be published annually in the Federal Register.	08/2011  Note: Legal deadline for the final rule is 01/01/2012. No NPRM had been published as of 08/03/2011.

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Unified Agenda	Expected Publication Date
HHS/CMS	Medicare Shared Savings Program: Accountable Care Organizations (CMS-1345-P) (0938-AQ22)	This proposed rule would implement Section 3022 of the ACA provisions relating to Medicare payments to providers of services and suppliers participating in Accountable Care Organizations (ACOs). Under these provisions, providers of services and suppliers can continue to receive traditional Medicare fee-for-service payments under Parts A and B, and be eligible for additional payments based on meeting specified quality and savings requirements.	04/07/2011  Note: NRPM was published on 04/07/2011 (76 F.R. 19528). Final action is expected 01/2012. Legal deadline for the final rule is 01/01/2012.
HHS/CMS	Medicaid and Children's Health Insurance Programs; Disallowance of Claims for FFP and Technical Corrections (CMS-2292-P) (0938-AQ32)	This proposed rule would provide policy guidance to States requesting a reconsideration of a disallowance of Medicaid claims under the Medicare Improvements for Patients and Providers Act (MIPPA). Also, this rule would address provisions of the Affordable Care Act concerning the reconsideration process, the change from 60 days to 1-year for overpayments, and changes to the disallowance repayment schedule.	07/2011  Note: Legal deadline for the final rule was 03/23/2010. NPRM was published on 08/03/2011 (76 F.R. 46684).
HHS/CMS	Face-to-Face Requirements for Home Health Services; Policy Changes and Clarifications Related to Home Health (CMS-2348-P) (0938-AQ36)	This proposed rule under the Affordable Care Act of 2010 would require a physician to have a face-to-face encounter with an individual prior to issuing a certification for home health services.	08/2011  Note: Legal deadline for the final rule was 01/01/2010. NPRM was published on 07/12/2011 (76 F.R. 41032).
HHS/CMS	Covered Outpatient Drugs (CMS-2345-P) (0938-AQ41)	This proposed rule would implement several provisions of the Affordable Care Act of 2010 that pertain to prescription drugs under the Medicaid program. It would revise the rebate formulas for covered outpatient drugs, revise the definition of average manufacturer price, and revise the Federal Upper Limits for multiple source drugs.	06/2011  Note: Legal deadline for the final rule was 01/01/2010. No NPRM had been published as of 08/03/2011.
HHS/CMS	Medicaid Automated Data System Requirements and Data Elements Necessary for Program Integrity, Program Oversight, and Administration (CMS-2317-P) (0938-AQ43)	This proposed rule would implement several provisions of the Affordable Care Act of 2010. It would implement the provision that requires States, for data submitted on or after January 1, 2010, to include data elements from the automated data system that CMS determines to be necessary for program integrity, program oversight, and administration, at such frequency as CMS shall determine. It also would implement the provision that requires for managed care patients that the managed care plans provide data to States at a frequency and level of detail as specified by CMS. In addition, the rule would implement the provision that provides for withholding of Federal Matching Payments to States that fail to report enrollee encounter data in the Medicaid Statistical Information System.	10/2011  Note: Legal deadline for the final rule is 01/01/2010.

<b>Department/ Agency</b>	<b>Title of Rule (RIN)</b>	<b>Abstract, as Provided in the Unified Agenda</b>	<b>Expected Publication Date</b>
HHS/CMS	Compliance Program For Providers and Suppliers (CMS-6037-P) (0938-AQ58)	This proposed rule implements several provisions of the Affordable Care Act. Section 6401 requires the Secretary to establish the core elements of a compliance program for Medicare, Medicaid and SCHIP providers and suppliers. The compliance program would now be a condition of enrollment. Section 6402(c) requires the Secretary to establish appropriate administrative remedies for any beneficiary that knowingly participated in fraud. Finally, section 6402(d) requires that the Secretary to establish a process for a provider or supplier to return an overpayment to the program, as well establish a process for CMS and its contractors to receive and apply the overpayment.	11/2011
HHS/CMS	Federal Medicaid Assistance Percentages—Methodologies for Calculation of Enhanced Rate (CMS-2327-P) (0938-AQ59)	The Affordable Care Act authorizes enhanced Federal Medical Assistance Percentages (FMAP) for newly eligible individuals as defined by the act. This proposed rule sets forth methodologies for FMAP calculations.	06/2011  Note: Legal deadline for the final rule is 01/01/2014. No NPRM had been published as of 08/03/2011.
HHS/CMS	Medicaid Eligibility Expansion Under the Affordable Care Act of 2010 (CMS-2349-P) (0938-AQ62)	The Affordable Care Act authorizes a major Medicaid expansion to individuals who are under 65, not pregnant, not receiving Medicare and not eligible for other mandatory eligibility categories. This proposed rule would set forth policies for Medicaid expansion including household income and household composition, coordination with Exchanges, simplifying and streamlining Medicaid eligibility determinations.	06/2011  Note: Legal deadline for the final rule is 01/01/2014. No NPRM had been published as of 08/03/2011.
HHS/CMS	Enrollment Requirement to Disclose Affiliation With Suspended, Revoked, or Excluded Providers (CMS-6038-P) (0938-AQ64)	This regulation would implement sections of the Affordable Care Act that require providers or suppliers seeking to enroll in Medicare, Medicaid, or CHIP to disclose any current or previous, direct or indirect affiliation with a provider that has uncollected debt, is subject to a payment suspension under a Federal health care program, has been excluded from Medicare, Medicaid or CHIP or has had its billing privileges denied or revoked. The Secretary may deny enrollment if it has been determined that a previous affiliation poses an undue risk of fraud to the program.	08/2011  Note: No NPRM had been published as of 08/03/2011.
HHS/CMS	Requirements To Implement American Health Benefit Exchanges and Other Provisions of the Affordable Care Act (CMS-9989-P) (0938-AQ67)	The Affordable Care Act requires the establishment of health insurance exchanges –new, competitive, consumer-centered health insurance marketplaces – that will put greater control and greater choice in the hands of individuals and small businesses. The exchanges will make purchasing health insurance easier by providing eligible consumers and businesses with “one-stop-shopping” where they can compare and purchase health insurance coverage. The Affordable Care Act authorized grants to the states to help them design and establish exchanges in time for millions of Americans to choose their coverage for 2014. This proposed rule would establish the requirements for exchanges.	06/2011  Note: NPRM was published on 07/15/2011 (76 F.R. 41866).
HHS/CMS	Public Use Files of Health Plan Data (CMS-9984-P) (0938-AQ69)	The Affordable Care Act requires generating public use files on data that HHS collects from health plans, and includes specific data and their application (or not) to the Trade Secrets Act. This rule would clarify statutory requirements under the Affordable Care Act.	12/2011

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Unified Agenda	Expected Publication Date
HHS/CMS	Transparency Reporting (CMS-9985-P) (0938-AQ72)	The Affordable Care Act requires group health plans and health insurance issuers to submit specific information to the Secretary, the State insurance commissioner, and to make the information available to the public. This includes information on claims payment policies, the number of claims denied, data on rating practices and other information as determined by the Secretary. The provision also requires plans and issuers to provide to individuals upon request the amount of cost sharing that the individual would be responsible for paying for a specific item or service provided by a participating provider. This interim final rule would implement information disclosure provisions in section 2715A of the Public Health Service Act [PHSA], as added by the Affordable Care Act.	09/2011
HHS/CMS	Uniform Explanation of Benefits, Coverage Facts, and Standardized Definitions (CMS-9982-P) (0938-AQ73)	The Affordable Care Act requires the Secretary to develop standards for use by group health plans and health insurance issuers in compiling and providing a summary of benefits and coverage explanation that accurately describes benefits and coverage. The Secretary must also set standards for the definitions of terms used in health insurance coverage, including specific terms set out in the statute. Plans and issuers must provide information according to these standards no later than 24 months after enactment. This proposed rule would implement the information disclosure provisions in section 2715 of PHSA , as added by the Affordable Care Act.	06/2011  Note: Legal deadline for the final rule was 03/23/2011. No NPRM had been published as of 08/03/2011.
HHS/CMS	Administrative Simplification: Compliance: Health Plan Certification (CMS-0037-P) (0938-AQ85)	This rule proposes to implement provisions of the Affordable Care Act of 2010 under Administrative Simplification to certify that data and information systems are in compliance with any applicable standards and associated operating rules for electronic funds transfers, eligibility for a health plan, health claim status, and health care payment and remittance advice.	02/2012  Note: According to the Unified Agenda, the first phase of compliance deadline is December 31, 2013; second phase of compliance deadline is December 31, 2015.
HHS/CMS	Establishment of the Consumer Operated and Oriented Plan Program (CMS-9983-P) (0938-AQ98)	Under section 1322 of the Affordable Care Act, a Consumer Operated and Oriented Plan program (CO-OP program) must be established to foster the creation of “qualified nonprofit health insurance issuers” that will offer qualified health plans in the individual and small group markets. Such qualified nonprofit issuers must operate with a strong consumer focus and use any profits to lower premiums, improve benefits, or improve the quality of health care delivered to plan members.	06/2011  Note: Grants and loans must be awarded by 7/1/2013. NPRM was published on 07/20/2011 (76 F.R. 43237).
HHS/AOA	Community Living Assistance Services and Supports (CLASS) Program—Designation of the CLASS Independence Benefit Plan and Enrollment Rules (0985-AA07)	The Department of Health and Human Services will issue rules to implement the Community Living Assistance Services and Supports (CLASS) program, which was enacted as part of the Affordable Care Act. Specifically, the rules will designate the CLASS Independence Benefit Plan and establish enrollment rules for the program. Participation in the program is voluntary.	10/2011  Note: Legal deadline for the final rule is 10/01/2012.

<b>Department/ Agency</b>	<b>Title of Rule (RIN)</b>	<b>Abstract, as Provided in the Unified Agenda</b>	<b>Expected Publication Date</b>
HHS/OS	Nondiscrimination Under the Affordable Care Act (0991-AB75)	The Department of Health and Human Services, Office for Civil Rights, will issue rules for covered entities with respect to 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.	09/2011
HHS/OS	Oversight and Assessment of the Administration of Home and Community Based Services (0991-AB79)	Section 2402 (a) of the Patient Protection and Affordable Care Act requires the Secretary of Health and Human Services to develop regulations to ensure that home and community based service systems are designed to allocate resources for services in a manner that is responsive to the changing needs and choices of beneficiaries receiving home and community based services.	10/2011  Note: Final action expected in 09/2012.



Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Unified Agenda	Expected Publication Date
HHS/OS	Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Office of Inspector General's Safe Harbors Under the Antikickback Status, Exclusion Authorities, and Civil Monetary Penalty (0991-AB81)	<p>This rule would: 1) Safe Harbor Provisions: Add safe harbors under the anti-kickback statute addressing arrangements in the following areas (subject to certain conditions): waivers of Federal health care program beneficiary cost-sharing amounts in the context of certain government sponsored clinical trials and in the context of certain emergency medical services furnished by suppliers owned or operated by States or municipalities; certain local transportation provided to Federal health care program beneficiaries; certain waived or reduced cost-sharing amounts under Medicare Part D (codifying in regulations section 101(e) of the Medicare Prescription Drug Improvement and Modernization Act of 2003); and certain discounts in the price of "applicable drugs" of manufacturers furnished to "applicable beneficiaries" under the Medicare Coverage Gap Discount Program (pursuant to section 3301 of the [ACA]). In addition, this rule would re-propose expanding the existing safe harbor for certain waivers of beneficiary co-insurance and deductible amounts for Part A or Part B services for Medicare SELECT policyholders in accordance with an agreement between the Medicare SELECT issuer and a provider or supplier, in certain contexts. 2) OIG's Authority To Impose Civil Money Penalties and Assessments (610 Review): Revise 42 CFR part 1003, addressing the Office of Inspector General's authority to propose the imposition of civil money penalties and assessments by reorganizing and simplifying existing regulatory text and eliminating obsolete references contained in the current regulations. Among the proposed revisions, this rule would establish separate subparts within part 1003 for various categories of violations; clarify the availability of exclusion for certain violations in addition to civil money penalties and assessments; date various references to managed care organization authorities; and clarify the application of section 1140 of the [SSA] with respect to the misuse of certain Departmental symbols, emblems, or names through Internet and e mail communications. 3) OIG's Exclusion Authority: In accordance with section 949 of the Medicare Prescription Drug Improvement and Modernization Act of 2003, and section 6402 of the [ACA], this rule would revise the OIG's exclusion authority to permit any Federal health care program to request a waiver of an OIG exclusion imposed under sections 1128(a)(1), 1128(a)(3), or 1128(a)(4) of the [SSA] if the exclusion would impose a hardship on beneficiaries. In addition, in accordance with sections 6406 and 6408 of the [ACA], the proposed rule would revise the OIG's exclusion authority to grant testimonial subpoena authority in exclusion cases; to add a new permissive exclusion authority for making false statements or misrepresentation of materials facts, and; to broaden the scope of certain permissive exclusion authorities. Finally, the proposed rule would revise current exclusion authorities in 42 CFR parts 1001, 1002, and 1005, to further clarify OIG's existing exclusion authorities. 4) Exceptions to the Beneficiary Inducement Prohibition for Certain Arrangements This proposed rule will codify section 6402(d)(2)(B) of the [ACA], entitled "Clarification of Treatment of Certain Charitable and Other Innocuous Programs." Section 1128A(a)(5) of the [SSA] provides for a civil monetary penalty for certain inducements offered to Medicare and Medicaid beneficiaries. Section 6402(d)(2)(B) of the ACA adds four exceptions to the definition of remuneration at section 1128A(i)(6) of the [SSA] for purposes of section 1128A(a)(5): certain remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs (as defined in section 1128(f) of the [SSA] and designated by the Secretary under regulations); certain offers or transfers in connection with retail rewards programs; certain unadvertised transfers of items or services to beneficiaries experiencing financial need; and certain waivers by PDP sponsors of Part D plans or MA organizations offering MA-PD plans of copayments otherwise owed by their enrollees for the first fill of a covered Part D drug that is a generic drug.</p>	<p>11/2011</p> <p>Note: Legal deadline for NPRM is 11/2011.</p>

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Unified Agenda	Expected Publication Date
DOL/EBSA	Ex Parte Cease and Desist and Summary Seizure Orders Under ERISA Section 521 (1210-AB48)	ERISA section 521, enacted under sec. 6605 of the Affordable Care Act (P.L. 111-148, 124 Stat. 780), authorizes the Secretary of Labor to issue a cease and desist order if it appears that a multiple employer welfare arrangement (MEWA) is fraudulent, creates an immediate danger to public safety or welfare, or can be reasonably expected to cause significant, imminent, and irreparable public injury. This section also authorizes the Secretary to issue a summary seizure order if it appears that a MEWA is in a financially hazardous condition. Regulatory guidance will provide standards for the issuance of such orders.	09/2011
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. The Department anticipates proposing rules that define the class of claims affected by the amendments and set the criteria for establishing entitlement to benefits under the amendments.	03/2012
TREAS/DO	Review and Approval Process for Waivers for State Innovation (1505-AC30)	This rule implements the procedures for developing, submitting and reviewing a Waiver for State Innovation described in section 1332 of the Patient Protection and the Affordable Care Act.	06/2011  Note: NPRM was published on 03/14/2011 (76 F.R. 13553).
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.	12/2011
TREAS/IRS	Development and Utilization of Uniform Explanation of Coverage Documents, Definitions, and Requirements To Provide Information Under the Patient Protection and Affordable Care Act (1545-BJ94)	These proposed regulations provide guidance concerning the development and utilization of uniform explanation of coverage documents, standardized definitions, and the provision of additional information under sections 2715 and 2715A of the Public Health Service Act, incorporated into section 9815 of the Internal Revenue Code by section 1563(f) of the Patient Protection and Affordable Care Act, P.L. 111-148.	06/2011  Note: No NPRM had been published as of 08/03/2011.
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 chapter 87 to include enrollments for eligible employees of tribes and tribal organizations under the provisions of the Affordable Care Act of 2010.	12/2011

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Unified Agenda	Expected Publication Date
OPM	Federal Employees Health Benefits Program; Tribes and Tribal Organizations (3206-AM40)	The U.S. Office of Personnel Management (OPM) proposes to amend the Federal Employees Health Benefits (FEHB) regulations at 5 CFR chapter 89 to include enrollments for eligible employees of tribes and tribal organizations under the provisions of the Affordable Care Act of 2010.	12/2011
OPM	Federal Employees Health Benefits Program; Disputed Claims and External Review Requirements (3206-AM42)	The U.S. Office of Personnel Management (OPM) proposes to amend the Federal Employees Health Benefits (FEHB) regulations at 5 CFR chapter 89 to include changes to resolution of disputed health claims and to provide for external review under the provisions of the Affordable Care Act of 2010.	12/2011
<b>Final Rules</b>			
HHS/HRSA	Designation of Medically Underserved Populations and Health Professional Shortage Areas (0906-AA44)	This rulemaking is mandated under the Affordable Care Act. It requires the Secretary to establish a committee to draft an interim final rule for designation of Medically Underserved Populations (MUPs) and Primary Care Health Professions Shortage Areas (HPSAs). A notice of intent to form the negotiated rulemaking committee was published on May 21, 2010 (75 FR 26167) and the Secretary announced committee membership on July 21, 2010. The rulemaking committee consists of technical experts representing stakeholders that will be significantly affected by this rule. A variety of federal and state programs target resources to underserved populations using MUP and HPSA designations. These designations have not been updated in many cases for over 20 years and may not reflect current conditions in many areas. The task of the rulemaking committee is to update the designations, which will likely involve revisions to the current methodologies to reflect changes in the prevailing values of the indicators and availability of data on other indicators of underservice. Prior to passage of the Affordable Care Act, the Department made several attempts to revise the designations. An initial NPRM was published on September 1, 1998, but due to the extensive comments received, another notice was published on June 3, 1999 announcing a decision to develop and publish a revised NPRM for public comment. The second NPRM was published on February 29, 2008, with the comment period extended twice (first on April 21, 2008, and again on June 2, 2008). Substantial comments were received. A Federal Register Notice published on July 23, 2008, announcing an Agency decision to carefully review these comments, develop a modified proposal, and publish another NPRM at a future date.	11/2011  Note: This rule is to be an interim final rule. Original NPRM was published 09/01/1998 (63 F.R. 46538). A second NRPM was published on 02/20/2008 and the comment period was extended twice.
HHS/CMS	Administrative Simplification: Adoption of Standard and Operating Rule for Electronic Funds Transfer (EFT) and Operating Rule for Remittance Advice (CMS-0024-IFC) (0938-AQ11)	This rule implements provisions of the Affordable Care Act of 2010 under Administrative Simplification that require the adoption of standards and operating rules for Electronic Funds Transfers (EFT) and operating rules for remittance advice, and to consider those operating rules developed by a qualified nonprofit entity that meets specific criteria.	12/2011  Note: Legal deadline for the final rule is 01/01/2012.

<b>Department/ Agency</b>	<b>Title of Rule (RIN)</b>	<b>Abstract, as Provided in the Unified Agenda</b>	<b>Expected Publication Date</b>
HHS/CMS	Administrative Simplification: Adoption of Authoring Organizations for Operating Rules and Adoption of Operating Rules for Eligibility and Claims Status (CMS-0032-IFC) (0938-AQ12)	This rule implements provisions of the Affordable Care Act of 2010 under Administrative Simplification that require the adoption of authoring organizations for operating rules and the adoption of operating rules for eligibility and claims status, and to consider those operating rules developed by a qualified nonprofit entity that meets specific criteria.	06/2011  Note: Legal deadline for the final rule was 07/01/2011. Rule was issued as an interim final rule on 07/08/2011 (76 F.R. 40458).
HHS/CMS	Medicaid Recovery Audit Contractors (CMS-6034-F) (0938-AQ19)	This final rule would provide guidance to States related to Federal/State funding of State start-up, operation and maintenance costs of Medicaid Recovery Audit Contractors (Medicaid RACs), and the payment methodology for State payments to Medicaid RACs in accordance with section 6411 of the Affordable Care Act. In addition, this rule includes requirements for States to assure that adequate appeals processes are in place for providers to dispute adverse determinations made by Medicaid RACs. Finally, the rule requires States and Medicaid RACs coordinate efforts with existing contractors and entities auditing Medicaid providers and with State and Federal law enforcement agencies.	08/2011  Note: NPRM was published on 11/10/2010 (75 F.R. 69037). Legal deadline for the final rule was 12/31/2010. No final rule was published as of 08/03/2011.
HHS/CMS	Payment Adjustment for Provider—Preventable Conditions Including Health Care-Acquired Conditions (CMS-2400-F) (0938-AQ34)	This rule, under the Affordable Care Act of 2010, would prohibit Medicaid payment for services related to health care acquired conditions.	06/2011  Note: NPRM was published on 02/17/2011 (76 F.R. 9283). Legal deadline for the final rule was 07/01/2011. Final rule was issued on 06/06/2011 (76 F.R. 32816).
HHS/CMS	Community First Choice Option (CMS-2337-F) (0938-AQ35)	This rule, under the Affordable Care Act of 2010, establishes an optional Medicaid benefit through which States could offer community-based attendant services and support to Medicaid beneficiaries with disabilities who would otherwise require the level of care offered in a hospital, nursing facility, or intermediate care facility for the mentally retarded.	08/2011  Note: NPRM was published on 02/25/2011 (76 F.R. 10736). No final rule was published as of 08/03/2011.

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Unified Agenda	Expected Publication Date
HHS/CMS	Changes to the Demonstration Review and Approval Process (CMS-2325-F) (0938-AQ46)	This rule implements provisions of the Affordable Care Act of 2010 and address concerns about transparency in the demonstration review and approval process. This rule establishes requirements for submitting new proposals and the requirements to amend or extend an approved demonstration project. This rule also provides guidance regarding public notice, monitoring, compliance, the evaluation of demonstration projects and the submission of reports to the Secretary for approved demonstrations.	07/2011  Note: NRPM was issued on 09/17/2010 (75 F.R. 56946). Legal deadline for the final rule was 09/19/2010. No final rule was published as of 08/03/2011.
HHS/CMS	Enhanced Federal Funding for Medicaid Eligibility Determination and Enrollment Activities (CMS-2346-F) (0938-AQ53)	The Affordable Care Act requires States' residents to apply, enroll, receive determinations, and participate in the State health subsidy programs known as "the Exchange". The Affordable Care Act requires many changes to State eligibility and enrollment systems and each State is responsible for developing a secure, electronic interface allowing the exchange of data. Existing legacy eligibility systems are not able to implement the numerous requirements. This rule is key to informing States about the higher rates that CMS will provide to help them update or build legacy eligibility systems that meet the ACA requirements.	06/2011  Note: NPRM was published on 11/08/2010 (75 F.R. 68583). Final rule was published on 04/19/2011 (76 F.R. 21950).
HHS/CMS	Internal Claims, Appeals, and External Review Processes Under the Affordable Care Act (CMS-9993-IFC2) (0938-AQ66)	The Affordable Care Act provides consumers with the right to appeal decisions made by their health carrier to an outside, independent decision maker, regardless on the State of residence or type of health insurance. Under interim final regulations issued earlier this year, non-grandfathered plans and issuers must comply with a State external review process or the Federal external review process. This rule would finalize the regulation and provide an opportunity to respond to public comments.	06/2011  Note: According to the Unified Agenda, the original interim final rule was issued on 07/23/2010 (75 F.R. 43330). A second interim final rule was published on 06/24/2011 (76 F.R. 37208), with technical corrections published on 07/26/2011 (76 F.R. 44491).
DOL/OSHA	Procedures for the Handling of Retaliation Complaints Under Section 1558 of the Affordable Care Act of 2010 (1218-AC55)	OSHA is promulgating 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), which added section 18C to the Fair Labor Standards Act. This section established a new whistleblower protection statute to be administered by OSHA that provides protection from retaliation to employees who engage in protected activities under the ACA. Pursuant to the statute, the procedures will follow those enacted under the Consumer Product Safety Improvement Act, 15 U.S.C. 2087(b), including remedies and legal burdens of proof provisions. Promulgation of a regulation is necessary to govern whistleblower investigations conducted under the new statute.	09/2011

Department/ Agency	Title of Rule (RIN)	Abstract, as Provided in the Unified Agenda	Expected Publication Date
TREAS/IRS	Indoor Tanning Services (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.	12/2011  Note: NPRM was published on 06/15/2010 (75 F.R. 33740).
TREAS/IRS	Development and Utilization of Uniform Explanation of Coverage Documents, Definitions, and Requirements To Provide Information Under the Patient Protection and Affordable Care Act (1545-BJ95)	These temporary regulations provide guidance concerning the development and utilization of uniform explanation of coverage documents, standardized definitions, and the provision of additional information under sections 2715 and 2715A of the Public Health Service Act, incorporated into section 9815 of the Internal Revenue Code by section 1563(f) of the Patient Protection and Affordable Care Act, P.L. 111-148.	06/2011  Note: No final rule was published as of 08/03/2011.
SSA	Regulations Regarding Income-Related Monthly Adjustment Amounts to Medicare Beneficiaries' Prescription Drug Premiums (3624F) (0960-AH22)	This subpart relates to section 1860D-13(a) of the Social Security Act (the Act), as added by section 3308 of the Patient Protection and Affordable Care Act (P.L. 111-148). Section 3308(a) establishes an income-related monthly adjustment (IRMAA) to the Medicare Part D premium. Beneficiaries enrolled in Medicare Part D who have modified adjusted gross income over a threshold amount established in the statute will pay an IRMAA in addition to the Medicare Part D standard monthly premium and any applicable premium increases as described in 42 CFR 423.286. The regulations in this subpart explain how we decide whether you are required to pay an IRMAA, and if you are, the amount of your adjustment.	08/2011  Note: Interim final rule was published on 12/07/2010 (75 F.R. 75884). Legal deadline for the final rule was 12/31/2010. It appears that the agency will be issuing revisions to the interim final rule. As of 08/03/2011, no revisions had been published.

**Source:** Information in the first three columns is verbatim as reported in the Unified Agenda of Federal Regulatory and Deregulatory Actions, July 7, 2011, 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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