



# Regulations Pursuant to the Patient Protection and Affordable Care Act (P.L. 111-148)

**Curtis W. Copeland**  
Specialist in American National Government

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## Summary

Federal regulations generally start with an act of Congress, and are the means by which statutes are implemented and many specific requirements are established. The Patient Protection and Affordable Care Act (PPACA, P.L. 111-148, March 23, 2010) is a recent and particularly noteworthy example of congressional delegation of rulemaking authority to federal agencies. This report identifies more than 40 provisions in PPACA (as amended by the Health Care and Education Reconciliation Act of 2010, P.L. 111-152, March 30, 2010) that require, permit, or contemplate rulemaking by federal agencies to implement the legislation.

Where new regulations are required in PPACA, this report also describes provisions in the act that prescribe the substance of certain regulations, procedural requirements regarding the development of those rules, and provisions that establish regulatory deadlines. Where PPACA permits, but does not require, certain regulations, the amount of discretion provided to the agencies appears to vary, as well as the implications of that discretion. In some cases, the agencies appear able to decide whether to take any action, and if so, whether that action takes the form of a regulation or some other method of policy implementation (e.g., adjudication, policy statements, guidance, or memoranda). Other sections in PPACA do not specifically require or permit the development of regulations, instead referring to regulations “issued by the Secretary” or “promulgated by the Secretary.” If these sections refer to existing rules, then new regulations may not be needed.

The report indicates that PPACA gives federal agencies substantial responsibility and authority to “fill in the details” of the legislation through subsequent regulations. Although some regulations are required in 2010, it seems likely that other regulations will be issued for years, or even decades to come. Also, although Congress delegates rulemaking authority for a variety of reasons, the manner in which Congress does so can determine who makes those decisions, and in what manner. When Congress requires that a regulation be issued or made effective by a particular date, that it contain certain substantive elements, and that the rule be developed following certain procedures, then the delegation of legislative rulemaking authority is somewhat limited and Congress retains a measure of control over the subsequent policymaking process. On the other hand, Congress grants substantial discretion to the regulatory agencies when it gives the heads of those agencies broad authority to “prescribe such regulations as may be necessary.” Even more discretion may be given to the agencies when Congress permits agencies to decide certain threshold issues. While the regulations are being developed, or after they are issued, Congress and individual Members have various oversight options, including oversight hearings, meeting with agency officials and filing comments, the Congressional Review Act, and restrictions on agency appropriations.

This report will not be updated.

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## Introduction

Federal regulations generally start with an act of Congress and are the means by which statutes are implemented and specific requirements are established. In *Building a Legislative-Centered Public Administration*, David H. Rosenbloom succinctly described why regulations are important, why Congress delegates rulemaking authority to federal agencies, and congressional responsibilities when such delegations are made:

Rulemaking and lawmaking are functional equivalents. Legislative (substantive) rules made by agencies have the force of law. When agencies make such rules, in effect they legislate. Congress can delegate its legislative authority to the agencies at its discretion for a wide variety of reasons: to alleviate its workload; to avoid a particularly nettlesome political issue; to focus highly specialized administrative expertise on a particular problem; for convenience; or simply because the agencies do not face the constraints of a legislature that is reconstituted every two years.... The agencies perform legislative functions for Congress at its discretion, pursuant to delegations of its authority. The Constitution's grant of legislative power to Congress encompasses a responsibility to ensure that delegated authority is exercised according to appropriate procedures.<sup>1</sup>

## Patient Protection and Affordable Care Act

The Patient Protection and Affordable Care Act (PPACA, P.L. 111-148, March 23, 2010) is a recent and particularly noteworthy example of congressional delegation of rulemaking authority to federal agencies.<sup>2</sup> PPACA contains numerous provisions stating that federal agencies “shall promulgate regulations,” or “shall, by regulation” take certain actions to implement the legislation. 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 said the following:

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>

An article in *CQ Weekly* made much the same point, stating that years of hard work would be needed to get the law implemented.

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<sup>1</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>2</sup> For more information on PPACA, see CRS Report R40942, *Private Health Insurance Provisions in Senate-Passed H.R. 3590, the Patient Protection and Affordable Care Act*, by Hinda Chaikind et al.; CRS Report R40970, *Medicare Program Changes in Senate-Passed H.R. 3590*, coordinated by Patricia A. Davis; and CRS Report R41037, *Medicaid and the Children’s Health Insurance Program (CHIP) Provisions in H.R. 3590, as Passed by the Senate*, coordinated by Kelly Wilkiki.

<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>.

Just the sheer volume of regulations that agencies must issue and enforce and the number of new programs and payment systems they must create and test is reason enough to raise questions about how they can get the job done. And as with any law, the agencies have wide latitude in the implementation. In fact, most prominent among the complaints from critics of the overhaul is the degree of discretion handed to Health and Human Services Secretary Kathleen Sebelius and to multiple divisions in her department. That's not to mention agencies ranging from the Department of Labor to the Internal Revenue Service, which will decide exactly how to implement the law's many provisions.<sup>4</sup>

## **This Report**

This report identifies provisions in PPACA that require, permit, or contemplate rulemaking by federal agencies to implement the legislation. To identify these provisions, CRS first searched through the text of the enrolled version of H.R. 3590 as passed by the House of Representatives and the Senate (because the text of the public law was not yet available) using a variety of terms (“regulation,” “rule,” “rulemaking,” and “regulatory”). CRS also searched through the text of H.R. 4872, the Health Care and Education Reconciliation Act of 2010 (P.L. 111-152, March 30, 2010), which made a number of health-related financing and revenue changes to PPACA.<sup>5</sup> (Hereafter, “PPACA” will refer to PPACA as amended by the reconciliation act.) Although these searches identified more than 40 regulatory provisions in PPACA, it is unclear whether they identified all such provisions in the act. (See the **Appendix** of this report for a table listing these provisions.)

Where new regulations are required in PPACA, this report also describes provisions in the act that prescribe the substance of certain regulations, procedural requirements regarding the development of those rules, and provisions that establish regulatory deadlines. The report concludes with some observations regarding congressional delegations of authority to regulatory agencies and opportunities for congressional oversight of these health care regulations. In brief, the report indicates that (1) many policy decisions are still to be decided in forthcoming regulations that are explicitly required or permitted in PPACA; (2) the manner in which Congress requires or permits rulemaking can determine who makes those decisions, and in what manner; and (3) while the regulations are being developed by executive branch agencies, or after they are issued, Congress has various oversight options.

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<sup>4</sup> John Reichard, “Health: After the Win, No Time to Lose,” *CQ Weekly*, April 5, 2010, p. 814, available at <http://library.cqpress.com/cqweekly/document.php?id=weeklyreport111-000003636588&PHPSESSID=7sgss0dfm1o1dtrkof8h2lvms5>.

<sup>5</sup> For more information on the reconciliation legislation, see CRS Report R41124, *Medicare: Changes Made by the Reconciliation Act of 2010 to the Patient Protection and Affordable Care Act (P.L. 111-148)*, coordinated by Patricia A. Davis; CRS Report R41125, *Medicaid and CHIP: Changes Made by the Health Care and Education Reconciliation Act of 2010 (HCERA, P.L. 111-152) to the Patient Protection and Affordable Care Act (PPACA, P.L. 111-148)*, coordinated by Evelyne P. Baumrucker and Cliff Binder; CRS Report R41126, *Private Health Insurance: Changes Made by H.R. 4872, the Health Care and Education Reconciliation Act of 2010*, by Hinda Chaikind et al.; and CRS Report R41128, *Health-Related Revenue Provisions in the Patient Protection and Affordable Care Act (P.L. 111-148)*, by Janemarie Mulvey.

## Mandatory Regulations

A number of provisions in PPACA specifically require federal agencies to issue regulations that define certain terms, establish substantive requirements, create certain programs, and determine the timing of particular events. Because the legislation specifically requires these actions to be implemented through regulations, federal agencies must take action and have no discretion to use other, non-regulatory techniques (e.g., adjudication, guidance documents, policy statements, letters, or memoranda). The mandatory regulatory provisions in PPACA include the following:

- Section 1001 of the legislation amended Part A of Title XXVII of the Public Health Service Act (PHSA, 42 U.S.C. §300gg et seq.) and created several new sections of that act.
  - Subsection (a) of the new Section 2714 in the PHSA (“Extension of Dependent Coverage”) states that a “group health plan and a health insurance issuer offering group or individual health insurance coverage that provides dependent coverage of children shall continue to make such coverage available for an adult child (who is not married) until the child turns 26 years of age.” Subsection (b) then states that “The Secretary shall promulgate regulations to define dependents to which coverage shall be made available under subsection (a).”<sup>6</sup>
  - Subsection (g) of the new Section 2715 of the PHSA (“Development and Utilization of Uniform Explanation of Coverage Documents and Standardized Definitions”) states that “The Secretary shall, by regulation, provide for the development of standards for the definitions of terms used in health insurance coverage,” including such insurance-related terms as “premium,” “deductible,” “co-insurance,” “co-payment,” and “preferred provider;” and such medical terms as “hospitalization,” “hospital outpatient care,” “physician services,” “skilled nursing care,” and “rehabilitation services.”
  - Subsection (b) of the new Section 2718 of the PHSA (“Bringing Down the Cost of Health Care Coverage”) states that a health insurance issuer offering group or individual health insurance coverage must provide an annual rebate to each enrollee under such coverage if the ratio of the amount of premium revenue expended by the issuer on certain costs to the total amount of premium revenue is less than certain levels. Paragraph (3) of that subsection states “The Secretary shall promulgate regulations for enforcing the provisions of this section and may provide for appropriate penalties.”
- Section 1201 of PPACA also amended the PHSA, creating several new sections. One of the new sections, Section 2702 (“Guaranteed Availability of Coverage”) generally requires each health insurance issuer that offers coverage (beginning in 2014) in the individual or group market in a state to accept every employer and individual in the state that applies for such coverage. Subsections 2702(b)(1) and

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<sup>6</sup> In most of these provisions, the “Secretary” referred to in PPACA appears to be the Secretary of Health and Human Services. In other cases (e.g., provisions that amend the Internal Revenue Code), the “Secretary” appears to be the Secretary of the Treasury.

- (2) allow issuers to restrict enrollment to open and special enrollment periods, and to establish special enrollment periods for qualifying events. Subsection 2702(b)(3) states “The Secretary shall promulgate regulations with respect to enrollment periods under paragraphs (1) and (2).”
- Section 3001 of PPACA (“Hospital Value-Based Purchasing Program”) adds a new subsection to Section 1886 of the Social Security Act (42 U.S.C. §1301 et seq.) that requires the Secretary to establish a hospital value-based purchasing program under which incentive payments are made to hospitals that meet certain performance standards. Paragraph (12) of the new subsection states that the Secretary “shall promulgate regulations to carry out the Program,” and says the regulations should include the selection of performance measures, the methodology used to calculate hospitals’ performance scores, and the methodology used to determine the amount of value-based incentive payments.
  - Section 6402 of the act (“Enhanced Medicare and Medicaid Program Integrity Provisions”) added a new Section 1128J to the Social Security Act. Subsection (h)(1) of that new section amends Section 1862 of the Social Security Act (at 42 U.S.C. §1395y) by adding a new section regarding Medicare on “Suspension of Payments Pending Investigation of Credible Allegations of Fraud.” Among other things, the subsection states that “The Secretary shall promulgate regulations to carry out this subsection.”
  - Section 9023 of the act (“Qualifying Therapeutic Discovery Project Credit”) adds a new section to the Internal Revenue Code of 1986 stating, in part, that the Secretary shall “provide a grant to each person who makes a qualified investment in a qualifying therapeutic discovery project in the amount of 50 percent of such investment. No grant shall be made under this subsection with respect to any investment unless such investment is made during a taxable year beginning in 2009 or 2010.” In establishing the time for payment of such grants, for investments of an ongoing nature, “the Secretary shall issue regulations to determine the date on which a qualified investment shall be deemed to have been made for purposes of this paragraph.”

Also, in the Health Care and Education Reconciliation Act of 2010 that amended PPACA, Section 1409 (“Codification of Economic Substance Doctrine and Penalties”) amended Section 7701 of the Internal Revenue Code of 1986 by inserting a new subsection stating, in part, that the “Secretary shall issue regulations requiring foreign taxes to be treated as expenses in determining pre-tax profit in appropriate cases.”

## **Substantive Rulemaking Requirements**

Many of the rulemaking requirements in PPACA give federal agencies substantial discretion in crafting the regulatory provisions that are required or permitted. For example, the previously mentioned requirement in Section 1001 of the act that the Secretary promulgate regulations defining “dependents” to which coverage shall be made available does not constrain the Secretary in any way in the development of those regulations. However, other parts of PPACA stipulate that the required regulations include certain substantive elements. For example:

- Subsection (c) of Section 1311 of PPACA (“Affordable Choices of Health Benefit Plans”) states that “The Secretary shall, by regulation, establish criteria

- for the certification of health plans as qualified health plans.” It goes on to say that the criteria must require that such plans meet eight minimum requirements (e.g., not employ marketing practices that discourage enrollment; ensure a sufficient choice of providers; include health plan networks that serve predominately low-income, medically underserved individuals; and utilize a standard format to present health benefits plan options).
- Section 1332 of PPACA (“Waiver for State Innovation”) permits states to apply to the Secretary for a waiver of any or all requirements of the section for plan years beginning on or after January 1, 2017. Subsection (a)(4)(B) of Section 1332 requires the Secretary to promulgate regulations relating to these state waivers. That subsection goes on to stipulate that the regulations provide processes (1) for public notice and comment at the state level, (2) that ensure the disclosure of the provisions of state law that the state seeks to waive and how the state will ensure compliance with certain other requirements in PPACA, (3) for providing public notice and comment after the application is received by the Secretary, (4) for the state to provide periodic reports to the Secretary regarding implementation of the program under the waiver, and (5) for the periodic evaluation of the program under the waiver by the Secretary.
  - Section 2402 of the act (“Removal of Barriers to Providing Home and Community-Based Services”) requires the Secretary of Health and Human Services to promulgate regulations to ensure that all states develop service systems that are designed to (1) “allocate resources for services in a manner that is responsive to the changing needs and choices of beneficiaries receiving non-institutionally-based long-term services and supports (including such services and supports that are provided under programs other than the State Medicaid program), and that provides strategies for beneficiaries receiving such services to maximize their independence, including through the use of client-employed providers”; (2) “provide the support and coordination needed for a beneficiary in need of such services (and their family caregivers or representative, if applicable) to design an individualized, self-directed, community-supported life”; and (3) “improve coordination among, and the regulation of, all providers of such services under federally and State-funded programs.”
  - Section 2702 of PPACA (“Payment Adjustment for Health-Acquired Conditions”) requires the Secretary of Health and Human Services to identify in regulations the state practices applicable to the Medicaid program that prohibit payment for health-care acquired conditions. It also says that the regulations “shall prohibit payments to States under section 1903 of the Social Security Act for any amounts expended for providing medical assistance for health care-acquired conditions specified in the regulations. The regulations shall ensure that the prohibition on payment for health care-acquired conditions shall not result in a loss of access to care or services for Medicaid beneficiaries.”
  - Subsection (b) of Section 4205 of the act (“Nutrition Labeling of Standard Menu Items at Chain Restaurants”) amends Section 403(q)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §343(q)(5)) by adding a new provision on “Restaurants, Retail Food Establishments, and Vending Machines.” Among other things, the new provision generally requires restaurants and retail food establishments to disclose on menus and menu boards (including a drive-through menu board) “a succinct statement concerning suggested daily caloric intake, as



specified by the Secretary by regulation.” The provision also says that this disclosure should be done “in a clear and conspicuous manner.” Also, the provision states that the “Secretary shall establish by regulation standards for determining and disclosing the nutrient content for standard menu items that come in different flavors, varieties, or combinations, but which are listed as a single menu item, such as soft drinks, ice cream, pizza, doughnuts, or children’s combination meals, through means determined by the Secretary, including ranges, averages, or other methods.” In promulgating regulations in this section, the Secretary is required to “consider standardization of recipes and methods of preparation, reasonable variation in serving size and formulation of menu items, space on menus and menu boards, inadvertent human error, training of food service workers, variations in ingredients, and other factors, as the Secretary determines.”

## Procedural Requirements

During the past 65 years, Congress and various Presidents have developed an elaborate set of procedures and requirements to guide the federal rulemaking process, including the Administrative Procedure Act (APA, 5 U.S.C. §551 et seq.), the Regulatory Flexibility Act, the Paperwork Reduction Act, the Unfunded Mandates Reform Act, and Executive Order 12866.<sup>7</sup> For example, Section 553 of the APA generally requires that agencies publish a notice of proposed rulemaking in the *Federal Register*, allow “interested persons” an opportunity to comment on the proposed rule, and then publish the final rule, which generally cannot take effect for at least 30 days.<sup>8</sup> In addition to these crosscutting rulemaking requirements, certain statutes require that particular procedures be followed in the development of rules under those statutes.

Some of the mandatory regulatory provisions in PPACA stipulate that certain consultative or rulemaking procedures be followed in developing the required rules. For example:

- Subsection (b)(2) of Section 1104 of PPACA (“Administrative Simplification”) amends Section 1173 of the Social Security Act (at 42 U.S.C. 1320d-2) and states, in part, that “The Secretary shall adopt operating rules under this subsection, by regulation.” In developing those rules, the subsection requires consideration of operating rules developed by a non-profit entity described in a previous subparagraph, and the recommendation that is required to be submitted by the National Committee on Vital Health Statistics. Finally, the subsection states that the Secretary “shall promulgate an interim final rule applying any standard or operating rule recommended by the National Committee on Vital and Health Statistics,” and “shall accept and consider public comments on any interim final rule published under this subparagraph for 60 days after the date of such publication.”<sup>9</sup>

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<sup>7</sup> For a discussion of these and other rulemaking requirements, see CRS Report RL32240, *The Federal Rulemaking Process: An Overview*, by Curtis W. Copeland.

<sup>8</sup> The APA contains numerous exceptions to these general requirements. For example, the APA (5 U.S.C. §553(b)(3)(B)) states that the notice and comment procedures do not apply when the agency finds, for “good cause,” that those procedures are “impracticable, unnecessary, or contrary to the public interest.”

<sup>9</sup> In interim final rulemaking, the agency issues a final rule without a prior notice of proposed rulemaking. The interim final rule is generally effective immediately, but with a post-promulgation opportunity for the public to comment. If the public comments persuade the agency that changes are needed in the interim final rule, the agency may revise the rule (continued...)

- Subsection (b)(2) of Section 1104 of the act also added a new subsection to Section 1173 of the Social Security Act concerning the review and amendment of the above-mentioned operating rules. It requires the Secretary to establish a review committee by January 1, 2014, with the committee's first report due by July 1, 2014, providing recommendations for updating and improving the operating rules. The subsection states that "Any recommendations to amend adopted standards and operating rules that have been approved by the review committee and reported to the Secretary under paragraph (2)(B) shall be adopted by the Secretary through promulgation of an interim final rule not later than 90 days after receipt of the committee's report."
- Subsection (a)(1) of Section 1321 of the act ("State Flexibility in Operation and Enforcement of Exchanges and Related Requirements") requires the Secretary to issue regulations setting standards for meeting the requirements Title I of PPACA "as soon as practicable after the date of enactment of this Act." In doing so, subsection (a)(2) requires the Secretary to consult with the National Association of Insurance Commissioners and its members, and with health insurance issuers, consumer organizations, and "such other individuals as the Secretary selects in a manner designed to ensure balanced representation among interested parties."
- Section 1333 of PPACA ("Provisions Relating to Offering of Plans in More than One State") requires the Secretary to issue regulations for the creation of health care choice compacts (under which two or more states may enter into certain agreements) "in consultation with the National Association of Insurance Commissioners."
- Section 3307 of the act ("Improving Formulary Requirements for Prescription Drug Plans") amends the Social Security Act to require the Secretary to identify "categories and classes of drugs for which the Secretary determines are of clinical concern." Prior to making that determination, the Secretary is required to establish the criteria to be used "through the promulgation of a regulation which includes a public notice and comment period."
- Section 8002 of the act ("Establishment of a National Voluntary Insurance Program for Purchasing Community Living Assistance Services and Support") amended the PHS Act by, among other things, adding a new Section 3203 ("CLASS Independence Benefit Plan") that requires the Secretary to develop at least three "actuarially sound benefit plans as alternatives for consideration for designation by the Secretary as the CLASS Independence Benefit Plan under which eligible beneficiaries shall receive benefits under this title." Subsection (a)(2) of this new section requires a "CLASS Independence Advisory Council" to evaluate the alternative plans and recommend the one that "best balances price and benefits to meet enrollee's needs in an actuarially sound manner." Using this information, Subsection (a)(3) requires the Secretary to designate a benefit plan as the CLASS Independence Benefit Plan, and to do so "along with details of the plan and the reasons for the selection by the Secretary, in a final rule that allows for a period of public comment."

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(...continued)

by publishing a final rule reflecting those changes. For more information, see Michael Asimow, "Interim Final Rules: Making Haste Slowly," *Administrative Law Review*, 51 (Summer 1999), pp. 703-755.

## Negotiated Rulemaking

One particularly notable procedural requirement is in Section 5602 of PPACA, which requires the Secretary of Health and Human Services to use a process called “negotiated rulemaking” to establish a “comprehensive methodology and criteria for designation of ... (A) medically underserved populations in accordance with section 330(b)(3) of the Public Health Service Act (42 U.S.C. §254b(b)(3)),” and “(B) health professions shortage areas under section 332 of the Public Health Service Act (42 U.S.C. §254e).” In negotiated rulemaking, representatives of federal agencies and affected parties work together in a committee to reach consensus on what can ultimately become a proposed rule. Although negotiated rulemaking is not appropriate for all regulations, advocates believe that the approach can speed rule development, reduce litigation, and generate more creative and effective regulatory solutions.<sup>10</sup>

Section 5602 requires the Secretary to publish a notice in the *Federal Register* announcing the intention to form a negotiated rulemaking committee “not later than 45 days after the date of the enactment of this Act.” As part of that notice, the target date for publication of the rule is required to be July 1, 2010. The negotiated rulemaking committee is required to be appointed not later than 30 days after the end of the comment period of the notice, and the facilitator of the committee is required to be appointed within 10 days after the committee is appointed. A preliminary committee report is required by April 1, 2010, with a final report required “not later than one month before the target publication date” (i.e., by June 1, 2010). The Secretary is required to publish an interim final rule by the target date, with a 90-day public comment period to follow. After considering those comments, the Secretary is to publish a final rule not later than one year after the target date.

## Deadlines for the Development or Implementation of Rules

Many of the mandatory regulatory provisions in PPACA do not stipulate when the regulations must be issued or take effect. However, several provisions require the development or implementation of regulations within particular time frames or by particular dates. For example:

- As noted previously in this report, Section 1001 of PPACA amended Part A of Title XXVII of the Public Health Service Act (42 U.S.C. §300gg et seq.) and created several new sections of that act. Subsection (a) of the new Section 2717 (“Ensuring the Quality of Care”) requires the Secretary to develop quality reporting requirements with respect to plan or coverage benefits and health care provider reimbursement structures. Subsection 2717(c) states that “Not later than 2 years after the date of enactment of the Patient Protection and Affordable Care Act, the Secretary shall promulgate regulations that provide criteria for determining whether a reimbursement structure is described in subsection (a).”
- Subsection (c) of Section 1104 of the act (“Administrative Simplification”) establishes specific dates by which three final rules are to be issued or effective. A final rule establishing a unique health plan identifier must be in effect by October 1, 2012. A final rule establishing a standard for electronic funds transfers must be adopted by January 1, 2012, and must be effective by January 1, 2014. A final rule to establish a transaction standard and a single set of associated

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<sup>10</sup> For more information, see CRS Report RL32452, *Negotiated Rulemaking*, by Curtis W. Copeland.

- operating rules for health claims attachments by January 1, 2014, and those rules must be in effect by January 1, 2016. Also, subsection 1104(b) requires that certain recommendations to amend adopted standards and operating rules be adopted through promulgation of an interim final rule within 90 days after receipt of a committee report.
- Subsection (l) of Section 1303 of the act (“Special Rules”) amends Section 1322(b) of PPACA (“Loans and Grants Under the CO-OP Program”) by adding a new paragraph stating, in part, “Not later than July 1, 2013, and prior to awarding loans and grants under the CO-OP program, the Secretary shall promulgate regulations with respect to the repayment of such loans and grants in a manner that is consistent with State solvency regulations and other similar State laws that may apply.”
  - As noted previously in this report, Section 1332 of PPACA (“Waiver for State Innovation”) permits states to apply to the Secretary for a waiver of any or all requirements of the section for plan years beginning on or after January 1, 2017. Subsection 1332(a)(4)(B) requires the Secretary to promulgate regulations relating to such waivers “Not later than 180 days after the date of enactment of this Act.”
  - Section 1333 of the act (“Provisions Relating to Offering of Plans in More than One State”) requires the Secretary to issue regulations by July 1, 2013, for the creation of health care choice compacts (under which two or more states may enter into certain agreements).
  - Section 2702 of the act (“Payment Adjustment for Health Care-Acquired Conditions”) requires the Secretary of Health and Human Services to identify in regulations the state practices applicable to the Medicaid program that prohibit payment for health-care acquired conditions. It goes on to require that the regulations “be effective as of July 1, 2011.”
  - Section 3007 of PPACA (“Value-Based Payment Modifier Under the Physician Fee Schedule”) added a new subsection to Section 1848 of the Social Security Act (at 42 U.S.C. §1395w-4). Subparagraph (p)(4)(B)(i) of that new subsection states that “Subject to the preceding provisions of this subparagraph, the Secretary shall begin implementing the payment modifier established under this subsection through the rulemaking process during 2013 for the physician fee schedule established under subsection (b).”
  - Subsection (b) of Section 4205 of the act (“Nutrition Labeling of Standard Menu Items at Chain Restaurants”) amends Section 403(q)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §343(q)(5)) by adding a new provision on “Restaurants, Retail Food Establishments, and Vending Machines.” Paragraph (x) of the new provision requires the Secretary to promulgate proposed regulations to carry out the clause “not later than 1 year after the date of enactment of this clause.”
  - Subsection (i) of Section 10201 of PPACA (“Amendments to the Social Security Act and Title II of This Act”) amends Section 1115 of the Social Security Act (at 42 U.S.C. §1315) by adding a new subsection (d). Paragraph (2) of that subsection states that “Not later than 180 days after the date of enactment of this

- subsection, the Secretary shall promulgate regulations relating to applications for, and renewals of, a demonstration project”
- Subsection (l) of Section 10501 of the act (“Amendments to the Public Health Service Act, the Social Security Act, and Title V of This Act”) adds a new subpart on “Training in Underserved Communities,” and requires the Secretary to establish a grant program to (among other things) assist in the recruitment of students from underserved rural communities. Paragraph (f) of this new subpart states “Not later than 60 days after the date of enactment of this section, the Secretary shall by regulation define ‘underserved rural community’ for the purposes of this section.”

In some of the provisions, PPACA provides only general time constraints on rulemaking. For example, Section 1321 of the act (“State Flexibility in Operation and Enforcement of Exchanges and Related Requirements”) states that the Secretary shall issue regulations setting standards for meeting the requirements under this title “as soon as practicable after the date of enactment of this Act.”

One provision in PPACA prohibits the development of regulations until a particular date. Subsection (a)(6)(D) of Section 3132 (“Hospice Reform”) states that “not earlier than October 1, 2013, the Secretary shall, by regulation, implement revisions to the methodology for determining the payment rates for routine home care and other services included in hospice care under this part, as the Secretary determines to be appropriate.”

## Discretionary Regulations

Other provisions in PPACA permit, but do not require, federal agencies to issue certain regulations. The amount of discretion provided to the agencies appears to vary with the wording of each provision, as do the implications of that discretion. In some cases, the agencies may be able to decide whether to take any action, and if so, whether that action takes the form of a regulation or some other method of policy implementation (e.g., adjudication, policy statements, guidance documents, or memoranda). As Jeffrey Lubbers noted in *A Guide to Federal Agency Rulemaking*,

It is accepted that agencies are generally free to decide whether to formulate policy through rulemaking or adjudication.... Apart from rulemaking and adjudication, there are, of course, a variety of informal means by which administrative agencies articulate policy under a statute. Among these are press releases, speeches, statements, letters, advisory opinions, rulings, negotiation and litigation strategies, and a host of other types of communications. The extent to which these informal means of articulating policy are binding on the public will vary, but their binding effect usually will be significantly less than that of a “rule” issued after rulemaking or an “order” after adjudication.<sup>11</sup>

He also said that congressional authorization to “make such rules and regulations as may be necessary ... clearly enables an agency to promulgate procedural, organizational, or other

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<sup>11</sup> Jeffrey S. Lubbers, *A Guide to Federal Agency Rulemaking*, 4<sup>th</sup> ed. (Chicago, IL: 2006), pp. 127-128.

‘housekeeping’ rules and probably also enables an agency to issue nonbinding guidelines or interpretations of its statutory mandate.”<sup>12</sup>

Provisions in PPACA that give agencies discretion in whether to issue regulations (as opposed to guidelines or other methods that are not specifically regulations) include the following:

- Subsection (d)(2)(B) of Section 1302 of PPACA (“Essential Health Benefits Requirements”) states that “The Secretary may issue regulations under which employer contributions to a health savings account (within the meaning of section 223 of the Internal Revenue Code of 1986) may be taken into account in determining the level of coverage for a plan of the employer.” Given the language of this subsection (“may issue regulations”), the Secretary appears to be allowed to take no action regarding employer contributions. If the Secretary elects to act, it is unclear whether the Secretary must do so through regulations, or whether the contributions can be allowed to be taken into account in other, non-regulatory ways (e.g., through some type of non-binding implementing guidance).
- Subsection (h) of Section 1311 of the act (“Affordable Choices of Health Benefit Plans”) states that, beginning on January 1, 2015, a qualified health plan may contract with a health care provider “only if such provider implements such mechanisms to improve health care quality as the Secretary may by regulation require.” Given this wording, the Secretary appears to be allowed not to require such improvement mechanisms. If the Secretary decides to require mechanisms to improve health care quality, it is unclear whether this subsection requires the Secretary to do so through regulations or whether other, non-regulatory methods can be used.
- Another provision in subsection (h) of Section 1311 (paragraph (1)(A)) places restrictions on contracts with hospitals greater than 50 beds, but goes on to say that the Secretary “may by regulation adjust the number of beds described in paragraph (1)(A).” This language appears to allow the Secretary not to take any action (thereby keeping the number of beds at 50). On the other hand, if the Secretary decides to adjust the number of beds, it is unclear whether the language in this subsection requires the Secretary to do so by issuing a regulation.
- Subsection (h) of Section 1322 of the act (“Federal Program to Assist Establishment and Operation of Nonprofit, Member-Run Health Insurance Issuers”) amends Section 501(c) of the Internal Revenue Code of 1986 adding “Co-Op Health Insurance Issuers” to the list of exempt organizations. The subsection goes on to say that the exemption applies only if the organization has “given notice to the Secretary, in such manner as the Secretary may by regulations prescribe, that it is applying for recognition of its status under this paragraph.” Given this construction, the Secretary arguably may decide not to specify the manner of notice. However, if the Secretary does elect to do so, it is unclear whether this subsection requires that the manner of notice be prescribed in a regulation.

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<sup>12</sup> *Ibid.*, p. 131.

- Section 1401 of the act (“Refundable Tax Credit Providing Premium Assistance for Coverage Under a Qualified Health Plan”) amended the Internal Revenue Code of 1986 and added a new Section 36B on “Refundable Credit for Coverage Under a Qualified Health Plan.” Subsection (g) of this new section states that “The Secretary shall prescribe such regulations as may be necessary to carry out the provisions of this section.” Given this language, the Secretary may conclude that regulations are not needed to accomplish the objectives of the new Section 36B. It is unclear from this language whether other, non-regulatory methods are available.
- Section 1513 of PPACA (“Shared Responsibility for Employers”) amends Chapter 43 of the Internal Revenue Code of 1986 by adding a new Section 4980H on “Shared Responsibility for Employers Regarding Health Coverage.” Subsection (3) of that section states that the “Secretary shall prescribe rules, regulations, or guidance for the repayment of any assessable payment (including interest) if such payment is based on the allowance or payment of an applicable premium tax credit or cost-sharing reduction with respect to an employee, such allowance or payment is subsequently disallowed, and the assessable payment would not have been required to be made but for such allowance or payment.” Assuming that the latter conditions are met, this subsection appears to require the Secretary to take some type of action. However, the “rules, regulations, or guidance” language suggests that any of those mechanisms would satisfy the statutory requirement, not just regulations.
- Section 1557 of PPACA (“Nondiscrimination”) prohibits the exclusion of an individual from participation, denial of benefits, or other forms of discrimination regarding any covered health program or activity. Subsection (c) states that the “Secretary may promulgate regulations to implement this section.” Given this language, the Secretary arguably may conclude that the section can be implemented without regulations. However, if the Secretary decides to act, it is unclear whether non-regulatory methods can be used to implement the section.
- Section 3507 of the act (“Presentation of Prescription Drug Benefit and Risk Information”) requires the Secretary to submit a report to Congress no later than one year after the date of enactment of PPACA determining whether the addition of quantitative summaries of the benefits and risks of prescription drugs in a standardized format to promotional labeling or print advertising would improve health care decision making by clinicians, patients, and consumers. If the Secretary determines in that report that quantitative summaries are needed, then the Secretary is required to promulgate “proposed regulations as necessary” to implement that format within three years after the date that the report is submitted. On the other hand, if the Secretary determines that quantitative summaries are not needed, then no proposed rule need be developed.
- Subsection (a) of Section 6401 of the act (“Provider Screening and Other Enrollment Requirements Under Medicare, Medicaid, and CHIP”) amends Section 1866(j) of the Social Security Act (at 42 U.S.C. 1395cc(j)) and requires the Secretary to establish procedures under which screening is conducted with respect to providers of medical or other items or services “not later than 180 days after the date of enactment of this paragraph.” Subsections (B) through (D) describe the level of screening to be conducted, application fees, and application and enforcement provisions. Finally, subsection (E) states that “The Secretary

may promulgate an interim final rule to carry out this paragraph.” Given this discretionary language, the Secretary appears able to conclude that regulations are not needed. If a regulatory approach is used, the Secretary may use regular notice and comment rulemaking, or may issue an interim final rule (which typically take effect immediately with a post-promulgation opportunity for public comment).

Also, Section 3014 of PPACA (“Quality Measurement”) amends the Social Security Act (at 42 U.S.C. §1395aaa(b)) to require the Secretary to “establish a pre-rulemaking process” under which certain steps occur regarding the selection of quality measures. Among other things, the amendment requires the Secretary to (1) make a list of quality measures being considered available to the public by December 1 of each year (beginning with 2011); (2) be provided with input from stakeholder groups by February 1 of each year (beginning with 2012); and (3) assess the quality impact of certain measures by March 1, 2012, and at least once every three years thereafter. Notably, however, this “pre-rulemaking process” is not specifically required to result in a regulation.

## **Other Regulatory Provisions**

In other sections of PPACA, the statutory language appears to contemplate the use of regulations to fulfill the underlying policy requirement, but the language does not specifically require or permit federal agencies to issue new regulations. One possibility is that these sections of the act refer to existing rules. If so, new regulations may not be needed to satisfy the requirements in PPACA. However, to the extent that implementing regulations are not already in existence, new rules may need to be established, or existing rules may need to be amended. Examples of these kinds of provisions include the following:

- Subsection (b) of Section 1302 of PPACA (“Essential Health Benefits Requirements”) generally requires the Secretary to “define the essential health benefits,” but also says that they must include certain elements (e.g., emergency services, maternity and newborn care, and prescription drugs). Subsection (d) of this section describes four levels of coverage (bronze, silver, gold, and platinum), and also says “Under regulations issued by the Secretary, the level of coverage of a plan shall be determined on the basis that the essential health benefits described in subsection (b) shall be provided to a standard population (and without regard to the population the plan may actually provide benefits to).”
- Section 1511 of the act (“Automatic Enrollment for Employees of Large Employers”) amends the Fair Labor Standards Act of 1938 (FLSA) by inserting a new Section 18A that states “In accordance with regulations promulgated by the Secretary, an employer to which this Act applies that has more than 200 full-time employees and that offers employees enrollment in 1 or more health benefits plans shall automatically enroll new full-time employees in one of the plans offered (subject to any waiting period authorized by law) and to continue the enrollment of current employees in a health benefits plan offered through the employer.”
- Section 1512 of the act (“Employer Requirement to Inform Employees of Coverage Options”) also amends the FLSA by inserting a new Section 18B stating “In accordance with regulations promulgated by the Secretary, an



employer to which this Act applies, shall provide to each employee at the time of hiring (or with respect to current employees, not later than March 1, 2013), written notice” to employees of the existence of an exchange, that the employee may be eligible for a tax credit and a cost sharing reduction, and that the employee will lose any employer contribution if the employee purchases a qualified health plan through the exchange.

- Section 3208 of the act (“Making Senior Housing Facility Demonstration Permanent”) amends Section 1859 of the Social Security Act (at 42 U.S.C. §1395w-28) by adding a new section stating, in part, that the service area of a Medicare Advantage senior housing facility plan described in that section may be limited to a senior housing facility in a geographic area “in accordance with regulations of the Secretary.”
- Subsection (b) of Section 6401 of the act (“Provider Screening and Other Enrollment Requirements Under Medicare, Medicaid, and CHIP”) amends Section 1902(a) of the Social Security Act (at 42 U.S.C. §1396a(a)) to, among other things, add requirements for “Provider and Supplier Screening, Oversight, and Reporting.” One of those requirements is that the state complies with the national system for reporting criminal and civil adverse provider actions to the Secretary “in accordance with regulations of the Secretary.”
- Section 6402 of the act (“Enhanced Medicare and Medicaid Program Integrity Provisions”) added a new Section 1128J to the Social Security Act. Subsection (h)(2) of Section 6402 requires the following: “by any individual or entity to whom the State has failed to suspend payments under the plan during any period when there is pending an investigation of a credible allegation of fraud against the individual or entity, as determined by the State in accordance with regulations promulgated by the Secretary for purposes of section 1862(o) and this subparagraph, unless the State determines in accordance with such regulations there is good cause not to suspend such payments.”
- Subsection (d) of Section 10108 of the act (“Free Choice Vouchers”) states that “The cost of any health plan shall be determined under the rules similar to the rules of section 2204 of the Public Health Service Act, except that such amount shall be adjusted for age and category of enrollment in accordance with regulations established by the Secretary.”

## **Concluding Observations**

The previous sections of this report illustrate that PPACA gives federal agencies substantial responsibility and authority to “fill in the details” of the legislation through subsequent regulations. The first of these implementing regulations are due in 2010, but some are not required to be promulgated or take effect until much later. These regulatory requirements are also likely to be reviewed and revised as agencies gain experience in implementing the statute. In addition, federal agencies are also likely to issue clarifying or implementing regulations regarding particular provisions in the act, even though the act does not specifically require or authorize

them to do so.<sup>13</sup> Therefore, it seems likely that there will be a great deal of regulatory activity relating to the many provisions in PPACA for years, or even decades to come.

As Henry J. Aaron and Robert D. Reischauer noted in their article entitled “The War Isn’t Over,” many of the regulations developed pursuant to the provisions in PPACA will likely “provoke controversy.”<sup>14</sup> Some of these controversies are likely to center on the contents of the rules that are developed (e.g., how the Secretary defines “dependents” to whom coverage is required to be made available pursuant to subsection (a) of Section 2714 of the act). Other controversies may focus on whether the agencies have satisfied the procedural requirements specified in PPACA, or the requirements in the myriad of other statutes and executive orders that determine the federal rulemaking process. Still other controversies may arise regarding whether federal agencies need to issue regulations in discretionary areas at all.

## **Wording of Regulatory Provisions Matters**

Congress can assign regulatory responsibilities to federal agencies in any number of ways, but the manner by which Congress does so can determine the amount of discretion given to the agencies and, conversely, the amount of control that Congress retains for itself. When Congress requires that a regulation be issued or made effective by a particular date, that it contain certain substantive elements, and that the rule be developed following certain procedures, then the delegation of legislative rulemaking authority is somewhat limited and Congress retains a measure of control over the subsequent policymaking process. On the other hand, Congress grants substantial discretion to the regulatory agencies when it gives the heads of those agencies broad authority to “prescribe such regulations as may be necessary.” Even more discretion may be given to the agencies when Congress permits agencies to decide certain threshold issues. For example, subsection (d)(2)(B) of Section 1302 of PPACA states that “The Secretary may issue regulations under which employer contributions to a health savings account ... may be taken into account in determining the level of coverage for a plan of the employer.” Therefore, the Secretary arguably may decide not to take any actions to allow those contributions to be taken into account. Some observers of the rulemaking process have previously expressed concerns that Congress often gives too much discretion to regulatory agencies.<sup>15</sup>

Congressional delegations of authority to rulemaking agencies may be necessary because Congress does not have the technical knowledge needed to legislate within particular areas, or because Congress cannot reach consensus on how particular issues should be resolved. Giving regulatory agencies discretion to decide how certain rules should be crafted can allow them to devise approaches that will yield the desired outcomes at the lowest costs. Conversely, constraining the agencies with unrealistic deadlines or with extremely detailed substantive requirements in statutes can result in rules that cost more than the benefits that they are expected

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<sup>13</sup> For example, on March 29, 2010, the Secretary of Health and Human Services told insurers that forthcoming regulations would “ensure that there is no ambiguity” that PPACA prohibits insurers from both denying an uninsured child coverage because of a pre-existing condition and denying treatments for an insured child’s pre-existing condition beginning in September 2010. Sarah Barr, “Sebelius Says Regulations Will Clarify Rules on Pre-Existing Condition Denials for Children,” *BNA Daily Report for Executives*, March 30, 2010, p. A-20.

<sup>14</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>15</sup> See, for example, David Schoenbrod, *Power Without Responsibility: How Congress Abuses the People Through Delegation* (New Haven: Yale University Press, 1993).

to provide.<sup>16</sup> Some regulatory observers have previously expressed concerns that congressional delegations of rulemaking authority are sometimes too specific.<sup>17</sup> Also, the Government Accountability Office (GAO) concluded in 1999 that some regulatory provisions that were considered burdensome by private sector companies were directly traceable to specific statutory requirements.<sup>18</sup>

Also, several of the procedural requirements in PPACA are likely to affect the degree to which the public is able to participate in the rulemaking process. For example, several provisions in the act require or permit federal agencies to issue interim final rules instead of going through the public notice and comment process. Although interim final rulemaking may speed the issuance of the associated regulation, doing so may not allow the public to comment before the rule becomes final. In addition, public participation may be limited when agencies are allowed to implement certain provisions through non-binding guidance or other non-regulatory mechanisms. In contrast, other provisions in PPACA specifically require notice and comment rulemaking, consultation with affected parties before a proposed rule is developed, comment periods after rules are published, or some combination of these requirements.

## **Congressional Oversight Options**

Regardless of whether congressional delegations of regulatory authority are broad or specific, 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>19</sup> As one author indicated,

[I]nvestigations conducted by congressional committees constitute another powerful device of formal political supervision.... The public legislative hearings, in which administrative action is carefully scrutinized and a commissioner or staff member is plied with questions, symbolizes the unparalleled sophistication of American congressional control over

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<sup>16</sup> For example, on January 15, 2010, the Federal Railroad Administration (FRA) within the Department of Transportation (DOT) published a final rule in the Federal Register defining criteria for “positive train control” systems that were required on certain passenger and freight rail lines by the Rail Safety Improvement Act of 2008 (P.L. 110-432, 122 Stat. 4854, October 16, 2008). ( U.S. Department of Transportation, Federal Railroad Administration, “Positive Train Control Systems,” 75 *Federal Register* 2598, January 15, 2010.) “Positive train control systems” refers to technology that can prevent accidents such as train-to-train collisions and train movements through a switch left in the wrong position. Congress enacted the statutory requirement in the wake of several serious rail accidents involving dozens of fatalities and hundreds of injuries. Although the rule was expected to reduce deaths and injuries by more than 50%, FRA estimated that the cost of the rule would be more than 20 times its estimated benefits. FRA noted this imbalance in the rule, but said it was “constrained by the requirements of [the Rail Safety Improvement Act of 2008], which do not provide latitude for implementing [positive train controls] differently” (p. 2685).

<sup>17</sup> See, for example, Committee for Economic Development, *Modernizing Government Regulation: The Need for Action*, April 1, 1998, available at [http://www.ced.org/images/library/reports/economy/report\\_regulation.pdf](http://www.ced.org/images/library/reports/economy/report_regulation.pdf).

<sup>18</sup> U.S. Government Accountability Office, *Regulatory Burden: Some Agencies’ Claims Regarding Lack of Rulemaking Discretion Have Merit*, GAO/GGD-99-20, January 8, 1999. GAO concluded that for 13 of 27 regulatory concerns that the businesses cited, the underlying statutes gave the rulemaking agencies no discretion in establishing the regulatory requirements at issue.

<sup>19</sup> 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.”

administrative action, in general and by [independent regulatory agencies], in particular. Individual oversight by representatives or senators also takes place. Through correspondence or meetings, the latter convey the concerns of their constituents.<sup>20</sup>

Another option is the Congressional Review Act (CRA, 5 U.S.C. §§801-808), which was enacted in 1996 in an attempt to reestablish a measure of congressional authority over rulemaking “without at the same time requiring Congress to become a super regulatory agency.”<sup>21</sup> The act generally requires federal agencies to submit all of their covered final rules to both houses of Congress and GAO before they can take effect.<sup>22</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>23</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>24</sup> After these rules are submitted, Congress can use the expedited procedures specified in the CRA (particularly in the Senate) 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>25</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>26</sup> Appropriations provisions can also be

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<sup>20</sup> Dominique Custos, “The Rulemaking Power of Independent Regulatory Agencies,” *The American Journal of Comparative Law*, vol. 54 (Fall 2006), p. 633.

<sup>21</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).

<sup>22</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>23</sup> For a detailed discussion of CRA procedures, see CRS Report RL31160, *Disapproval of Regulations by Congress: Procedure Under the Congressional Review Act*, by Richard S. Beth.

<sup>24</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 Morton Rosenberg.

<sup>25</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 Morton Rosenberg, 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>26</sup> See CRS Report RL34354, *Congressional Influence on Rulemaking and Regulation Through Appropriations Restrictions*, by Curtis W. Copeland.

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 be prompted by 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 that they may be somewhat less frequent when Congress and the President are of the same party.<sup>27</sup>

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<sup>27</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. Regulatory Provisions in PPACA

**Table A-I. Regulatory Provisions in PPACA**

Section of PPACA	Regulatory Provision	Regulatory Deadlines
<b>Mandatory Regulations</b>		
Section 1001 (creating a new Section 2714 of the Public Health Service Act (PHSA))	“The Secretary shall promulgate regulations to define dependents to which coverage shall be made available.”	None
Section 1001 (creating a new Section 2715 of the PHSA)	“The Secretary shall, by regulation, provide for the development of standards for the definitions of terms used in health insurance coverage ... ”	None
Section 1001 (creating a new Section 2717 of the PHSA)	“ ... the Secretary shall promulgate regulations that provide criteria for determining whether a reimbursement structure is described in subsection (a).”	Promulgation of regulations within two years after the date of enactment (i.e., by March 23, 2012).
Section 1001 (creating a new Section 2718 of the PHSA)	“The Secretary shall promulgate regulations for enforcing the provisions of this section and may provide appropriate penalties.”	None
Section 1104	“The Secretary shall adopt operating rules under this subsection, by regulation ... ” and “shall promulgate an interim final rule applying any standard or operating rule recommended by the National Committee on Vital and Health Statistics.”	Final rule to establish a unique health plan identifier must be effective by October 1, 2012. Final rule establishing a standard for electronic funds transfers must be adopted by January 1, 2012, and effective by January 1, 2014. Final rule to establish a transaction standard and single set of rules for health claims attachments by January 1, 2014, and in effect by January 1, 2016. Committee-recommended rules must be promulgated as interim final within 90 days of the committee’s report.
Section 1201 (creating a new Section 2702 of the PHSA)	“The Secretary shall promulgate regulations with respect to enrollment periods under paragraphs (1) and (2).”	This section applies to enrollments starting in 2014.
Subsection 1303(l)	“ ... the Secretary shall promulgate regulations with respect to the repayment of such loans and grants ...”	Promulgation by July 1, 2013.
Subsection 1311(c)	“The Secretary shall, by regulation, establish criteria for the certification of health plans as qualified health plans.”	None
Section 1321	“The Secretary shall ... issue regulations setting standards for meeting the requirements under this title, and the amendments made by this title, with respect to ...”	Promulgation “as soon as practicable after the date of enactment of this Act.”

<b>Section of PPACA</b>	<b>Regulatory Provision</b>	<b>Regulatory Deadlines</b>
Subsection 1332(a)(4)(B)	“... the Secretary shall promulgate regulations relating to waivers under this section that provide ...”	Promulgation of rules within 180 days of enactment (i.e., by September 19, 2010).
Section 1333	“the Secretary shall ... issue regulations for the creation of health care choice compacts under which 2 or more States may enter into an agreement under which ...”	Regulations are to be issued by July 1, 2013.
Section 2402	“The Secretary of Health and Human Services shall promulgate regulations to ensure that all States develop service systems that are designed to ...”	None
Section 2702	“The Secretary of Health and Human Services ... shall identify current State practices that prohibit payment for health care-acquired conditions and shall incorporate the practices identified ... in regulations.”	Regulations must be effective by July 1, 2011.
Section 3001	“The Secretary shall promulgate regulations to carry out the Program, including the selection of measures ... the methodology ... that is used to calculate hospital performance scores, and the methodology used to determine the amount of value-based incentive payments ...”	None
Section 3007	“... the Secretary shall begin implementing the payment modifier established under this subsection through the rulemaking process ...”	Implementation to begin during 2013.
Subsection 3132(a)(6)(D)	“... the Secretary shall, by regulation, implement revisions to the methodology for determining payment rates for routine home care and other services included in hospice care under this part ...”	Implementation not earlier than October 1, 2013.
Section 3307	“The Secretary shall establish the criteria under clause (ii)(II) and any exceptions under clause (i)(II) through the promulgation of a regulation which includes a public notice and comment period.”	None (although the amendments in this section apply to plan years 2011 and beyond).
Subsection 4205(b)	“... statement concerning suggested daily caloric intake, as specified by the Secretary by regulation ...” and “the Secretary shall establish by regulation standards for determining and disclosing the nutrient content for standard menu items ...”	Promulgation of proposed regulations within one year of enactment (i.e., by March 23, 2011).

<b>Section of PPACA</b>	<b>Regulatory Provision</b>	<b>Regulatory Deadlines</b>
Section 5602	“The Secretary of Health and Human Services ... shall establish, through a negotiated rulemaking process...a comprehensive methodology and criteria for designation of (A) medically underserved populations ... [and](B) health professions shortage areas ...”	Target date for publication of the rule required to be July 1, 2010.
Section 6402 (adding a new Section 1128J to the Social Security Act)	“The Secretary shall promulgate regulations to carry out this subsection.”	Requirements must be in effect by January 1, 2011.
Section 8002 (adding a new section 3203 to the PHSA)	“The Secretary shall publish such designation ... in a final rule that allows for a period of public comment.”	Designation by October 1, 2012.
Section 9023	“ ... the Secretary shall issue regulations to determine the date on which a qualified investment shall be deemed to have been made for purposes of this paragraph.”	None
Subsection 10201(i)	“ ... the Secretary shall promulgate regulations relating to applications for, and renewals of, a demonstration project ...”	Promulgation of the rule within 180 days after enactment (i.e., by September 19, 2010).
Subsection 10501(l)	“The Secretary shall by regulation define ‘underserved rural community’ for the purposes of this section.”	Regulation required within 60 days after enactment (i.e., by May 22, 2010).
Section 1409 (Health Care and Education Reconciliation Act of 2010)	“The Secretary shall issue regulations requiring foreign taxes to be treated as expenses in determining pre-tax profit in appropriate cases.”	None
<b>Discretionary Regulations</b>		
Subsection 1302(d)(2)(B)	“The Secretary may issue regulations under which employer contributions to a health savings account ... may be taken into account in determining the level of coverage for a plan of the employer.”	None
Subsection 1311(h)	A qualified health plan may contract with a health care provider “only if such provider implements such mechanisms to improve health care quality as the Secretary may by regulation require.”  “The Secretary may by regulation adjust the number of beds described in paragraph (1)(A).”	None



<b>Section of PPACA</b>	<b>Regulatory Provision</b>	<b>Regulatory Deadlines</b>
Subsection 1322(h)	An exemption applies only if the organization has given notice to the Secretary “in such manner as the Secretary may by regulations prescribe, that it is applying for recognition of its status under this paragraph.”	None
Section 1401	“The Secretary shall prescribe such regulations as may be necessary to carry out the provisions of this section ... ”	None
Section 1513	“The Secretary shall prescribe rules, regulations, or guidance for the repayment of any assessable payment ... ” if certain conditions are met.	None
Section 1557	“The Secretary may promulgate regulations to implement this section.”	None
Section 3014	“The Secretary shall establish a pre-rulemaking process under which the following steps occur ... ”	None
Section 3507	“If the Secretary determines... that the addition of quantitative summaries ... would improve health care decisionmaking ..., then the Secretary...shall promulgate proposed regulations as necessary to implement such format.”	Promulgation of proposed rules within three years of the submission of a report (which is required by March 23, 2011).
Section 6401(a)	“The Secretary may promulgate an interim final rule to carry out this paragraph.”	Procedures are required within 180 days after enactment (i.e., by September 19, 2010).
<b>Other Regulatory Provisions</b>		
Subsection 1302(b)	“Under regulations issued by the Secretary ... ”	None
Section 1511	“In accordance with regulations promulgated by the Secretary ... ”	None
Section 1512	“In accordance with regulations promulgated by the Secretary ... ”	Substantive requirements must be implemented by March 1, 2013.
Section 3208	“ ... in accordance with regulations of the Secretary.”	None
Subsection 6401(b)	“ ... in accordance with regulations of the Secretary.”	None
Section 6402 (adding a new Section 1128J to the Social Security Act)	“ ... in accordance with regulations promulgated by the Secretary ... ”	None
Subsection 10108(d)	“ ... in accordance with regulations established by the Secretary ... ”	None

**Source:** CRS.

## **Author Contact Information**

Curtis W. Copeland  
Specialist in American National Government  
cwcopeland@crs.loc.gov, 7-0632