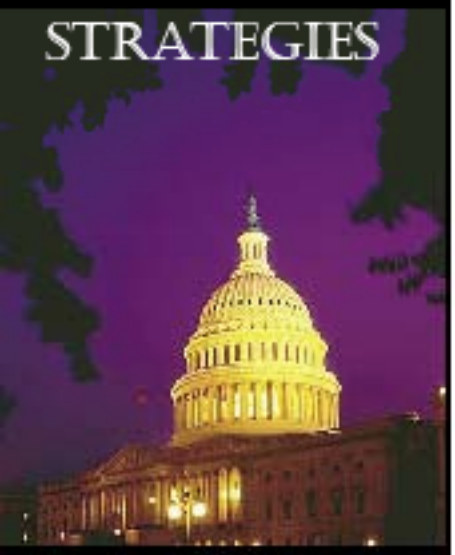
HART HEALTH STRATEGIES



Health Policy Briefing

*January 17, 2011*

# House Renews Scheduled Vote on PPACA Repeal

## *Republicans Target PPACA*

Delaying legislative business for a week after the Arizona shooting which wounded **Rep. Gabrielle Gifford**, the House has rescheduled action on H.R. 2, to repeal the PPACA, with seven hours of debate beginning this Tuesday and a final vote on Wednesday. Republicans rejected Democrat admonitions to delay the repeal vote until after **President Obama's** State of the Union address on January 25th. In **Speaker Boehner's** letter of invitation to the President he said "Recent events have reminded us of the imperfect nature of our representative democracy, but also how much we cherish the ideal that our government exists to serve the people….Even in the wake of tragedy, we must never waiver from our obligation to carry out their will and provide solutions to keep moving our nation forward."

CBO estimated the repeal would reduce revenue by $770 billion through 2021 and cut spending by $540 billion over the same period. Another thrust at the PPACA will come when H.R. 4 (renumbered from H.R. 144) is taken up to repeal the 1099 tax-reporting provision under the PPACA. In addition, **Rep. Phil Gingrey** has announced he will introduce medical malpractice reform legislation which would cap non-economic damages at $250,000 and allow punitive damages in the same amount only when compensatory damages are awarded and when it is proven by clear and convincing evidence that a person acted with malicious intent to hurt a patient or deliberately failed to avoid unnecessary injury. The bill, patterned after California's med-mal law, is expected to receive priority consideration in the House Judiciary Committee after it is introduced.

## *House Ways and Means Subcommittee Chairs*

Last week **House W&Ms Chairman Dave Camp** announced the following subcommittee chairmen:

♦**Rep. Wally Herger,** Subcommittee on Health;

♦**Rep. Kevin Brady** for Trade;

♦**Rep. Charles Boustany** for Oversight;

♦**Rep. Pat Tiberi** for Select Revenue Measures;

♦**Rep. Geoff Davis** for Human Resources; and

♦**Rep. Sam Johnson** for Social Security.

## *Inside*

## PPACA Implementation

The CRS has detailed the voluminous regulatory calendar related to PPACA in a new report based on the December 2010 edition of the Unified Agenda of Federal Regulatory and Deregulatory Actions. (See Attachment). HHS and related agencies have already issued 29 proposed rules and 18 are in the final rule stage with CMS expected to issue regulations on ACOs this month and on new home and community-based care options for Medicaid in February. Last week the IOM Committee on Defining and Revising an Essential Health Benefits Package for Qualified Health Plans held its first meeting to make recommendations to HHS on methods for determining and updating the "essential" insurance benefits that qualified health plans must offer to participate in health insurance exchanges. Republican and insurance industry oriented witnesses generally urged the committee to steer clear of specific mandated benefits and instead recommend general categories of benefits in order to keep insurance costs down and make plans more affordable. In general, disease organizations and Democrat oriented witnesses urged the committee to define in detail a broad spectrum of benefits which plans must offer. The IOM is expected to issue their recommendations by September and HHS is scheduled to issue its proposed rules by the end of this year.

## MedPAC Recommendations on Medicare

The Medicare Payment Advisory Commission recommended that payment rates for hospital inpatient and outpatient services be increased by 1% in FY 2012 and adjust hospital payments to account for overpayments due to documentation and coding improvements (DCI). MedPAC said the rule would increase spending by $250-$750 million in 2012, but save between $1-5 billion over 5 years as overpayments are recouped. The commission also voted unanimously to recommend that Congress give a 1% increase in reimbursements for physicians and other Part B providers in 2012 which is estimated to cost about $2 billion. In addition, MedPAC recommended that hospice programs receive a 1% increase in 2012 while long-term care hospitals receive no increase in payment rates. The commission also voted to recommend increasing the payment rates for ambulatory surgical centers (ASCs) by 0.5% for FY 2012 and require ASCs to submit cost and quality data to CMS. In an unprecedented move, the commission also recommended that Congress impose a copayment for each 60-day Medicare home health period while exempting Medicaid eligible individuals. Discussed was a copay of about $150 per period.

## FDA Issues

### *Senators Question FDA on BPCI*

**Senators Enzi, Hagan, Hatch and Kerry** have written the FDA questioning the agency's description of the type of exclusivity granted for brand-name or innovator biotech companies under the Biologics Price Competition and Innovation Act (BPCI). They said that while data exclusivity prohibits the FDA from allowing another manufacturer of a highly similar biologic to rely on the FDA's prior finding of safety, purity and potency for the innovator product, for a limited period of time, it does not prohibit or prevent another manufacturer from developing its own data to justify FDA approval of a full biologics license application rather than an abbreviated application that relies on the prior approval of a reference product.

# Summary

More than 40 provisions in the Patient Protection and Affordable Care Act (PPACA, P.L. 111-148, March 23, 2010, as amended) specifically require or permit federal agencies to issue regulations to implement the act's requirements. This report describes the final rules implementing PPACA that had been published in the *Federal Register* during the first 8½ months of implementation.

As of December 7, 2010, at least 18 final rules had been issued implementing certain provisions in PPACA. An **Appendix** to this report lists these 18 final rules, including a summary of their requirements and their effective dates. PPACA specifically required that some of the rules be published. Other rules cited particular sections of PPACA as the statutory authority, but those sections did not specifically require the agencies to accomplish the underlying policy objectives through the rulemaking process. Most of the final rules were issued without a prior notice of proposed rulemaking, with the agencies often invoking the "good cause" exception in the Administrative Procedure Act (APA, 5 U.S.C. §551 *et seq.)* for not allowing the public to comment before the final rules were issued. In several of the rules, the issuing agencies also stated that Congress had specifically authorized the issuance of final rules without first issuing a proposed rule. Most of the final rules permitted post-promulgation public comments, with the comment periods ending on or after the dates that the rules took effect. Most of the rules were considered "economically significant" (i.e., with an annual impact on the economy of at least $100 million), so the agencies provided estimates of their costs, benefits, and transfers.

This report will not be updated; its intent is to describe the initial rules being issued pursuant to PPACA, not to serve as an ongoing compendium of all PPACA-related rules.

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# Introduction

As discussed in a previous CRS report,[1] more than 40 provisions in the Patient Protection and Affordable Care Act (PPACA, P.L. 111-148, March 23, 2010, as amended) specifically require or permit federal agencies to issue regulations to implement the act's policy objectives. A number of these PPACA regulatory provisions require that the rules be issued or take effect by a certain date, and some of those deadlines occurred during the first several months of the act's implementation. For example:

- Section 10501(l) of the act requires the Secretary of the Department of Health and Human Services (HHS) to establish a grant program to (among other things) assist in the recruitment of students in underserved rural communities. The section also states "Not later than 60 days after the date of enactment of this section [i.e., by May 22, 2010], the Secretary shall by regulation define 'underserved rural community' for the purposes of this section."
- Section 1332(a)(4)(b) states that "the Secretary shall promulgate regulations relating to waivers under this section," and requires that the rule be promulgated within 180 days of enactment (i.e., by September 19, 2010).
- Section 10201(i) of PPACA states that the Secretary of the Department of Health and Human Services (HHS) "shall promulgate regulations relating to applications for, and renewals of, a demonstration project…," and requires that the rule be issued within 180 days of enactment (i.e., by September 19, 2010).

Federal agencies have begun issuing the regulations that were called for in PPACA. Also, agencies have issued other regulations citing the act's authority, even though PPACA does not specifically require or otherwise mention rulemaking in those areas.

This report describes the final rules that were published in the *Federal Register* within the first 8½ months of the act's implementation (i.e., as of December 7, 2010).[2] An **Appendix** to this report lists these rules, including summaries of their requirements and their effective dates. The report will not be updated; its intent is to describe the initial rules being issued pursuant to PPACA, not to serve as an ongoing compendium of all PPACA-related rules.

# Final Rules to Implement PPACA

As of December 7, 2010, federal agencies had issued at least 18 final rules implementing certain provisions in PPACA. The act specifically required that some of the rules be issued. For example:

[1] See CRS Report R41180, *Regulations Pursuant to the Patient Protection and Affordable Care Act (PPACA)*, by Curtis W. Copeland, for a summary of the provisions that required or permitted rulemaking. Shortly after PPACA was enacted, Congress passed and the President signed the Health Care and Education Reconciliation Act of 2010 (HCERA, P.L. 111-152, March 30, 2010), which amended various health care and revenue provisions in PPACA. This report considers both acts under the general heading of PPACA.

[2] To identify these rules and documents, CRS conducted searches through the electronic *Federal Register* at GPO Access (http://www.gpoaccess.gov/fr/advanced.html) using the term "Patient Protection and Affordable Care Act." Rules in which PPACA was mentioned but not cited as the statutory authority were eliminated from the search results.

- Section 6402(a) of PPACA required the Secretary of HHS to "promulgate a regulation that requires, not later than January 1, 2011, all providers of medical or other items or services and suppliers under the programs under titles XVIII and XIX that qualify for a national provider identifier to include their national provider identifier on all applications to enroll in such programs and on all claims for payment submitted under such programs." On May 5, 2010, the Centers for Medicare and Medicaid Services (CMS) within HHS published a final rule implementing this requirement.[3] The rule took effect on July 6, 2010.
- Section 1001 of PPACA added a new Section 2714 to the Public Health Service Act. Subsection (a) of the new section 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)." On May 13, 2010, the Internal Revenue Service (IRS), the Employee Benefits Security Administration (EBSA) within the Department of Labor, and HHS jointly published a final rule implementing this requirement.[4] The rule took effect on July 12, 2010, and it was generally applicable to group health plans, and to group and individual health insurance issuers, for plan years beginning on or after September 23, 2010.
- As noted previously in this report, Section 10501(l) of the act required the Secretary to issue a rule by May 22, 2010, defining the term "underserved rural community" for the purposes of a grant program designed to assist in the recruitment of students to those communities. On May 26, 2010, the Health Resources and Services Administration (HRSA) within HHS published a final rule pursuant to this directive.[5] The rule was effective on June 25, 2010.

## Most Final Rules Not Specifically Required by PPACA

Other final rules cited particular sections of PPACA as the statutory authority, but those sections did not specifically require the agencies to accomplish the stated objectives through the rulemaking process. For example:

- On May 5, 2010, HHS published a final rule implementing the early retiree reinsurance program that was established by Section 1102 of PPACA.[6] Although

[3] U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, "Medicare and Medicaid Programs; Changes in Provider and Supplier Enrollment, Ordering and Referring, and Documentation Requirements; and Changes in Provider Agreements," 75 *Federal Register* 24437, May 5, 2010.

[4] U.S. Department of the Treasury, Internal Revenue Service; Department of Labor, Employee Benefits Security Administration; Department of Health and Human Services, "Group Health Plans and Health Insurance Issuers Relating to Dependent Coverage of Children to Age 26 Under the Patient Protection and Affordable Care Act; Interim Final Rule and Proposed Rule," 75 *Federal Register* 27122, May 13, 2010.

[5] U.S. Department of Health and Human Services, Health Resources and Services Administration, "Publish Health Service Act, Rural Physician Training Grant Program, Definition of 'Underserved Rural Community,'" 75 *Federal Register* 29447, May 26, 2010.

[6] U.S. Department of Health and Human Services, Office of the Secretary, "Early Retiree Reinsurance Program," 75 *Federal Register* 24450, May 5, 2010. This program provides reimbursement to participating employment-based plans (continued...)

that section of the act required the Secretary to establish this reinsurance program within 90 days after enactment (i.e., by June 21, 2010), it did not specifically state that the program had to be implemented through regulations. The rule took effect on June 1, 2010.

- Also on May 5, 2010, HHS published a final rule implementing a requirement in Section 1103(a) of PPACA (as amended by Section 10102(b) of the act) that the Secretary establish a mechanism, including an internet website, through with individuals in any state could identify affordable health insurance coverage options.[7] Although the act required the agency to develop a "standardized format" to be used in the presentation of this information, PPACA did not require that this mechanism and format be established through rulemaking. The rule took effect on May 10, 2010, and the website became active on July 1, 2010.
- On June 15, 2010, the IRS published a final rule providing guidance on the indoor tanning services excise tax imposed through Section 10907 of PPACA.[8] That section of the act requires that the tax be remitted "at such time and in such manner as provided by the Secretary," but it does not specifically require the issuance of regulations.[9] The IRS rule took effect the day it was published, and applies to amounts paid after June 30, 2010. The rule expires on or before June 11, 2013.
- Section 1251 of PPACA states that certain provisions of the statute (subtitles A and C of Title I on "Immediate Improvements in Health Care Coverage for All Americans" and "Quality Health Insurance Coverage for All Americans," respectively) do not apply to group health plans and health insurance coverage in existence as of the date that the legislation was enacted (March 23, 2010). Although Section 1251 does not specifically require that new regulations be issued with regard to these "grandfathered" health plans, on June 17, 2010, the IRS, EBSA, and HHS jointly published a final rule implementing this section.[10] The rule became effective on June 14, 2010 (three days before it was published), although certain amendments took effect on July 12, 2010.
- On June 28, 2010, IRS, EBSA, and HHS jointly published a final rule implementing several new sections of the Public Health Service Act that were added by Section 1001 of PPACA: (1) Section 2704 (prohibiting preexisting condition exclusions); (2) Section 2711 (regarding lifetime and annual dollar limits on benefits); (3) Section 2712 (prohibiting rescissions); and (4) Section

(...continued)

for a portion of the cost of health benefits for early retirees and their spouses, surviving spouses, and dependents.

[7] U.S. Department of Health and Human Services, Office of the Secretary, "Health Care Reform Insurance Web Portal Requirements," 75 *Federal Register* 24470, May 5, 2010. The address of this website is http://www.healthcare.gov/.

[8] U.S. Department of the Treasury, Internal Revenue Service, "Indoor Tanning Services; Cosmetic Services; Excise Taxes," 75 *Federal Register* 33683, June 15, 2010.

[9] It does, however, state that every person receiving a payment for services on which a tax is imposed "shall collect the amount of the tax from the individual on whom the service is performed and remit such tax quarterly to the Secretary at such time and in such manner as provided by the Secretary."

[10] U.S. Department of the Treasury, Internal Revenue Service; Department of Labor, Employee Benefits Security Administration; Department of Health and Human Services, "Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan Under the Patient Protection and Affordable Care Act; Interim Final Rule and Proposed Rule," 75 *Federal Register* 34538, June 17, 2010.

2719A (regarding patient protections).[11] None of these four sections specifically required that new regulations be issued. The final rule takes effect on August 27, 2010, and is generally applicable to group health plans and group health issuers for plan years beginning on or after September 23, 2010. It is applicable to individual health insurance issuers for policy years beginning on or after January 1, 2014, except that for enrollees under the age of 19, the regulations apply for policy years starting on or after September 23, 2010.

- Section 1001 of PPACA also added a new Section 2713 to the Public Health Service Act on "Coverage of Preventive Health Services." On July 19, 2010, IRS, EBSA, and HHS published a final rule implementing this new section. Although PPACA required the Secretary of HHS to take certain actions (e.g., establishing when certain statutory provisions would take effect), the legislation did not specifically require that those actions be accomplished through the rulemaking process. The rule takes effect on September 17, 2010, and applies to group health plans and insurers for plan years starting on or after September 23, 2010.
- In addition, Section 1001 of PPACA (and amendments in Section 10101) added a new Section 2719 to the Public Health Service Act regarding internal claims and appeals and external appeals processes for group health plans and health issuers that are not grandfathered plans. On July 23, 2010, IRS, EBSA, and HHS published a final rule implementing this new section.[12] Although PPACA allowed the Secretary of HHS to deem an existing external review process to be in compliance, it did not specifically require regulations. The rule takes effect on September 21, 2010, and applies to group health plans and insurers for plan years starting on or after September 23, 2010.

Although PPACA did not specifically require the agencies to issue any of these rules, the agencies' use of rulemaking to accomplish the underlying statutory objectives does not appear to be either improper or unusual. In fact, to the extent that those requirements were intended to be binding on the public, rulemaking may have been the agencies only viable option to implement the statutory provisions. For example, if an agency issues a guidance document, policy statement, or other non-rule document with the intent of legally binding the public, it could be subject to a possible judicial challenge for not having properly promulgated the policy through the APA rulemaking process. Case law and guidance from OMB indicate that agencies should not attempt to bind affected parties through policy statements and other non-rule documents.[13] Also, to the

[11] U.S. Department of the Treasury, Internal Revenue Service; Department of Labor, Employee Benefits Security Administration; Department of Health and Human Services, "Patient Protection and Affordable Care Act: Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, and Patient Protections," 75 *Federal Register* 37188, June 28, 2010.

[12] U.S. Department of the Treasury, Internal Revenue Service; Department of Labor, Employee Benefits Security Administration; Department of Health and Human Services, "Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Internal Claims and Appeals and External Review Processes Under the Patient Protection and Affordable Care Act," 75 *Federal Register* 43330, July 23, 2010.

[13] 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."

extent that PPACA changed existing regulatory requirements, new rules would have to be issued to amend those regulations.

## No Prior Opportunity to Comment

The Administrative Procedure Act (APA, 5 U.S.C. §551 *et seq.*) establishes the basic requirements for the rulemaking process, and generally requires that federal agencies publish a notice of proposed rulemaking (NPRM) in the *Federal Register*, give "interested persons" an opportunity to comment on the proposed rule (usually at least 30 days), and after considering the public comments, publish a final rule. The APA also provides certain exceptions to the NPRM requirement. For example, 5 U.S.C. §553(b)(3)(B) permits agencies to issue final rules without a prior NPRM when the agency finds, for "good cause," that notice and comment procedures are "impracticable, unnecessary, or contrary to the public interest."[14] A process known as "interim final" rulemaking can be viewed as a particular application of the good cause exception, in which an agency issues a final rule without an NPRM, 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 by publishing a final rule reflecting those changes.[15]

Most of the PPACA-related final rules that had been published as of December 7, 2010, were issued without pre-publication public comment. Twelve of the 18 final rules were issued as interim final rules. The issuing agencies frequently said that they invoked the APA's "good cause" exception to notice and comment because of the tight time constraints set by PPACA, and for other reasons. For example:

- In the May 5, 2010, rule on the early retiree insurance program, HHS noted that PPACA required the program to be established by June 21, 2010, but said that in a practical sense, the program had to begin operations by June 1, 2010. Because of the short time frame provided after the enactment of PPACA on March 23, 2010, HHS said "we find good cause to waive the notice of proposed rulemaking and to issue this final rule on an interim basis without prior comment."[16]
- In the May 26, 2010, rule on underserved rural communities, HHS stated that issuing a prior proposed rule and taking comments was "impractical" because the department was required to publish the rule within 60 days after the enactment of PPACA, and "those procedures take significantly longer than 60 days."[17] HHS also said that it believed it was unnecessary to undertake notice and comment because the rule would have limited impact, and because the funds for the program "might become available with little notice and awarding the funds quickly would serve an important public interest."[18]

[14] 5 U.S.C. §553(b).

[15] For more information, see Michael Asimow, "Interim Final Rulemaking: Making Haste Slowly," *Administrative Law Review*, 51 (Summer 1999), pp. 703-755.

[16] 75 *Federal Register* 24460.

[17] 75 *Federal Register* 29448.

[18] Ibid.

In five final rules jointly issued by IRS, EBSA, and HHS,[19] the agencies indicated that Congress had specifically authorized the use of interim final rulemaking. All five of the rules contained the following language.

> Section 9833 of the Code, section 734 of ERISA (the Employee Retirement Income Security Act), and section 2792 of the (Public Health Service or PHS) Act authorize the Secretaries of the Treasury, Labor, and HHS (collectively, the Secretaries) to promulgate any interim final rules that they determine are appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B of title I of ERISA, and part A of title XXVII of the PHS Act, which include PHS Act sections 2701 through 2728 and the incorporation of those sections into ERISA section 715 and Code section 9815.[20]

Even without specific statutory permission to issue these interim final rules, the agencies indicated that they would have done so under the "good cause" exception in Section 553(b) of the APA. For example, in the June 17 rule on "grandfathered health plans," the agencies said that even if the specific authorization for interim final rulemaking had not existed, "the Secretaries have determined that it would be impracticable and contrary to the public interest to delay putting the provisions in these interim final regulations in place until a full public notice and comment process was completed."[21] The agencies pointed out that numerous provisions of PPACA were applicable for plan years beginning on or after September 23, 2010 (six months after enactment), and that there was not sufficient time to draft and publish proposed rules, receive and consider comments, and draft and publish final regulations before that date.[22]

In most cases, the agencies issuing the rules provided explanations for why final rules were being issued without an NPRM. However, in the IRS rule on the indoor tanning services excise tax, the agency simply said that it had "been determined" that the notice and comment requirements of the Administrative Procedure Act did not apply to these regulations, but provided no further explanation (e.g., who made that determination, or why).[23]

All 12 of the interim final rules permitted the public a post-promulgation opportunity to comment. As **Table 1** below indicates, all of these rules took effect on or before the dates that the comment periods expired.

[19] These were the May 13 rule on dependent coverage of children to age 26; the June 17 rule on "grandfathered" health plans; the June 28 rule on preexisting condition exclusions and other matters; the July 19 rule on preventive services; and the July 23 rule on internal claims and appeals and external review processes.

[20] See, for example, 75 *Federal* Register 2715; 75 *Federal Register* 34545; 75 *Federal Register* 37195; and 75 *Federal Register* 41729.

[21] 75 *Federal Register* 34545.

[22] Agencies often publish final rules without prior proposed rules, and frequently cite the "good cause" exception. For example, in 1998, GAO determined that about half of the 4,000 final rules published that year had no prior NPRM, and that the agencies most commonly cited the "good cause" exception. See U.S. General Accounting Office, *Federal Rulemaking: Agencies Often Published Final Actions Without Proposed Rules*, GAO-98-126, August 31, 1998.

[23] 75 *Federal Register*33685. IRS also said that it had "been determined" that the rule was not a "significant regulatory action" as defined in Executive Order 12866, so a regulatory assessment was not required. The rule was not reviewed by the Office of Information and Regulatory Affairs at the Office of Management and Budget prior to publication.

**Table 1. Effective Dates and Comment Periods for PPACA Interim Final Rules**

| Publication Date | Agency/Agencies | Subject | Effective Date | End of Comment Period |
|---|---|---|---|---|
| 05/05/10 | HHS/CMS | National Provider Identifier | 07/06/10 | 07/06/10 |
| 05/05/10 | HHS | Web Portal Requirements | 05/10/10 | 06/04/10 |
| 05/05/10 | HHS | Early Retiree Insurance Program | 06/01/10 | 06/04/10 |
| 05/13/10 | IRS/EBSA/HHS | Coverage of Children to Age 26 | 07/12/10 | 08/11/10 |
| 05/26/10 | HHS | Underserved Rural Communities | 06/25/10 | 07/26/10 |
| 06/17/10 | IRS/EBSA/HHS | Grandfathered Health Plans | 06/14/10[a] | 08/16/10 |
| 06/28/10 | IRS/EBSA/HHS | Preexisting Condition Exclusions | 08/27/10 | 08/27/10 |
| 07/19/10 | IRS/EBSA/HHS | Preventive Services | 09/17/10 | 09/17/10 |
| 07/23/10 | IRS/EBSA/HHS | Internal Claims/ Appeals and External Review Processes | 09/21/10 | 09/21/10 |
| 07/30/10 | HHS/OCIIO | Pre-Existing Condition Insurance Plan Program | 07/30/10 | 09/28/10 |
| 11/17/10 | Treasury/IRS; DOL/EBSA; HHS/OCIIO | Amendment to Grandfathered Health Plans Rule | 11/15/10 | 12/17/10 |
| 12/01/10 | HHS/OCIIO | Medical Loss Ratio Requirements | 01/01/11 | 01/31/11 |

**Source:** CRS, using information provided in the preambles to the agencies' rules.

a. Certain amendments took effect July 12, 2010.

## Costs, Benefits, and Transfers

Executive Order 12866 on "Regulatory Planning and Review" requires that covered agencies (generally, all executive branch agencies except independent regulatory agencies like the Securities and Exchange Commission) prepare a cost-benefit analysis before publishing any rule that the administrator of the Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB) determines to be "economically significant."[24] The executive order defines a regulatory action as economically significant if it is expected to have at least a $100 million annual impact on the economy or "adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or State, local,

[24] The President, Executive Order 12866, "Regulatory Planning and Review," 58 *Federal Register* 51735. The cost-benefit requirements are in Section 6(a)(3)(C) of the order. The definition of an "economically significant" rule is in Section 3(f)(1) of the order.

or tribal government or communities." OMB Circular A-4 requires agencies to present the information in a standardized accounting statement, showing costs, benefits, and transfers separately.[25]

IRS did not indicate whether the June 15, 2010, rule on the indoor tanning services excise tax was economically significant or not, and did not provide any estimates of the rule's costs, benefits, or transfers. Several of the other final rules issued pursuant to PPACA were not considered economically significant, so the issuing agencies did not conduct a formal cost-benefit analysis or accounting statement. For example:

- In the May 5, 2010, rule on web portal requirements, HHS estimated that the total cost of the rule would be about $17 million in 2010, and about $15 million per year thereafter—well below the $100 million threshold to be considered economically significant.[26]
- CMS said that the May 5, 2010, rule requiring the use of National Provider Identification numbers was not economically significant because most providers and suppliers were already meeting the requirements.[27]
- HHS said that the May 26, 2010, rule on "underserved rural communities" was "technical in nature" and "will not change grant or funding eligibility for any other grant program."[28]
- CMS said that the November 15, 2010, rule on upper reimbursement limits withdrew those regulatory provisions that were superseded by PPACA, and was not economically significant.[29]
- OCIIO said that the November 17, 2010, rule amending the previously issued rule on "grandfathered" health plans was significant, but not economically significant.

However, other final rules issued pursuant to PPACA were considered economically significant by either OIRA or the issuing agencies because they were expected to have at least a $100 million impact on the economy. The issuing agencies provided information on their estimated costs, benefits, and transfers in the preambles to the rules. **Table 2** below summarizes that information.

[25] See http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf for a copy of OMB Circular A-4. Transfers occur when wealth or income is redistributed without any direct change in aggregate social welfare (e.g., federal Medicare payments to doctors and hospitals).

[26] 75 *Federal Register* 24480.

[27] 75 *Federal Register* 24447.

[28] 75 *Federal Register* 29450.

[29] 75 *Federal Register* 69596.

**Table 2. Cost, Benefit, and Transfer Estimates of PPPACA Final Rules**

| Agency/Subject/Date | Annual Costs | Annual Benefits | Annual Transfers |
|---|---|---|---|
| HHS<br>Early retiree reinsurance program<br>05/05/10 | $39.8 million (paperwork costs). | HHS said the benefits were "not estimated." | $1,250 million (from the federal government to eligible sponsors and for the administration of the program). |
| IRS/EBSA/HHS<br>Dependent coverage of children who have not attained age 26<br>05/13/10 | $10.4 million (in 2010 dollars). Also, to the extent that the rule results in increased use of health care services, there will be additional costs to achieve the health benefits. | Qualitative benefits of expanding coverage options for the 19-25 population (mid-range estimate of 0.65 million), which should decrease the cost-shifting of uncompensated care onto those with insurance, increase preventive health care, and result in a healthier population. Also, greater job mobility. | $5,275 million (mid-range estimate; range from $3,483 million to $6,895 million). If premiums increase, there will be a transfer from individuals with family coverage who do not have dependents ages 19 to 25 from those who do have such dependents. |
| IRS/EBSA/HHS<br>Grandfathered health plans<br>06/17/10 | $24.7 million (mid-range estimate in 2010 dollars; range of $21.2 million to $26.9 million), due to the requirement to notify participants and beneficiaries, and to maintain documents. | Qualitative benefits of plan continuity; potentially slower rate of premium growth; incentives to employers to continue coverage; greater certainty about what changes can be made without affecting grandfather status. | Cost-sharing provisions may lead to transfers of wealth from premium payers overall to individuals using covered services. Subsequent changes could lead to transfers from non-grandfathered to grandfathered plans. |
| IRS/EBSA/HHS<br>Preexisting condition exclusions, lifetime and annual dollar limits on benefits, rescissions, and patient protections<br>06/28/10 | $4.9 million (in 2010 dollars). | Qualitative benefits of expanded coverage for children with preexisting conditions and individuals who face rescissions, lifetime limits, and annual limits as a result of high health costs. Also, improved health outcomes, improved worker productivity, and reduced financial strain. | Small transfer from those paying premiums in the group market to those obtaining the increased protections. |
| IRS/EBSA/HHS<br>Coverage of preventive services under PPACA<br>07/19/10 | Qualitative discussion of new costs to health care system when beneficiaries increase use of preventive services. Magnitude of increased use depends on "price elasticity of demand" and percentage change in prices facing those with reduced cost sharing or newly gaining coverage. | Qualitative benefits of expanding coverage and eliminating cost sharing, resulting in increased access and utilization of services, which are expected to result in reduced illnesses, reduced morbidity and mortality, increased productivity, and savings from lower health care costs. | Qualitative discussion of transfers expected to the extent that costs previously paid out-of-pocket now covered by group health plans and insurers. Risk pooling will result in higher average premiums. Rule expected to result in small transfer from those who use less preventive services to those who use more. |

| Agency/Subject/Date | Annual Costs | Annual Benefits | Annual Transfers |
|---|---|---|---|
| IRS/EBSA/HHS<br>Internal claims and appeals and external review processes<br>07/23/10 | $51.6 million | Qualitative benefits include a more uniform, rigorous, and consumer friendly system of claims and appeals processing, which will lead to a range of direct and indirect benefits (e.g., providing benefits consistent with the established terms of plans). | Reversals estimated at $24.4 million, part of which is a transfer from plans and issuers to those receiving payments for denied benefits. |
| HHS/OCIIO<br>Pre-existing condition insurance plan program<br>07/30/10 | $1,939,020 for reporting and recordkeeping | Qualitative benefits of increasing access to health care and reduced financial strain for participants. Also likely to improve health outcomes and worker productivity. | $5 billion in federal funds to contractors to aid in administering the program from 07/01/10 to 12/31/13. |
| HHS/CMS<br>Hospital inpatient prospective payment systems for acute care hospitals<br>08/16/10 | N/A | N/A | $440 million decrease in FY2011 operating payments and $21 million decrease in FY2011 capital payments. Long-term care hospitals expected to have an increase in payments of $22.5 million. |
| HHS/CMS<br>Updates the Home Health Prospective Payment System outlier policy<br>11/17/10 | N/A | N/A | Net savings estimated at $960 million in calendar year 2011. |
| HHS/CMS<br>Hospital outpatient prospective payment systems<br>11/24/10 | N/A | N/A | Increased expenditures of about in FY2011 from OPPS provisions of $3.2 billion, and $230 million from ASC provisions. |
| HHS/CMS<br>Payment policies under the physicians fee schedule<br>11/29/10 | N/A | N/A | PPACA provisions estimated to increase expenditures by $1.97 billion. |
| HHS/OCIIO<br>Medical loss ratio requirements<br>12/01/10 | Mid-range estimated costs of $34.7 to $37.4 million per year in 2011 to 2013 for capturing and reporting data, and providing rebate notifications. | Qualitative benefits of increased transparency, increased quality of medical care, and improved health. | Mid-range estimated transfers of $863.5 million to $930 million in 2011 to 2013 from shareholders or stakeholders to enrollees. |

**Source:** CRS, using information provided in the preambles to the agencies' rules.

**Notes:** Unless otherwise indicated, estimates are in 2010 dollars and reflect a 3% discount rate.

# Concluding Observations

Although Congress sometimes specifically requires or permits federal agencies to issue regulations on particular issues, the agencies can also decide to issue regulations to accomplish statutory requirements when not directed to do so. The initial regulations pursuant to PPACA are a clear illustration of that principle. The legislation contained more than 40 provisions that either required or permitted federal agencies to issue regulations, but most of the final rules issued pursuant to PPACA during the first 8½ months after enactment were not specifically mentioned in the act. The agencies may be choosing to use rulemaking as opposed to other possible implementation mechanisms (e.g., guidance documents or policy memoranda) to carry out PPACA provisions because only regulations developed through the APA rulemaking process carry the force of law and can be binding on the public. If an agency attempts to bind the public through some mechanism other than a rule, the agency's actions could be subject to judicial review and possible reversal.

Similarly, although PPACA requires that certain final rules be issued without prior notice and comment,[30] federal agencies are also doing so without such requirements. The agencies frequently invoked the "good cause" exception to notice and comment provided in the APA, stating that the requirements in PPACA that certain programs be quickly implemented made it impractical for them to develop and publish a proposed rule, take comments on the proposal, and then develop and publish the final rule. The agencies also frequently said that it was similarly impractical for them to wait 30 days after publication to put those rules into effect (as is also generally required by the APA).

Although most of the PPACA-related final rules were issued without a prior opportunity for comment, the agencies did allow the public to comment on most of those rules after they were published. And even though the comment periods for these rules ended on or before the rules took effect, the agencies may still be persuaded to change them at some point in the future. Nevertheless, comments on final rules are generally believed to be less likely to result in changes to the rules than if comments were permitted prior to the final rules being published and made effective.[31] Because the agencies said that they were using interim final rulemaking because of tight deadlines in PPACA for rulemaking and implementation, as those deadlines become longer, it is possible that the agencies may be more willing to permit full notice and comment rulemaking.

## Congressional Oversight Options

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

[30] For example, Section 1104(b)(2) of PPACA requires that the Secretary of HHS promulgate two interim final rules.

[31] For example, although the Administrative Conference of the United States endorsed the use of interim final and direct final rulemaking, it also said that "prepromulgation comment is generally considered preferable because agencies are perceived by commenters as more likely to accept changes in a rule that has not been promulgated as a final rule—and potential commenters are more likely to file comments in advance of the agency's 'final' determination." See "Recommendation 95-4, Procedures for Noncontroversial and Expedited Rulemaking," available at http://www.law.fsu.edu/library/admin/acus/305954.html.

process by, among other things, meeting with agency officials and filing public comments.[32] 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 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.[33]

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."[34] 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.[35] It also established expedited legislative procedures (primarily in the Senate) by which Congress may disapprove agencies' final rules by enacting a joint resolution of disapproval.[36] The definition of a covered rule in the CRA is quite broad, arguably including any type of document (e.g., legislative rules, policy statements, guidance, manuals, and memoranda) that the agency wishes to make binding on the affected public.[37] 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.[38] Perhaps most notably, it is likely that a President would veto a resolution of disapproval to protect rules developed under his own administration, and it may be difficult for Congress to muster the two-thirds vote in both houses needed to overturn the veto. Congress can also use regular (i.e., non-CRA) legislative procedures to disapprove agencies' rules, but such legislation may prove even more difficult to enact than a CRA resolution of

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[32] 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."

[33] Dominique Custos, "The Rulemaking Power of Independent Regulatory Agencies," *The American Journal of Comparative Law*, vol. 54 (Fall 2006), p. 633.

[34] 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).

[35] If a rule is considered "major" (e.g., has a $100 million annual effect on the economy), then the CRA generally prohibits it from taking effect until 60 days after the date that it is submitted to Congress.

[36] For a detailed discussion of CRA procedures, see CRS Report RL31160, *Disapproval of Regulations by Congress: Procedure Under the Congressional Review Act*, by Richard S. Beth.

[37] 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.

[38] The rule overturned in March 2001 was the Occupational Safety and Health Administration's ergonomics standard. This reversal was the result of a unique set of circumstances in which the incoming President (George W. Bush) did not veto the resolution disapproving the outgoing President's (William J. Clinton's) rule. 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.

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.[39] 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 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.[40]

[39] See CRS Report RL34354, *Congressional Influence on Rulemaking and Regulation Through Appropriations Restrictions*, by Curtis W. Copeland.

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

# Appendix. Final Rules Implementing PPACA (as of December 7, 2010)

| Publication Date/Citation | Department/Agency or Office | Summary | Dates |
|---|---|---|---|
| May 5, 2010<br><br>75 *Federal Register 24437* | Department of Health and Human Services (HHS)/Centers for Medicare and Medicaid Services (CMS) | Interim final rule implementing the requirement in Section 6402(a) of PPACA that providers of medical or other items or services to include their National Provider Identifier (NPI) on all applications to enroll and on all claims for payment. The rule also requires physicians and eligible professionals to order and refer covered items to be enrolled in Medicare, and adds requirement to provide documentation on referrals to programs at high risk of waste and abuse. | Effective on July 6, 2010.<br><br>Comment period ended July 7, 2010. |
| May 5, 2010<br><br>75 *Federal Register 24470* | HHS/Office of the Secretary | Interim final rule implementing the requirement in Section 1103(a) of PPACA to establish a website through which individuals and small businesses can obtain information about the insurance coverage options available in their state. The rule adopts the categories of information that will be collected and displayed, and the data required from issuers and requested from states, associations, and high risk pools. | Effective on May 10, 2010. The initial version of the website became available July 1, 2010.<br><br>Comment period ended June 4, 2010. |

| Publication Date/Citation | Department/Agency or Office | Summary | Dates |
|---|---|---|---|
| May 5, 2010<br>75 *Federal Register 24450* | HHS/Office of the Secretary | Interim final rule implementing the Early Retiree Reinsurance Program in Section 1102 of PPACA. This temporary program (ends by January 1, 2014) provides reimbursement to participating employment-based plans for a portion of the cost of health benefits for early retirees and their spouses/dependents (certain claims between $15,000 and $90,000). | Effective on June 1, 2010.<br>Comment period ended June 4, 2010. |
| May 13, 2010<br>75 *Federal Register* 27122 | Department of the Treasury(Treasury)/Internal Revenue Service (IRS); Department of Labor (DOL)/Employee Benefits Security Administration (EBSA); HHS | Interim final rule implementing the requirements in Section 1001 of PPACA for group health plans and health insurance coverage in the group and individual markets regarding dependent coverage of children who have not attained age 26. | Effective on July 12, 2010. The requirements generally apply for plan years beginning on or after September 23, 2010.<br>Comment period ended August 11, 2010. |
| May 26, 2010<br>75 *Federal Register* 29447 | HHS | Interim final rule (required by Section 10501(l) of PPACA) defining "underserved rural community" for purposes of the Rural Physician Training Grant Program in Section 749B of the Public Health Service Act. | Effective on June 25, 2010.<br>Comment period ended July 26, 2010. |
| June 15, 2010<br>75 *Federal Register* 33683 | Treasury/IRS | Final and temporary rules providing guidance on the indoor tanning services excise tax imposed by Section 10907 of PPACA. | Effective on June 15, 2010 The tax applies to payments after June 30, 2010.<br>No comments requested. |
| June 17, 2010<br>75 *Federal Register* 34538 | Treasury/IRS; DOL/EBSA; HHS | Interim final rule implementing the rules for group health plans and health insurance coverage in the group and individual markets regarding status as a "grandfathered" health plan (Section 1251 of PPACA). | Effective on June 14, 2010, except that certain amendments are effective July 12, 2010.<br>Comment period ended August 10, 2010. |

| Publication Date/Citation | Department/Agency or Office | Summary | Dates |
|---|---|---|---|
| June 28, 2010<br>75 *Federal Register* 37188 | Treasury/IRS; DOL/EBSA; HHS | Interim final rule implementing the rules for group health plans and health insurance coverage in the group and individual markets regarding preexisting condition exclusions, lifetime and annual dollar limits on benefits, rescissions, and patient protections (Sections 2704, 2711, 2712, and 2719A of PPACA). | Effective on August 27, 2010. Some of the requirements apply for plan years starting on or after September 23, 2010, while other requirements begin for plan years starting on or after January 1, 2014.<br>Comment period ended August 27, 2010. |
| July 19, 2010<br>75 *Federal Register* 41726 | Treasury/IRS; DOL/EBSA; HHS | Interim final rule implementing the requirements for group health plans and health insurance coverage in the group and individual markets (Section 2713 of the Public Health Service Act as revised by PPACA). | Effective on September 17, 2010. Applicable to group health plans and group health insurers for plan years beginning on or after September 23, 2010.<br>Comment period ended September 17, 2010. |
| July 23, 2010<br>75 *Federal Register* 43330 | Treasury/IRS; DOL/EBSA; HHS | Interim final rule implementing the requirements regarding internal claims and appeals and external review processes for group health plans and health insurance coverage in the group and individual markets (Section 2719 of the Public Health Service Act as revised by PPACA). | Effective September 21, 2010. Applicable to group health plans and group health insurers for plan years beginning on or after September 23, 2010.<br>Comment period ended September 21, 2010. |
| July 30, 2010<br>75 *Federal Register* 45014 | HHS/Office of Consumer Information and Insurance Oversight (OCIIO) | Interim final rule implementing the requirement in Section 1101 of PPACA regarding the establishment of a temporary high risk insurance pool program to provide coverage to uninsured individuals with pre-existing conditions. | Effective on July 30, 2010.<br>Comment period ended September 28, 2010. |
| August 16, 2010<br>75 *Federal Register* 50042 | HHS/CMS | Final rule revising the Medicare hospital inpatient prospective payment systems for operating and capital-related costs of acute care hospitals to (among other things) implement certain provisions in PPACA. | Effective on October 1, 2010. (Proposed rule was published May 4, 2010.) |

| Publication Date/Citation | Department/Agency or Office | Summary | Dates |
|---|---|---|---|
| November 15, 2010<br>75 *Federal Register* 69591 | HHS/CMS | Final rule implementing Section 2503(a) of PPACA by withdrawing provisions on upper reimbursement limits and other matters. | Effective on December 15, 2010. (Proposed rule was published September 3, 2010.) |
| November 17, 2010<br>75 *Federal Register* 70114 | Treasury/IRS; DOL/EBSA; HHS/OCIIO | Interim final rule amending the June 17, 2010, interim final rule on "grand-fathered" health plans. The amendment permits certain changes in policies, certificates, or contracts of insurance without loss of "grandfathered" status. | Effective on November 15, 2010.<br>Comment period ended December 17, 2010. |
| November 17, 2010<br>75 *Federal Register* 70372 | HHS/CMS | Final rule that (among other things) updates the Home Health Prospective Payment System outlier policy in accordance with Section 3131 of PPACA. | Effective on January 1, 2011. (Proposed rule was published July 23, 2010.) |
| November 24, 2010<br>75 *Federal Register* 71800 | HHS/CMS | Final rule implementing PPACA provisions regarding (1) the Medicare hospital outpatient prospective payment system, (2) the Medicare ambulatory surgical center payment system, (3) payments to hospitals for direct graduate medical education and indirect medical education costs, and (4) limitations on certain physician referrals to hospitals in which they have a financial interest. | Effective on January 1, 2011, except certain provisions effective on December 2, 2010. Various applicability dates.<br>Comment period ends January 3, 2011. |
| November 29, 2010<br>75 *Federal Register* 73170 | HHS/CMS | Final rule with comment period addressing changes to the physician fee schedule and other Medicare Part B policies. Among other things, the rule "addresses, implements, or discusses" provisions in PPACA. | Effective on January 1, 2011.<br>Comment period ends January 3, 2011. |
| December 1, 2010<br>75 *Federal Register* 74864 | HHS/OCIIO | Interim final rule implementing medical loss ratio requirements for health insurers under Section 2718(a)-(c) of the Public Health Service Act as amended by PPACA. | Effective on January 1, 2011.<br>Comment period ends January 31, 2011. |

**Source:** CRS, using information provided in the preambles to the agencies' rules.

## Author Contact Information

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