U.S. GOVERNMENT ACCOUNTABILITY OFFICE
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July 28, 2015

The Honorable Orrin G. Hatch
Chairman
The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate

The Honorable Lamar Alexander
Chairman
The Honorable Patty Murray
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable John Kline
Chairman
The Honorable Robert "Bobby" Scott
Ranking Member
Committee on Education and the Workforce
House of Representatives

The Honorable Fred Upton
Chairman
The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Paul Ryan
Chairman
The Honorable Sander M. Levin
Ranking Member
Committee on Ways and Means
House of Representatives

Subject: *Department of the Treasury, Internal Revenue Service; Department of Labor, Employee Benefits Security Administration; Department of Health and Human Services: Coverage of Certain Preventive Services Under the Affordable Care Act*

Pursuant to section 801(a)(2)(A) of title 5, United States Code, this is our report on major rules promulgated by the Department of the Treasury, Internal Revenue Service (IRS); Department of Labor, Employee Benefits Security Administration (DOL); Department of Health and Human

Services (HHS) (collectively, the Departments) entitled "Coverage of Certain Preventive Services Under the Affordable Care Act" (RINs: 1545-BJ58; 1545-BM37; 1545-BM39; 1210-AB67; 0938-AS50). We received the rules on July 14, 2015. They were published in the *Federal Register* as final rules on July 14, 2015. 80 Fed. Reg. 41,318.

The combined final rules relate to coverage of certain preventive services under section 2713 of the Public Health Service Act (PHS Act), added by the Patient Protection and Affordable Care Act, as amended, and incorporated into the Employee Retirement Income Security Act of 1974 and the Internal Revenue Code. Section 2713 of the PHS Act requires coverage without cost sharing of certain preventive health services by non-grandfathered group health plans and health insurance coverage. According to the Departments, the regulations finalize provisions from three rulemaking actions: (1) interim final regulations issued in July 2010 related to coverage of preventive services, (2) interim final regulations issued in August 2014 related to the process an eligible organization uses to provide notice of its religious objection to the coverage of contraceptive services, and (3) proposed regulations issued in August 2014 related to the definition of "eligible organization," which would expand the set of entities that may avail themselves of an accommodation with respect to the coverage of contraceptive services.

Enclosed is our assessment of the Departments' compliance with the procedural steps required by section 801(a)(1)(B)(i) through (iv) of title 5 with respect to the rules. Our review of the procedural steps taken indicates that the Departments complied with the applicable requirements.

If you have any questions about this report or wish to contact GAO officials responsible for the evaluation work relating to the subject matter of the rules, please contact Shirley A. Jones, Assistant General Counsel, at (202) 512-8156.

signed

Robert J. Cramer
Managing Associate General Counsel

Enclosure

cc: Deputy Director/ODRM
Department of Health and Human Service

Assistant Secretary, Employee Benefits
Security Administration
Department of Labor

Chief, Publications and Regulations Branch
Internal Revenue Service
Department of the Treasury

ENCLOSURE

REPORT UNDER 5 U.S.C. § 801(a)(2)(A) ON MAJOR RULES
ISSUED BY THE
DEPARTMENT OF THE TREASURY,
INTERNAL REVENUE SERVICE;
DEPARTMENT OF LABOR,
EMPLOYEE BENEFITS SECURITY ADMINISTRATION;
DEPARTMENT OF HEALTH AND HUMAN SERVICES
ENTITLED
"COVERAGE OF CERTAIN PREVENTIVE SERVICES
UNDER THE AFFORDABLE CARE ACT"
(RINs: 1545-BJ58; 1545-BM37; 1545-BM39; 1210-AB67; 0938-AS50)

(i) Cost-benefit analysis

The Departments analyzed the potential costs, benefits, and transfers associated with the final rules, and provided a table which depicts an accounting statement summarizing the Departments' assessment of the benefits, costs, and transfers associated with the final rules. It is expected that all non-grandfathered plans are already complying with the provisions of the July 2010 and August 2014 interim final regulations. Therefore, benefits related to those regulations have been experienced and costs have already been incurred. Accordingly, the Departments have provided an assessment of the impacts of existing provisions already experienced and expected in the future, in addition to the anticipated impacts of new provisions in the final rules.

The Departments anticipate four qualitative benefits as increased access to and utilization of recommended preventive services, will lead to the following benefits: (1) prevention and reduction in transmission of illnesses as a result of immunization and screening of transmissible diseases; (2) delayed onset, earlier treatment, and reduction in morbidity and mortality as a result of early detection, screening, and counseling; (3) increased productivity and reduced absenteeism; and (4) savings from lower health care costs. The Departments also note that there are qualitative benefits to eligible for-profit entities from not being required to facilitate access to or pay for services that contradict their owners' religious beliefs.

The Departments anticipate qualitative costs to include: (1) new costs to the health care system when individuals increase their use of preventive services in response to the changes in coverage and cost-sharing requirements of preventive services (the magnitude of this effect on utilization depends on the price elasticity of demand and the percentage change in prices facing those with reduced cost sharing or newly gaining coverage); (2) administrative costs to eligible for-profit entities to provide self-certification to issuers or third-party administrators or notice to HHS; and (3) administrative costs to issuers and third-party administrators for plans sponsored by eligible closely held for-profit entities to provide notice to enrollees.

(ii) Agency actions relevant to the Regulatory Flexibility Act (RFA), 5 U.S.C. §§ 603-605, 607, and 609

The Departments certified that these final regulations will not have a significant economic impact on a substantial number of small entities.

(iii) Agency actions relevant to sections 202-205 of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. §§ 1532-1535

The Departments stated that the final rule includes no mandates on state, local, or tribal governments. The Departments note that health insurance issuers, third-party administrators and eligible organizations would incur costs to comply with the provisions of these final regulations. However, the Departments state that consistent with policy embodied in UMRA, these final regulations have been designed to be the least burdensome alternative while achieving the objectives of the Patient Protection and Affordable Care Act.

(iv) Other relevant information or requirements under acts and executive orders

Administrative Procedure Act, 5 U.S.C. §§ 551 et seq.

The Departments explain that the final rule finalizes provisions from three prior rulemaking actions: (1) interim final regulations issued in July 2010 related to coverage of preventive services (75 Fed. Reg. 41,726, July 19, 2010); (2) interim final regulations issued in August 2014 related to the process an eligible organization uses to provide notice of its religious objection to the coverage of contraceptive (76 Fed. Reg. 46,621, Aug. 3, 2011); and (3) proposed regulations issued in August 2014, related to the definition of ''eligible organization,'' which would expand the set of entities that may avail themselves of an accommodation with respect to the coverage of contraceptive services (79 Fed. Reg. 51,118, August 27, 2014).

Additional regulations related to this rule include:

- final regulations that finalized the definition of religious employer in the 2011 amended interim final regulations without modification (77 Fed. Reg. 8,725 February 15, 2012);
- an advance notice of proposed rulemaking which solicited comments on how to provide for coverage of recommended preventive services, including contraceptive services, without cost sharing, while simultaneously ensuring that certain nonprofit organizations with religious objections to contraceptive coverage would not be required to contract, arrange, pay, or refer for that coverage (77 Fed. Reg. 16,501, March 21, 2012);
- proposed regulations to simplify and clarify the definition of ''religious employer'' for purposes of the religious employer exemption, and proposed accommodations for group health plans established or maintained by certain nonprofit religious organizations with religious objections to contraceptive coverage (and group health insurance coverage provided in connection with those plans) and for insured student plans arranged by certain nonprofit religious organizations that are institutions of higher education with religious objections to contraceptive coverage (78 Fed. Reg. 8,456, Feb. 6, 2013);
- final regulations which simplified and clarified the definition of religious employer for purposes of the religious employer exemption and established accommodations for health coverage established or maintained or arranged by eligible organizations (78 Fed. Reg. 39,870, July 2, 2013); and
- interim final regulations that amended the July 2013 final regulations in light of the United States Supreme Court's interim order in connection with an application for an injunction in *Wheaton College v. Burwell* (134 S. Ct. 2806 (2014)), and provided an alternative process that an eligible organization may use to provide notice of its religious objection to the coverage of contraceptive services regulations (79 Fed. Reg. 51,092, August 27, 2014).

The Departments also stated that in addition to these regulations, the Departments released six sets of Frequently Asked Questions (FAQs) regarding the preventive services coverage requirements, and the Departments released FAQs about Affordable Care Act Implementation Parts II, V, XII, XIX, XX, and XXVI to answer outstanding questions, including questions related to the coverage of preventive services. According to the Departments, these FAQs provided guidance related to compliance with the 2010 and 2014 interim final regulations and addressed issues related to specific services required to be covered without cost sharing, subject to reasonable medical management, under recommendations and guidelines specified in section 2713 of the PHS Act.

The Departments received more than 75,000 comments in response to the August 2014 proposed regulations. According to the Departments, numerous comments addressed matters outside the scope of the proposed regulations and were not addressed in the final rules. To the extent comments addressed matters that were within the scope of the proposed regulations, those portions of the comments were considered and all significant comments related to matters within the scope of the proposed regulations were discussed in the final rules.

Additionally, IRS has determined that section 553(b) of APA (5 U.S.C. chapter 5) does not apply to this rule.

Paperwork Reduction Act (PRA), 44 U.S.C. §§ 3501-3520

The final rules contain information collection requirements (ICRs) that are subject to review by the Office of Management and Budget (OMB). To derive average costs, the Departments used data from the U.S. Bureau of Labor Statistics' May 2014 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). For HHS and DOL, there are three relevant regulatory sections with ICRs: ICRs Regarding Self-Certification; ICRs Regarding Notice to HHS; and a Notice of Availability of Separate Payments for Contraceptive Services. The rule also provides for a Letter to HHS Regarding Ownership Structure; however an entity is not required to avail itself of this process in order to qualify as a closely held for-profit entity, according to the Departments. Further, the Departments state that this provision is not subject to PRA as it will affect fewer than 10 entities in a 12-month period. HHS has included a table in the final rules summarizing the annual recordkeeping and reporting requirements broken down between the three ICR regulation sections, and the total number of respondents stated is 210, with total annual burden hours of 217.88, a total labor cost of reporting $11,319, total capital maintenance costs of $56, with a total cost of $11,375.

DOL provided its own PRA analysis for the same ICRs, and the summary costs of the annual recordkeeping and reporting requirements are the same as those provided by HHS. DOL states that it submitted an ICR to OMB in accordance with PRA contemporaneously with the publication of the interim final regulation, for OMB's review under the emergency PRA procedures. OMB approved the ICR on August 27, 2014, under OMB Control Number 1210–0150 through February 28, 2015. Contemporaneously with the publication of the emergency ICR, DOL published a separate *Federal Register* notice informing the public that it intends to request OMB to extend the approval for 3 years and soliciting comments on the ICR. DOL submitted the extension request to OMB on February 27, 2015. OMB approved the ICR extension on April 14, 2015, which currently is scheduled to expire on April 30, 2018.

DOL also submitted an ICR to OMB in accordance with 44 U.S.C. 3507(d), for the ICR contained in the August 2014 proposed regulations contemporaneously with the publication of

the proposal that solicited public comments on the ICR. OMB filed a comment regarding the proposed ICR on October 16, 2014, stating that it was not approving the ICR associated with the proposed rule at the proposed rule stage and requesting DOL resubmit the ICR at the final rule stage after taking into account public comments. OMB assigned OMB Control Number 1210–0152 to the proposed ICR. DOL states that although no public comments were received in response to the ICRs contained in the August 2014 interim final and proposed regulations that specifically addressed the paperwork burden analysis of the information collections, DOL stated that the comments that were submitted contained information relevant to the costs and administrative burdens attendant to the proposals. DOL states that it took into account the public comments in connection with making changes to the proposal, analyzing the economic impact of the proposals, and developing the revised paperwork burden analysis which it summarized. In connection with publication of this final rule, DOL submitted ICRs to OMB as a revision to OMB Control Number 1210–0150 for eligible nonprofit organizations and under new OMB Control Number 1210–0152 for eligible for-profit organizations and received OMB approval for both ICRs.

Statutory authorization for the rule

The Department of the Treasury's regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of title 26 of the U.S. Code.

The Department of Labor's regulations are adopted pursuant to the authority contained in 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. No. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. No. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. No. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. No. 111–148, 124 Stat. 119, as amended by Pub. L. No. 111–152, 124 Stat. 1029; Secretary of Labor's Order 1–2011, 77 Fed. Reg. 1,088 (Jan. 9, 2012).

The Department of Health and Human Services' regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

Executive Order No. 12,866 (Regulatory Planning and Review)

DOL and HHS state that they anticipate that these regulations—most notably the policies first established in the 2010 interim final rule—are likely to have economic impacts of $100 million or more in any one year, and therefore meet the definition of ''significant rule'' under Executive Order 12,866. Therefore, the Departments provided an assessment of the potential costs, benefits, and transfers associated with these final regulations. In accordance with the provisions of Executive Order 12,866, these final regulations were reviewed by OMB.

According to IRS, notwithstanding the determinations of DOL and HHS, IRS has determined that this Treasury rule is not a significant regulatory action as defined in Executive Order 12,866, and therefore, a regulatory assessment is not required.

Executive Order No. 13,132 (Federalism)

In the Departments' views, these final regulations have federalism implications, but the federalism implications are substantially mitigated because, with respect to health insurance issuers, 45 states are either enforcing the requirements related to coverage of specified

preventive services (including contraception) without cost sharing pursuant to state law or otherwise are working collaboratively with HHS to ensure that issuers meet these standards. As stated in the rule, in five states HHS ensures that issuers comply with these requirements, and the final regulations are not likely to require substantial additional oversight of states by HHS.

According to the Departments, in general, section 514 of ERISA provides that state laws are superseded to the extent that they relate to any covered employee benefit plan, and preserves state laws that regulate insurance, banking, or securities. They noted further that ERISA also prohibits states from regulating a covered plan as an insurance or investment company or bank and that the Health Insurance Portability and Accountability Act of 1996 (HIPAA) added a new preemption provision to ERISA (as well as to the PHS Act) narrowly preempting state requirements on group health insurance coverage. States may continue to apply state law requirements but not to the extent that such requirements prevent the application of the federal requirement that group health insurance coverage provided in connection with certain group health plans (or student health insurance issuers) provide coverage for specified preventive services without cost sharing. The Departments noted that HIPAA's Conference Report stated that the conferees intended the narrowest preemption of state laws with regard to health insurance issuers (H.R. Conf. Rep. No. 104–736, 104th Cong. 2d Session 205, 1996). As discussed in the rules, state insurance laws that are more stringent than the federal requirement are unlikely to ''prevent the application of'' the preventive services coverage provision, and therefore are unlikely to be preempted. Accordingly, as stated in the rules, states have significant latitude to impose requirements on health insurance issuers that are more restrictive than those in federal law. The Departments state that guidance conveying this interpretation was published in the *Federal Register* on April 8, 1997 (62 Fed. Reg. 16,904) and December 30, 2004 (69 Fed. Reg. 78,720), and these final regulations implement the preventive services coverage provision's minimum standards and do not significantly reduce the discretion given to states under the statutory scheme.

The Departments state that the PHS Act provides that states may enforce the provisions of title XXVII of the PHS Act as they pertain to issuers, but that the Secretary of HHS will enforce any provisions that a state does not have authority to enforce or that a state has failed to substantially enforce. As HHS stated in the rule, when exercising its responsibility to enforce provisions of the PHS Act, HHS works cooperatively with the state to address the state's concerns and avoid conflicts with the state's exercise of its authority. According to the rule, HHS has developed procedures to implement its enforcement responsibilities and to afford states the maximum opportunity to enforce the PHS Act's requirements in the first instance. In compliance with Executive Order 13,132's requirement that agencies examine closely any policies that may have federalism implications or limit the policymaking discretion of states, the Departments state that they have engaged in numerous efforts to consult and work cooperatively with affected state and local officials. The Departments state that throughout the process of developing the final regulations, to the extent feasible within the specific preemption provisions of ERISA and the PHS Act, the Departments have attempted to balance states' interests in regulating health insurance coverage and health insurance issuers, and the rights of individuals intended to be protected in the PHS Act, ERISA, and the Internal Revenue Code.