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August 2, 2010

The Honorable Tom Harkin
Chairman
The Honorable Michael B. Enzi
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable George Miller
Chairman
The Honorable John Kline
Ranking Member
Committee on Education and Labor
House of Representatives

The Honorable Henry A. Waxman
Chairman
The Honorable Joe Barton
Ranking Member
Committee on Energy and Commerce
House of Representatives

Subject: *Department of the Treasury, Internal Revenue Service; Department of Labor, Employee Benefits Security Administration; and Department of Health and Human Services: Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act*

Pursuant to section 801(a)(2)(A) of title 5, United States Code, this is our report on a major rule promulgated by the Department of the Treasury, Internal Revenue Service (IRS); Department of Labor, Employee Benefits Security Administration (EBSA); and Department of Health and Human Services (HHS) (collectively, the agencies), entitled “Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act” (RINs: 1545-BJ60; 1210-AB44; 0938-AQ07). We received the rule from the Department of Health and Human Services on July 15, 2010, from the Department of the Treasury, Internal Revenue Service, on July 16, 2010, and from the Department of Labor on July 19, 2010. They were published in the *Federal Register*

as interim final rules with request for comments on July 19, 2010. 75 Fed. Reg. 41,726. Comments are due on or before September 17, 2010. These interim final rules are effective on September 17, 2010.

These interim final rules implement the rules for group health plans and health insurance coverage in the group and individual markets under provisions of the Patient Protection and Affordable Care Act regarding preventive health services. These interim final regulations generally apply to group health plans, group health insurance issuers, and individual health insurance issuers for plan years beginning on or after September 23, 2010.

The interim final regulations are effective on September 17, 2010. The Congressional Review Act requires a 60-day delay in the effective date of a major rule from the date of publication in the *Federal Register* or receipt of the rule by Congress, whichever is later. 5 U.S.C. § 801(a)(3)(A). However, notwithstanding the 60-day delay requirement, any rule that an agency for good cause finds that notice and public procedures are impractical, unnecessary, or contrary to the public interest is to take effect when the promulgating agency so determines. §§ 553(d)(3), 808(2). Accordingly, the agencies found good cause to forego the notice and comment procedures based on specific statutory authority granted in section 9833 of the Internal Revenue Code (the Code), section 734 of the Employee Retirement Income Security Act (ERISA), and section 2792 of the Public Health Service Act (PHS Act).

Enclosed is our assessment of the agencies' compliance with the procedural steps required by section 801(a)(1)(B)(i) through (iv) of title 5 with respect to the rule. Our review of the procedural steps taken indicates that the agencies 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 rule, please contact Shirley A. Jones, Assistant General Counsel, at (202) 512-8156.

signed

Robert J. Cramer
Managing Associate General Counsel

Enclosure

cc: Phyllis C. Borzi
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ENCLOSURE

REPORT UNDER 5 U.S.C. § 801(a)(2)(A) ON A MAJOR RULE
ISSUED BY THE
DEPARTMENT OF THE TREASURY,
INTERNAL REVENUE SERVICE;
DEPARTMENT OF LABOR,
EMPLOYEE BENEFITS SECURITY ADMINISTRATION;
DEPARTMENT OF HEALTH AND HUMAN SERVICES,
ENTITLED
"INTERIM FINAL RULES FOR GROUP HEALTH PLANS AND
HEALTH INSURANCE ISSUERS RELATING TO COVERAGE
OF PREVENTIVE SERVICES UNDER THE
PATIENT PROTECTION AND AFFORDABLE CARE ACT"
(RINS: 1545-BJ60; 1210-AB44; 0938-AQ07)

(i) Cost-benefit analysis

The agencies analyzed the potential costs and benefits of these interim final regulations. The agencies anticipate the qualitative costs from 2011 to 2013 to include new costs to the health care system resulting when beneficiaries increase their use of preventive services in response to the changes in coverage and cost-sharing requirements of preventive services. The agencies note that 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.

The agencies anticipate four qualitative benefits from 2011 to 2013. First, individuals will experience improved health as a result of reduced transmission, prevention or delayed onset, and earlier treatment of disease. Second, healthier workers and children will be more productive with fewer missed days of work or school. Third, some of the recommended preventive services will result in savings due to lower health care costs. Fourth, the cost of preventive services will be distributed more equitably.

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

The agencies determined that the Act does not apply to these interim final rules and the agencies are not required to either certify that the regulations would not have a significant economic impact on a substantial number of small entities or conduct a regulatory flexibility analysis. The agencies reached this determination because the Act applies to rules subject to notice-and-comment procedures and the agencies made a good cause finding that no notice of proposed rulemaking was necessary. Nevertheless, the agencies stated that they carefully considered the likely impact of

the regulations on small entities in connection with their assessment under Executive Order 12,866 (discussed below).

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

The agencies determined that these interim final regulations are not subject to the Unfunded Mandates Reform Act because they are being issued as interim final regulations. However, the agencies note that consistent with the policy embodied in the Unfunded Mandates Reform Act, these interim final regulations have been designed to be the least burdensome alternative for state, local, and tribal governments, and the private sector, while achieving their objectives.

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

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

The agencies state that section 9833 of the Internal Revenue Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries of the IRS, EBSA, 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. The agencies state that rules set forth in these interim final regulations govern the applicability of the requirements in these sections and are therefore appropriate to carry them out. Therefore, according to the agencies the foregoing interim final rule authority applies to these interim final regulations.

In addition, the agencies note that under section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. § 551 et seq.) a general notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. The agencies state that the provisions of the APA that ordinarily require a notice of proposed rulemaking do not apply here because of the specific authority granted by section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act. However, even if the APA were applicable, 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. The Secretaries believe it is not possible to have a full notice and comment process and to publish final regulations in the brief 6-month time period between enactment of the Affordable Care Act and the date regulations are needed.

The Secretaries further find that issuance of proposed regulations would be insufficient because the provisions of the Affordable Care Act protect significant

rights of plan participants and beneficiaries and individuals covered by individual health insurance policies and it is essential that participants, beneficiaries, insureds, plan sponsors, and issuers have certainty about their rights and responsibilities. The Secretaries state that the proposed regulations are not binding and cannot provide the necessary certainty. By contrast, the agencies note that the interim final regulations provide the public with an opportunity for comment, but without delaying the effective date of the regulations.

Additionally, IRS has also determined that section 553(b) of the APA (5 U.S.C. chapter 5) does not apply to these interim final regulations.

Paperwork Reduction Act, 44 U.S.C. §§ 3501–3520

According to the agencies, these interim final regulations are not subject to the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. § 3501 *et seq.*) because it does not contain a “collection of information” as defined in 44 U.S.C. § 3502(11).

Statutory authorization for the rule

IRS’ temporary regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Internal Revenue Code.

EBSA’s interim final 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, 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); section 512(d), Pub. L. No. 110–343, 122 Stat. 3881; sections 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 6–2009, 74 Fed. Reg. 21,524 (May 7, 2009).

HHS’ interim final 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)

EBSA and HHS state that the Office of Management and Budget (OMB) has determined that this regulation is economically significant within the meaning of section 3(f)(1) of the Executive Order, because it is likely to have an annual effect on the economy of \$100 million in any one year. Accordingly, OMB has reviewed these rules pursuant to the Executive Order.

According to IRS, notwithstanding the determinations of EBSA and HHS, IRS has determined that this Treasury decision is not a significant regulatory action for

purposes of Executive Order 12,866 and therefore, a regulatory assessment is not required.

Executive Order No. 13,132 (Federalism)

In EBSA's and HHS' view, these interim final regulations have federalism implications, because they have direct effects on the states, the relationship between the national government and states, or on the distribution of power and responsibilities among various levels of government. However, in EBSA's and HHS' view, the federalism implications of these interim final regulations are substantially mitigated because, with respect to health insurance issuers, EBSA and HHS expect that the majority of states will enact laws or take other appropriate action resulting in their meeting or exceeding the federal standards.

In its submission to the Comptroller General, IRS did not include an analysis of the interim final rules under the Order.