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August 12, 2010

The Honorable Max Baucus  
Chairman  
The Honorable Charles E. Grassley  
Ranking Member  
Committee on Finance  
United States Senate

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 Internal Claims and Appeals and External Review Processes 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 Internal Claims and Appeals and External Review Processes Under the Patient Protection and Affordable Care Act” (RINs: 1545-BJ63; 1210-AB45; 0991-AB70). We received the rule from EBSA and IRS on July 23, 2010, and from HHS on July 28, 2010. They were published in the *Federal Register* as interim final rules with request for comments on July 23, 2010. 75 Fed. Reg. 43,330. These interim final rules are open for comment until September 21, 2010, and have an effective date of September 21, 2010.

These interim final rules implement 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. The regulations will generally affect health insurance issuers; group health plans; and participants, beneficiaries, and enrollees in health insurance coverage and in group health plans. The regulations provide plans and issuers with guidance necessary to comply with the law. These rules will generally apply to group health plans, group health insurance issuers, and individual insurance issuers for plan years beginning on or after September 23, 2010.

The Congressional Review Act requires major rules to have a 60-day delay in their effective date following their publication in the *Federal Register* or receipt by Congress, whichever is later. 5 U.S.C. § 801(a)(3)(A). However, notwithstanding the 60-day requirement, any rule that an agency for good cause finds that the notice and public comment procedures are impractical, unnecessary, or contrary to the public interest is to take effect when the promulgating agency so determines. 5 U.S.C. § 808(2). The agencies determined that they had good cause to waive prior notice and comment procedures in this case because of the specific authority granted by section 9833 of the Internal Revenue Code, section 734 of ERISA, and section 2792 of the Public Health Service Act. Therefore, the requirement to have a 60-day delay does not apply to this rule.

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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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 INTERNAL CLAIMS  
AND APPEALS AND EXTERNAL REVIEW PROCESSES UNDER THE  
PATIENT PROTECTION AND AFFORDABLE CARE ACT  
(RINS: 1545-BJ63; 1210-AB45; 0991-AB70)

(i) Cost-benefit analysis

The Internal Revenue Service (IRS), the Employee Benefits Security Administration (EBSA), and the Department of Health and Human Services (HHS) (collectively, the agencies) analyzed the costs and benefits of this final rule. In assessing the benefits of this rule, the agencies found the following:

A more uniform, rigorous, and consumer friendly system of claims and appeals processing will provide a broad range of direct and indirect benefits that will accrue to varying degrees to all of the affected parties. These interim final regulations could improve the extent to which employee benefit plans provide benefits consistent with the established terms of individual plans. While payment of these benefits will largely constitute transfers, the transfers will be welfare improving, because incorrectly denied benefits will be paid. Greater certainty and consistency in the handling of benefit claims and appeals and improved access to information about the manner in which claims and appeals are adjudicated should lead to efficiency gains in the system, both in terms of the allocation of spending across plans and enrollees as well as operational efficiencies among individual plans. This certainty and consistency can also be expected to benefit, to varying degrees, all parties within the system, particularly consumers, and to lead to broader social welfare gains.

The agencies estimated the costs of this rule to (1) administer and conduct the internal and external review process, (2) prepare and distribute required disclosures and notices, and (3) bring plan and issuers' internal and external claims and appeals procedures into compliance with the new requirements. The agencies estimate these costs to be between \$51.2 million and \$51.6 million per year for the period 2011 to 2013, depending on the discount rate. The agencies also estimated the dollar amount

of claim denials reversed in the external review process. While this amount is a cost to plans, it represents a payment of benefits that should have previously been paid to participants, but was denied. Part of this amount is a transfer from plans and issuers to those now receiving payment for denied benefits. These transfers will improve equity, because incorrectly denied benefits will be paid. Part of the amount could also be a cost if the reversal leads to services and hence resources being utilized now that had been denied previously. The agencies estimated the amount attributable to reversals to be between \$24.4 million and \$24.7 million per year for the period 2011 to 2013, depending on the discount rate.

The agencies stated that they crafted the rules to secure the protections intended by Congress in the most economically efficient manner possible.

(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 a notice of proposed rulemaking was not necessary. Nevertheless, the agencies stated that they carefully considered the likely impact of the regulations on small entities.

(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 did not publish a notice of proposed rulemaking for this interim final rule. An agency may waive publishing a notice of proposed rulemaking if it finds for good cause that a notice-and-comment procedure is impractical, unnecessary, or contrary to the public interest. 5 U.S.C. § 553(b). The agencies found that statutory deadlines provided good cause to waive the notice of proposed rulemaking as impracticable and contrary to the public interest.

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

HHS determined that this interim final rule contains information collection requirements under the Act. HHS submitted the first new information collection to the Office of Management and Budget (OMB) for review under the title “Affordable Care Act Internal Claims and Appeals and External Review Disclosures” and OMB Control Number 0938-1098. For this requirement, HHS estimates that in the first year there will be 27,829 respondents with 132,035,000 responses incurring an annual burden of 566,000 hours and an annual burden cost of \$20,700,000. HHS submitted the second new information collection to OMB for review under the title “Affordable Care Act Recordkeeping Requirements” and OMB Control Number 0938-1098. For this requirement, HHS estimates that in the first year there will be 490 respondents with 7,350 responses incurring an annual burden of 1,800 hours and an annual burden cost of zero. HHS noted that because this burden is borne solely by the insurers offering coverage in the individual health insurance market, and these insurers are assumed to process all claims in-house, there is no annual cost burden associated with this collection of information.

Statutory authorization for the rule

IRS promulgated this interim final rule under the authority of sections 7805 and 9833 of title 26, United States Code. EBSA promulgated this interim final rule under the authority of sections 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c of title 29, United States Code; sections 300gg-5 note and 651 note of title 42, United States Code; section 101(g) of the Health Insurance Portability and Accountability Act of 1996;<sup>1</sup> sections 1001, 1201, and 1562(e) of the Patient Protection and Affordable Care Act<sup>2</sup> and Secretary of Labor Order 6-2009.<sup>3</sup> HHS promulgated this interim final rule under the authority of sections 300gg through 300gg-63, 300gg-91, and 300gg-92 of title 42, United States Code.

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

EBSA and HHS determined that these interim final rules are economically significant under the Order because they are likely to have an annual effect on the economy of \$100 million or more in any one year. OMB reviewed the rules under the Order. Notwithstanding the determinations by EBSA and HHS, for purposes of IRS, a

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<sup>1</sup> Pub. L. No. 104-191, 110 Stat. 1936, 1953–54 (Aug. 21, 1996).

<sup>2</sup> Pub. L. No. 111-148, 124 Stat. 119, 130–138, 154–161, 270 (Mar. 23, 2010) (as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (Mar. 30, 2010)).

<sup>3</sup> 74 Fed. Reg. 21,524 (May 7, 2009).

determination was made that the relevant Department of the Treasury decision was not a significant regulatory action under the Order.

Executive Order No. 13,132 (Federalism)

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