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June 11, 2014

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

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

Subject: *Department of Health and Human Services: Patient Protection and Affordable Care Act; Exchange and Insurance Market Standards for 2015 and Beyond*

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 Health and Human Services (HHS) entitled “Patient Protection and Affordable Care Act; Exchange and Insurance Market Standards for 2015 and Beyond” (RIN: 0938-AS02). We received the rule on May 20, 2014. It was published in the *Federal Register* as a final rule on May 27, 2014. 79 Fed. Reg. 30,240.

The final rule addresses various requirements applicable to health insurance issuers, Affordable Insurance Exchanges (Exchanges), Navigators, non-Navigator assistance personnel, and other entities under the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 (collectively referred to as the Affordable Care Act).

Specifically, the rule establishes standards related to product discontinuation and renewal, quality reporting, non-discrimination standards, minimum certification standards and responsibilities of qualified health plan (QHP) issuers, the Small Business Health Options Program, and enforcement remedies in federally-facilitated Exchanges. It also finalizes: a modification of HHS’s allocation of reinsurance collections if those collections do not meet HHS’s projections; certain changes to allowable administrative expenses in the risk corridors calculation; modifications to the way HHS calculates the annual limit on cost sharing; an approach to index the required contribution used to determine eligibility for an exemption from the shared responsibility payment under section 5000A of the Internal Revenue Code; grounds for imposing civil money penalties on persons who provide false or fraudulent information to the Exchange and on persons who improperly use or disclose information; updated standards for the consumer assistance programs; standards related to the opt-out provisions for self-funded, non-federal governmental plans and related to the individual market provisions under the Health Insurance Portability and Accountability Act of 1996 including excepted benefits; standards

regarding how enrollees may request access to non-formulary drugs under exigent circumstances; amendments to Exchange appeals standards and coverage enrollment and termination standards; and time-limited adjustments to the standards relating to the medical loss ratio (MLR) program.

Enclosed is our assessment of HHS's 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 HHS 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: Ann Stallion
Deputy Director, ODRM
Department of Health and Human Services

REPORT UNDER 5 U.S.C. § 801(a)(2)(A) ON A MAJOR RULE
ISSUED BY THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
ENTITLED
"PATIENT PROTECTION AND AFFORDABLE CARE ACT;
EXCHANGE AND INSURANCE MARKET STANDARDS
FOR 2015 AND BEYOND"
(RIN: 0938-AS02)

(i) Cost-benefit analysis

HHS performed a cost-benefit analysis in conjunction with the final rule. HHS did not quantify the benefits, but listed the following qualitative benefits: ensure access to affordable and quality health insurance coverage for all individuals; minimize unnecessary terminations of coverage and ensure predictability and continuity for consumers; allow consumers to make informed choices; lower out-of-pocket costs for individuals who purchase fixed indemnity insurance; possible reduction in cost sharing due to adjustment in methodology for calculating annual limitations on cost-sharing; help ensure sufficiency of funds in the reinsurance payment pool; ensure consumer protection and privacy and security of personally identifiable information; discourage fraudulent or criminal activity by consumer assistance personnel and entities; provide additional flexibility to Federally-facilitated Small Business Health Options Program (FF-SHOPs) and employers and allow employers to select plans with updated rate information; and improve consistency of medical loss ratio (MLR) calculations among issuers in states with merged individual and small group markets and improve accuracy of rebate payments.

HHS estimated the annual costs would be \$48.78 million using a 7 percent discount rate (\$49.52 million using a 3 percent discount rate), which includes costs to enrollees related to enrollee satisfaction survey (ESS) and Marketplace survey; recertification of certified application counselors by states; costs to states to submit recommendations to not implement employee choice in 2015; administrative costs incurred by survey vendors to appeal application denials; administrative costs to qualified health plan (QHP) issuers related to data submissions for quality rating system (QRS) and ESS administration; costs related to notice and disclosure requirements for certified application counselor recertification; consumer authorization for Navigators and non-Navigator personnel; and a reduction in costs for issuers in the individual market due to discontinuation of certification of creditable coverage. HHS also noted the following qualitative costs: costs to certified application counselors to obtain required training for recertification; reduction in costs to consumers due to ability to make requests to dismiss appeals by telephone; and costs to issuers to comply with the standards for expedited review of a formulary exception request based on exigent circumstances.

HHS estimated the annual transfers would be \$2.93 million using a 7 percent discount rate (\$2.99 million using a 3 percent discount rate), which includes transfer of rebate dollars to enrollees from shareholders or nonprofit stakeholders, resulting from adjustment in MLR methodology for issuers in states with merged individual and small group markets. HHS also noted the following qualitative transfers: possible reduction in rebates paid by issuers to enrollees due to adjustment in MLR methodology for issuers affected by the November 2013 transitional policy and unexpected costs during the implementation of the Exchanges, and to account for ICD-10 conversion costs; possible transfer of transitional reinsurance program

funds collected by the federal government to non-grandfathered reinsurance-eligible plans in the individual market; possible increase in total risk corridors payment amounts made by the federal government and decrease in total risk corridors receipts.

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

The Regulatory Flexibility Act (RFA) requires agencies that issue a rule to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. HHS determined that the provisions of this final rule will not affect a substantial number of small issuers and will not impose any costs on small employers. HHS determined that some of the entities that voluntarily act as Navigators and non-Navigator assistance personnel, or as designated certified application counselor organizations, may be small entities and will incur costs to comply with the provisions of this final rule, but expects that such costs will be low.

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

Section 202 of the Unfunded Mandates Reform Act (UMRA) of 1995 requires that agencies assess anticipated costs and benefits before issuing any final rule that includes a federal mandate that could result in expenditure in any one year by state, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. In 2014, that threshold level is approximately \$141 million. The final rule includes mandates on state governments and the private sector. HHS expects issuers, non-Navigator assistance personnel, certified application counselors and Exchanges to incur costs of approximately \$13 million in 2014 and approximately \$85 million in 2015 onwards to comply with the provisions of this final rule, and issuers in the individual market to experience a reduction in costs of approximately \$26 million, beginning in 2015, due to the discontinuation of the certification of creditable coverage. These amounts are below the UMRA threshold, but HHS stated that consistent with policy embodied in UMRA, the final rule was designed to be the least burdensome alternative for state, local, and tribal governments, and the private sector while achieving the objectives of the Affordable Care Act.

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

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

On March 21, 2014, HHS published a notice of proposed rulemaking in the *Federal Register*. 79 Fed. Reg. 15,808. HHS received approximately 220 comments on the proposed rule, from a wide variety of stakeholders, including but not limited to states, tribes, tribal organizations, health plans, consumer groups, employer groups, healthcare providers, industry experts, and members of the public. HHS responded to the comments in the final rule.

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

The final rule contains information collection requirements that are subject to review by the Office of Management and Budget (OMB). In the final rule, HHS solicits public comment on each issue that contains such requirements and plans to address such comments at the time the 30-day notice is published to solicit public comments. HHS also submitted to OMB a

proposed information collection regarding the 2015 transition to employee choice for its emergency review.

Statutory authorization for the rule

The final rule is authorized by sections 1201, 1302(b), 1302(c), 1311(b), 1311(c)(3), 1311(c)(4), 1311(d)(4)(K), 1311(k), 1312, 1312(a), 1321, 1321(c)(1), 1321(c)(2), 1321(d), 1341, 1342, 1343, 1411(e)(4)(C), 1411(f)(1), 1411(f)(2), 1411(h), and 1501(b) of the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, and sections 2718, 2722, 2722(a)(2), 2723(b), 2741-2744, 2763, and 2791(c) of the Public Health Service Act, as amended.

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

HHS determined that the final rule is economically significant because it is likely to have economic impacts of \$100 million or more in any one year. Therefore, HHS submitted the rule to OMB for review and has provided an assessment of the potential costs, benefits, and transfers associated with the final rule.

Executive Order No. 13,132 (Federalism)

HHS determined the final rule had federalism implications and engaged in efforts to consult with and work cooperatively with affected states. HHS consulted with stakeholders on policies related to the operation of Exchanges, including the SHOP and the premium stabilization programs. HHS held a number of listening sessions with state representatives and consulted with state representatives through regular meetings with the National Association of Insurance Commissioners and regular contact with states through the Exchange Establishment grant and Exchange Blueprint approval processes.

HHS stated that it attempted to balance the states' interests in regulating health insurance issuers and other entities, with creating a federal baseline for protecting the consumers' interests. HHS certified that the Centers for Medicare & Medicaid Services' Center for Consumer Information and Insurance Oversight complied with the requirements of Executive Order 13,132 for the final rule in a meaningful and timely manner.