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December 22, 2011

The Honorable Tom Harkin
Chairman
The Honorable Michael B. Enzi
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; Establishment of Consumer Operated and Oriented Plan (CO-OP) Program*

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, entitled "Patient Protection and Affordable Care Act; Establishment of Consumer Operated and Oriented Plan (CO-OP) Program" (RIN: 0938-AQ98). We received the rule on December 12, 2011. It was published in the *Federal Register* as a final rule on December 13, 2011, with an effective date of February 13, 2012. 76 Fed. Reg. 77,392

The final rule implements the Consumer Operated and Oriented Plan (CO-OP) program, which provides loans to foster the creation of consumer governed, private, nonprofit health insurance issuers to offer qualified health plans in the Affordable Insurance Exchanges (Exchanges). Starting in 2014, individuals and small businesses will be able to purchase private health insurance through state-based competitive marketplaces called Exchanges. Insurance companies will compete for new business on the basis of price and value and consumers will have a choice of health plans to fit their needs. The goal of this program is to create a new CO-OP in every state in order to expand the number of health plans available in the Exchanges with a focus on integrated care and greater plan accountability. The

Departments of Health and Human Services, Labor, and the Treasury are seeking public input, providing guidance, and issuing regulations implementing Exchanges in several phases.

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
Program Manager
Department of Health and
Human Services

ENCLOSURE

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;
ESTABLISHMENT OF CONSUMER OPERATED
AND ORIENTED PLAN (CO-OP) PROGRAM"
(RIN: 0938-AQ98)

(i) Cost-benefit analysis

HHS states that it prepared a regulatory impact analysis. HHS believes that there will be costs involved in administration of the program, and currently estimates that these could be approximately $10 million a year on an annualized present value basis, as shown in HHS's Accounting Statement. Actual administrative costs may be higher or lower and are expected to vary over time.

Additionally, HHS states the benefits will include the opportunity to foster and spread emerging models of integrated delivery systems, both to improve health outcomes and to lower health costs. HHS notes that CO-OPs can adopt new models and new arrangements that are more patient-centered than the current fragmented delivery system. According to HHS, improved delivery systems may provide better health outcomes due to coordinated care, better chronic disease management, and improved quality of care. In addition, HHS believes that by adding competition to state markets, CO-OPs have the potential to promote efficiency, reduce premiums and/or premium growth, and improve service and benefits to enrollees. HHS notes that by their nature, traditional cooperatives, on which the CO-OP program is modeled, focus on responsiveness to their members and accountability to member needs, which may create flexibility to reduce administrative costs. HHS states that direct savings could be substantial after the initial start-up period and resulting attempts to maintain or regain market share by traditional insurance issuers competing with CO-OPs could lead to system-wide savings across millions of enrollees.

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

The Regulatory Flexibility Act (RFA) requires agencies to determine whether final rules would have a "significant economic impact on a substantial number of small entities" and, if so, to prepare a Regulatory Flexibility Analysis to identify options that could mitigate the impact of the proposed regulation on small businesses. According to HHS, all CO-OPs established under the program will be private

nonprofit organizations and qualify as small entities under the RFA. HHS interprets the requirement as applying only to regulations with negative impacts but routinely prepares a voluntary Regulatory Flexibility Analysis for regulations with significant positive impacts. HHS states that the positive economic impacts of the program on CO-OPs will clearly be "significant," particularly in the effects on thousands of small businesses that are likely to purchase insurance through the Exchanges and would benefit from the lower premium costs that CO-OPs will likely create. Moreover, HHS notes that small businesses will have the opportunity to create consortia to help sponsor CO-OPs and may actively pursue these savings. In light of the benefits to these small entities, HHS has prepared a voluntary Regulatory Flexibility Analysis. HHS states that its economic analysis and preamble constitute that analysis.

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

HHS states that the final rule does not contain any federal mandates resulting in expenditure by the private sector, or state, local, and tribal governments, in aggregate, of $100 million or more in any one year.

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

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

The final rule was issued using the notice and comment procedures found at 5 U.S.C. § 553. HHS states that a request for comment relating to Exchanges was published on August 3, 2010, and Initial Guidance to States on Exchanges was published on November 18, 2010. Additionally, HHS notes that a proposed rule for the application, review, and reporting process for waivers for state innovation was published on March 14, 2011 (76 Fed. Reg. 13,553). On July 15, 2011, HHS states that two proposed regulations were published to implement components of the Exchange: "Establishment of Exchanges and Qualified Health Plans" (76 Fed. Reg. 41,866) and "Standards Related to Reinsurance, Risk Corridors and Risk Adjustment" (76 Fed. Reg. 41,930). On August 17, 2011, HHS notes that three proposed regulations were published "Eligibility Changes Under the Affordable Care Act of 2010" (76 Fed. Reg. 51,148), "Exchange Functions in the Individual Market: Eligibility Determinations; Exchange Standards for Employers" (76 Fed. Reg. 51,202), and "Health Insurance Premium Tax Credit" (76 Fed. Reg. 50,931). HHS states that that it has considered the comments received and is finalizing the provisions set forth in the proposed rule. HHS explains that additional regulations will be published to implement Exchange-related components of the Affordable Care Act.

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

HHS states that it solicited comments on the extension of the information collection requests associated with the implementation of the CO-OP program (for example, application, reporting) currently approved under 0938–1139 in a 60-day notice that was published on August 5, 2011 (76 Fed. Reg. 47,591). According to HHS, the Office of Management and Budget (OMB) previously reviewed and approved the Information Collection Request under emergency processing according to 5 C.F.R. part 1320.13. HHS notes that it did not receive any public comments regarding this extension and therefore, is finalizing the information collection.

Statutory authorization for the rule

HHS states that the final rule is authorized under sections 1301–1304, 1311–1312, 1321, 1322, 1324, 1334, 1342–1343, and 1401–1402, Pub. L. 111–148, 124 Stat. 119 (42 U.S.C. § 18042).

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

HHS states that the final rule is economically significant and, accordingly, the Office of Management and Budget has reviewed this final rule.

Executive Order No. 13,132 (Federalism)

Executive Order 13,132 on Federalism establishes requirements that an agency must meet when a proposed rule imposes substantial costs on state and local governments, preempts state law, or otherwise has federalism implications. HHS states that this final rule does not trigger these requirements.