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United States Government Accountability Office
Washington, DC 20548

B-324419

February 22, 2013

The Honorable Max Baucus
Chairman
The Honorable Orrin G. Hatch
Ranking Member
Committee on Finance
United States Senate

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

The Honorable Dave Camp
Chairman
The Honorable Sander Levin
Ranking Member
Committee on Ways and Means
House of Representatives

Subject: *Department of Health and Human Services, Centers for Medicare & Medicaid Services: Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests*

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, Centers for Medicare & Medicaid Services (CMS) entitled "Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests" (RIN: 0938-AR33). We received the rule on February 6, 2013. It was published in the *Federal Register* as a final rule on February 8, 2013. 78 Fed. Reg. 9458.

The final rule will require applicable manufacturers of drugs, devices, biologicals, or medical supplies covered by Medicare, Medicaid or the Children's Health Insurance Program (CHIP) to report annually to the Secretary of Health and Human Services

(HHS) certain payments or transfers of value provided to physicians or teaching hospitals (“covered recipients”). In addition, applicable manufacturers and applicable group purchasing organizations (GPOs) are required to report annually certain physician ownership or investment interests. The Secretary of HHS is required to publish applicable manufacturers' and applicable GPOs' submitted payment and ownership information on a public website.

The rule has an effective date of April 9, 2013. Applicable manufacturers and applicable GPOs must begin to collect the required data on August 1, 2013, and report the data to CMS by March 31, 2014.

Enclosed is our assessment of CMS’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 CMS 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
"MEDICARE, MEDICAID, CHILDREN'S HEALTH INSURANCE PROGRAMS;
TRANSPARENCY REPORTS AND REPORTING OF PHYSICIAN OWNERSHIP
OR INVESTMENT INTERESTS"
(RIN: 0938-AR33)

(i) Cost-benefit analysis

CMS performed a cost-benefit analysis in conjunction with the final rule with comment period. CMS anticipates that much of the total estimated burden of this final rule will fall on applicable manufacturers and applicable GPOs. CMS has estimated that the total cost of these provisions will be approximately $269 million in the first year and $180 million annually thereafter. They stated that they have no empirical ability to estimate the monetary benefits of this provision; however, there are nonmonetary benefits, which are difficult to quantify. Increased transparency regarding the extent and nature of relationships between physicians, teaching hospitals, and industry manufacturers will permit patients to make better informed decisions when choosing health care professionals and making treatment decisions, and deter inappropriate financial relationships which can sometimes lead to increased health care costs. Additionally, increased transparency about the owners and investors in GPOs will allow purchasers to make better informed decisions and identify potential conflicts of interest with ordering physicians.

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

CMS estimated that the final rule will not have a significant impact on a substantial number of small entities. Further, CMS determined that the final rule will not have a significant impact on the operations of a substantial number of small rural hospitals. CMS included the information required for its regulatory flexibility analysis as part of its regulatory impact analysis.

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

CMS stated in the final rule that this regulation does not impose any costs on state or local governments.

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

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

On December 19, 2011, CMS published a proposed rule in the *Federal Register*. 76 Fed. Reg. 78,742. CMS solicited public comment on a number of proposals regarding transparency reports and the reporting of physician ownership or investment interests. CMS received approximately 373 timely public comments. Most of the public comments addressed provisions included in the proposed rule. CMS received some comments that were outside the scope of the proposed rule and, therefore, were not addressed in the final rule. CMS summarized the public comments that were within the scope of the proposals, responded to those comments, and described the CMS final policy.

This final rule was not published in time for applicable manufacturers and applicable GPOs to begin collecting the information required in section 1128G of the Social Security Act on January 1, 2012, as provided in the statute. In the proposed rule, CMS indicated that it would not require applicable manufacturers and applicable GPOs to begin collecting the required information until after the publication of the final rule. After consideration of the public comments received and given the timing of the final rule, CMS established that data collection will begin on August 1, 2013, and must be reported to CMS by March 31, 2014. CMS also established that there would be no retroactive reporting.

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

The final rule contains information collection requirements subject to the Paperwork Reduction Act. The information collections contained in this rulemaking are numerous and somewhat complex. The final rule describes information collections relating to: A) Recordkeeping and Reporting of Payments or Other Transfers of Value and Physician Ownership and Investment Interests; B) Registration for Applicable Manufacturers and Applicable GPOs; C) Attestation; D) Assumptions Document; E) Information Collections Regarding Review and Correction by Physicians and Teaching Hospitals; F) Notice of Resolved Disputes by Applicable Manufacturers and Applicable GPOs; and G) Notice of Errors or Omissions.

Regarding A, CMS stated that in the proposed rule, it requested comment on the information required in the proposed regulation, but did not include all the data elements it expected applicable manufacturers and applicable GPOs to report, nor did it include detailed information about the mechanism for submission, amendment, or correction. For that reason, CMS also published a 60-day notice elsewhere in the same day (Feb. 8, 2013) *Federal Register* seeking public comment on the information collection. 78 Fed. Reg. 9394. As part of the process, CMS is seeking public comment on templates that contain the data specifications for the system CMS will build. Regarding B-F above, CMS states that it has yet to seek the

Office of Management and Budget (OMB) approval for the information collections associated with these provisions. CMS plans to seek public comment consistent with the requirement of the Paperwork Reduction Act and request OMB approval at a later date. Consistent with 5 C.F.R. part 1320, these provisions will not be effective until OMB approves the collection of information. Regarding G, CMS has not yet established the content or form of this notice, and therefore, as with B-F above, has yet to seek OMB approval for the information collections associated with this provision. CMS stated that it plans to seek public comment consistent with the requirement of the Paperwork Reduction Act and request OMB approval at a later date. Consistent with 5 C.F.R. part 1320, these provisions will not be effective until OMB approves the collection of information.

CMS explained that it plans to obtain approval for the information collections in a step-wise fashion as it develops the system for receiving and displaying the required information and for allowing covered recipients and physician owners or investors to review the reported data prior to display on the CMS website.

Statutory authorization for the rule

The final rule is authorized by the requirements in section 6002 of the Affordable Care Act, which added section 1128G to the Social Security Act.

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

CMS determined that the final rule is an economically significant rule under the Executive Order. The final rule has been reviewed by the Office of Management and Budget.

Executive Order No. 13,132 (Federalism)

CMS determined that the final rule does preempt certain elements of state law, but the regulatory standard simply follows the express preemption provision in the statute. Because of this and the fact that this regulation does not impose any costs on state or local governments, CMS determined that the requirements of Executive Order 13,132 are not applicable.