U.S. GOVERNMENT ACCOUNTABILITY OFFICE
441 G St. N.W.
Washington, DC 20548

B-327815

February 29, 2016

The Honorable Orrin G. Hatch
Chairman
The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate

The Honorable Fred Upton
Chairman
The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Kevin Brady
Chairman
The Honorable Sander M. Levin
Ranking Member
Committee on Ways and Means
House of Representatives

Subject: *Department of Health and Human Services, Centers for Medicare & Medicaid Services: Medicare Program; Reporting and Returning of Overpayments*

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 Program; Reporting and Returning of Overpayments" (RIN: 0938-AQ58). We received the rule on February 11, 2016. It was published in the *Federal Register* as a final rule on February 12, 2016. 81 Fed. Reg. 7654.

The final rule requires providers and suppliers receiving funds under the Medicare program to report and return overpayments by the later of the date that is 60 days after the date on which the overpayment was identified, or the date any corresponding cost report is due, if applicable. According to CMS, the requirements in this rule are meant to ensure compliance with applicable statutes, promote the furnishing of high quality care, and to protect the Medicare Trust Funds against fraud and improper payments. CMS also states that this rule provides needed clarity and consistency in the reporting and returning of self-identified overpayments.

The Congressional Review Act (CRA) 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). This final rule has a stated effective date of March 14, 2016. We received the rule on February 11, 2016, and it was published in the *Federal Register* on February 12, 2016. Therefore, the final rule does not have the full required 60-day delay in its effective date.

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, with the exception of the 60-day delay in effective date.

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

ENCLOSURE

REPORT UNDER 5 U.S.C. § 801(a)(2)(A) ON A MAJOR RULE
ISSUED BY THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES,
CENTERS FOR MEDICARE & MEDICAID SERVICES
ENTITLED
"MEDICARE PROGRAM; REPORTING AND
RETURNING OF OVERPAYMENTS"
(RIN: 0938-AQ58)

(i) Cost-benefit analysis

The Centers for Medicare & Medicaid Services (CMS) prepared a cost benefit analysis of the final rule. The final rule states that a provider or supplier must (1) report and return an overpayment to the Secretary of Health and Human Services, the state, an intermediary, a carrier, or a contractor to the correct address by the later of 60 days after the overpayment was identified or the date the corresponding cost report is due, and (2) notify the Secretary, the state, an intermediary, a carrier, or a contractor in writing of the reason for the overpayment. The costs associated with these requirements are the time and effort necessary for providers and suppliers to identify, report, and return overpayments in the manner described in this rule. CMS projected an annual cost burden of between $120.87 million and $201.45 million. The former represents CMS's low-end estimate, while the latter is CMS's high-end estimate. CMS's primary, or midrange, projection is an estimate of $161.16 million. The requirements in the final rule are meant to ensure compliance with applicable statutes, promote the furnishing of high quality care, and to protect the Medicare Trust Funds against fraud and improper payments. The potential financial benefits of this final rule from the standpoint of its effectiveness in recouping overpayments are not easily quantifiable, as CMS does not have sufficient data on which to base a monetary estimate of recovered funds.

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

CMS states that the Regulatory Flexibility Act requires agencies to analyze options for regulatory relief of small businesses, if a rule has a significant impact on a substantial number of small entities. For purposes of RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.5 million to less than $38.5 million in any one year. With a maximum cost of $201,450,000 CMS states that it does not believe that the reporting and returning of overpayments identified by providers and suppliers of services will have a significant impact on a substantial number of small entities. CMS did not prepare an analysis for RFA because the Secretary of Health and Human Services has determined that the final rule will not have significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Social Security Act requires CMS to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of RFA. CMS stated that it did not prepare an analysis for section 1102(b) because the Secretary has

determined that the notice will not have a significant impact on the operations of a substantial number of small rural hospitals.

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

CMS states that section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending $100 million in any one year in 1995 dollars, updated annually for inflation. For 2015, the threshold was approximately $144 million. CMS concluded that this notice will have no consequential effect on state, local, or tribal governments, in the aggregate, or on the private sector.

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

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

On February 16, 2012, CMS published a proposed rule in the *Federal Register* (77 Fed. Reg. 9179) that would implement the provisions of section 1128J(d) of the Social Security Act. In response to the proposed rule, CMS states that it received approximately 200 timely pieces of correspondence. CMS summarized the proposals, responded to the public comments received, and detailed the changes made to the proposals.

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

CMS states that there are information collection requirements (ICRs) in the final rule that have been revised from the proposed rule. In the proposed rule, CMS stated that a provider or supplier must (1) report and return an overpayment to the Secretary, the state, an intermediary, a carrier, or a contractor to the correct address by the later of 60 days after the overpayment was identified or the date the corresponding cost report is due, and (2) notify the Secretary, the state, an intermediary, a carrier, or a contractor in writing of the reason for the overpayment. The burden associated with this requirement was the time and effort necessary to report and return the overpayment in the manner described under the proposed regulation (42 C.F.R. § 401.305). CMS estimated that approximately 125,000 providers and suppliers (or roughly 8.5 percent of the total number of Medicare providers and suppliers) would report and return overpayments in a typical year under the provisions. CMS estimated this based on the improper payment rate for the Medicare Fee-for-Service program, which was approximately 12 percent in FY 2014 and FY 2015, and CMS expects that some number of improper payments will be identified by sources other than providers and suppliers themselves. We projected that each of these providers and suppliers would, on average, separately report and return approximately three to five overpayments. In addition, CMS estimated that it would take a provider or supplier approximately 2.5 hours to complete the applicable reporting form and return an overpayment. CMS determined that the two main categories of individuals who would most likely complete and submit the applicable reporting form included (1) accountants and auditors (external and in-house); and (2) miscellaneous in-house administrative personnel. Using Bureau of Labor Statistics (BLS) data for May of 2010, CMS calculated an aggregate annual ICR cost burden—attributable to the impacted 125,000 providers and suppliers, and using the range of three to five overpayments, of $34.78 million and $57.97 million, respectively. CMS is developing an ICR for the Office of Management and Budget's (OMB) review and approval that will authorize the collection of the applicable reporting form. The public will have an opportunity to review the information collection and submit comments. CMS states that it

plans to announce the ICR under the required 60-day and 30-day *Federal Register* notice and comment periods.

In the final rule, however, CMS states that there are two major changes from the projected burden in the proposed rule, described above. First, CMS is increasing the per report hour burden from 2.5 hours to 6 hours. Second, CMS must use more recent BLS data from May of 2014 in calculating the hourly wage. Therefore, CMS projected an annual ICR cost burden of between $120.87 million and $201.45 million. The former represents CMS's low-end estimate, while the latter is CMS's high-end estimate. The $161.16 million estimate represents CMS's primary, or mid-range, projection. While CMS has used a range of values to illustrate the possible burden estimates that providers may incur, it cannot submit a range of values for OMB approval. For purposes of OMB review and approval, CMS stated that it will use the mid-range estimate related to four reported and returned overpayments. CMS included a table with the revised estimated ICR burden of the regulatory provision (42 C.F.R. § 401.305).

Statutory authorization for the rule

CMS promulgated the rule under the authority of section 6402(a) of the Patient Protection and Affordable Care Act which established section 1128J(d) of the Social Security Act.

Executive Order No. 12,866 and 13,563 (Regulatory Planning and Review)

CMS states that Executive Orders 12,866 and 13,563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis must be prepared for major rules with economically significant effects ($100 million or more in any one year). The annual burden costs for reporting and returning of overpayments, are estimated between $120.87 million and $201.45 million. Since there may be years where the burden costs exceed $100 million, CMS states that it believes the rule is a major rule and economically significant. In accordance with the provisions of Executive Order 12,866, the rule was reviewed by OMB.

Executive Order No. 13,132 (Federalism)

CMS states that Executive Order 13,132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. Since this notice does not impose any costs on state or local governments, the requirements of EO 13,132 are not applicable.