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December 15, 2011

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 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 and Medicaid Programs: Hospital Outpatient Prospective Payment; Ambulatory Surgical Center Payment; Hospital Value-Based Purchasing Program; Physician Self-Referral; and Patient Notification Requirements in Provider Agreements*

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 and Medicaid Programs: Hospital Outpatient Prospective Payment; Ambulatory Surgical Center Payment; Hospital Value-Based Purchasing Program; Physician Self-Referral; and

Patient Notification Requirements in Provider Agreements" (RIN: 0938-AQ26). We received the rule on November 2, 2011. It was published in the *Federal Register* as a final rule with comment period on November 30, 2011. 76 Fed. Reg. 74,122. Comments must be received by January 3, 2012.

The final rule with comment period revises the Medicare hospital outpatient prospective payment system (OPPS) for calendar year (CY) 2012 to implement applicable statutory requirements and changes arising from CMS's continuing experience with this system. In the final rule with comment period, CMS describes the changes to the amounts and factors used to determine the payment rates for Medicare hospital outpatient services paid under the OPPS. In addition, this final rule with comment period updates the revised Medicare ambulatory surgical center (ASC) payment system to implement applicable statutory requirements and changes arising from our continuing experience with this system. In this final rule with comment period, CMS set forth the relative payment weights and payment amounts for services furnished in ASCs, specific healthcare common procedure coding system (HCPCS) codes to which these changes apply, and other rate setting information for the CY 2012 ASC payment system. CMS is revising the requirements for the Hospital Outpatient Quality Reporting (OQR) Program, adding new requirements for ASC Quality Reporting System, and making additional changes to provisions of the Hospital Inpatient Value-Based Purchasing (VBP) Program. CMS is also allowing eligible hospitals and critical access hospitals (CAH) participating in the Medicare Electronic Health Record (EHR) Incentive Program to meet the clinical quality measure reporting requirement of the EHR Incentive Program for payment year 2012 by participating in the 2012 Medicare EHR Incentive Program Electronic Reporting Pilot. Finally, CMS is making changes to the rules governing the whole hospital and rural provider exceptions to the physician self-referral prohibition for expansion of facility capacity and changes to provider agreement regulations on patient notification requirements.

The rule has an effective date of January 1, 2012. 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). We received the rule on November 2, 2011, but it was not published in the *Federal Register* until November 30, 2011. Therefore, the final rule with comment period does not have the 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.

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,
CENTERS FOR MEDICARE & MEDICAID SERVICES
ENTITLED
"MEDICARE AND MEDICAID PROGRAMS: HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT; AMBULATORY SURGICAL CENTER PAYMENT; HOSPITAL VALUE-BASED PURCHASING PROGRAM; PHYSICIAN SELF-REFERRAL; AND PATIENT NOTIFICATION REQUIREMENTS IN PROVIDER AGREEMENTS"
(RIN: 0938-AQ26)

(i) Cost-benefit analysis

CMS states that it prepared a regulatory impact analysis that, to the best of its ability, presents the costs and benefits of the final rule with comment period. In the proposed rule (76 Fed. Reg. 42,371), CMS solicited public comments on the regulatory impact analysis.

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

For purposes of the RFA, CMS estimates that most hospitals, ASCs, and community mental health centers (CMHC) are small entities as that term is used in the RFA. For purposes of the RFA, CMS believes that most hospitals are considered small businesses according to the Small Business Administration's size standards with total revenues of $34.5 million or less in any single year. According to CMS, most ASCs and most CMHCs are considered small businesses with total revenues of $10 million or less in any single year. 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. CMS states that this analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, CMS defines a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. CMS estimates that the final rule with comment period may have a significant impact on approximately 704 small rural hospitals. CMS states that the analysis above and the preamble provide a regulatory flexibility analysis and a regulatory impact analysis. CMS concluded that most classes of hospitals paid under the OPPS will experience only a modest increase or minimal decrease in payment for services furnished under the OPPS in CY 2012.

(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 the final rule with comment period does not mandate any requirements for state, local, or tribal governments, nor will it affect private sector costs.

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

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

On July 18, 2011, CMS issued a proposed rule (76 Fed. Reg. 42,170) entitled, "Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment; Ambulatory Surgical Center Payment; Hospital Value-Based Purchasing Program; Physician Self-Referral; and Provider Agreement Regulations on Patient Notification Requirements." CMS addressed the comments received in the final rule with comment period.

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

CMS states that in the CY 2012 OPPS/ASC proposed rule, the agency solicited public comments on each of the issues that contained information collection requirements.

Statutory authorization for the rule

CMS states that the final rule is authorized under sections 1102 and 1871 of the Social Security Act. 42 U.S.C. §§ 1302 and 1395hh.

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

The final rule with comment period has been designated as an "economically" significant rule under section 3(f)(1) of Executive Order 12,866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

Executive Order No. 13,132 (Federalism)

CMS examined the OPPS and ASC provisions included in this final rule with comment period in accordance with Executive Order 13,132, Federalism, and determined that they will not have a substantial direct effect on state, local, or tribal governments, preempt state law, or otherwise have a federalism implication.