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

B-327545

November 24, 2015

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: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Short Inpatient Hospital Stays; Transition for Certain Medicare-Dependent, Small Rural Hospitals Under the Hospital Inpatient Prospective Payment System; Provider Administrative Appeals and Judicial Review*

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: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Short Inpatient Hospital Stays; Transition for Certain Medicare-Dependent, Small Rural Hospitals Under the Hospital Inpatient Prospective Payment System; Provider Administrative Appeals and Judicial Review" (RINs: 0938-AS42; 0938-AS11). We received the rule on October 30, 2015. It was published in the *Federal Register* as a final rule with comment period; final rule on November 13, 2015. 80 Fed. Reg. 70,298.

The final rule with comment period revises the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for CY 2016 to implement applicable statutory requirements and changes arising from CMS's continuing experience with these systems. In the final rule with comment period, CMS

described the changes to the amounts and factors used to determine the payment rates for Medicare services paid under OPPS and those paid under the ASC payment system. In addition, the final rule with comment period updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program. Further, the final rule includes certain finalized policies relating to the hospital inpatient prospective payment system: changes to the 2-midnight rule under the short inpatient hospital stay policy, and a payment transition for hospitals that lost their status as a Medicare-dependent, small rural hospital (MDH) because they are no longer in a rural area due to the implementation of the new Office of Management and Budget (OMB) delineations in FY 2015 and have not reclassified from urban to rural before January 1, 2016. In addition, the final rule finalizes certain 2015 proposals and addresses public comments received relating to the changes in the Medicare regulations governing provider administrative appeals and judicial review relating to appropriate claims in provider cost reports.

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). The final rule has a stated effective date of January 1, 2016. The rule was received on October 30, 2015, and was published in the *Federal Register* on November 13, 2015. Therefore, the final rule does not have the required 60-day delay in its effective date. The 60-day delay in effective date can be waived, however, if the agency finds for good cause that delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the findings and its reasons in the rule issued. 5 U.S.C. §§ 553(d)(3), 808(2). CMS determined that the revisions were simply technical corrections that brought § 405.1835 of the Provider Reimbursement Review Board (Board) appeals regulations into full conformity with section 1878(a)(1)(B) of the Act, and maintained consistency between § 405.1811 of the contractor hearing officer appeals regulations and § 405.1835 of the Board appeals regulations. CMS stated that the revisions did not represent changes in policy, nor did they have a substantive effect, and the public interest was best served by timely correction of these technical errors.

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
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: HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEMS AND QUALITY REPORTING PROGRAMS; SHORT INPATIENT HOSPITAL STAYS; TRANSITION FOR CERTAIN MEDICARE-DEPENDENT, SMALL RURAL HOSPITALS UNDER THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEM; PROVIDER ADMINISTRATIVE APPEALS AND JUDICIAL REVIEW"
(RINs: 0938-AS42; 0938-AS11)

(i) Cost-benefit analysis

The Centers for Medicare & Medicaid Services (CMS) analyzed the economic effects of various provisions of this final rule with comment period. CMS estimated that the update to the conversion factor and other adjustments (not including the effects of outlier payments, the pass-through estimates, and the application of the frontier state wage adjustment for calendar year (CY) 2016) will decrease total outpatient prospective payment system (OPPS) payments by 0.3 percent in CY 2016. The changes to the ambulatory payment classification (APC) weights, the changes to the wage indexes, the continuation of a payment adjustment for rural sole community hospitals (SCHs), including essential access community hospitals (EACHs), and the payment adjustment for cancer hospitals will not increase OPPS payments because these changes to the OPPS are budget neutral. However, these updates will change the distribution of payments within the budget neutral system. CMS estimated that the total change in payments between CY 2015 and CY 2016, considering all payments, including the adjustment to the conversion factor to address the inflation in OPPS payment rates resulting from excess packaged payment under the OPPS for laboratory tests, changes in estimated total outlier payments, pass-through payments, and the application of the frontier state wage adjustment outside of budget neutrality, in addition to the application of the hospital outpatient department (OPD) fee schedule increase factor after all adjustments required by statute, will decrease total estimated OPPS payments by 0.4 percent. CMS estimated the total increase (from changes to the ASC provisions in this final rule with comment period as well as from enrollment, utilization, and case-mix changes) in Medicare expenditures under the ASC payment system for CY 2016 compared to CY 2015 to be approximately $128 million.

In the accounting statement accompanying this final rule with comment period, CMS estimated that the CY 2016 hospital OPD fee schedule increase in this rule will result in annualized monetized transfers of $133 million from the federal government to outpatient hospitals and other providers receiving payment under hospital OPPS. CMS also estimates that the CY 2016 update to the ASC payment system will result in annualized monetized transfers of $10 million from the federal government to Medicare providers and suppliers.

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

CMS estimated that most hospitals, ASCs, and community mental health centers (CMHCs) are small entities as that term is used in the RFA. For purposes of RFA, most hospitals are

considered small businesses according to the Small Business Administration's size standards with total revenues of $38.5 million or less in any single year or by the hospital's not-for-profit status. Most ASCs and most CMHCs are considered small businesses with total revenues of $15 million or less in any single year. CMS estimates that this final rule with comment period may have a significant impact on approximately 649 small rural hospitals. CMS included a table in the rule summarizing the estimated impact of the CY 2016 changes for the hospital outpatient prospective payment systems. CMS stated that the preamble of this final rule with comment period constitutes its Regulatory Flexibility Analysis and its Regulatory Impact Analysis under the Act.

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

CMS determined that this final rule with comment period does not mandate any requirements for state, local, or tribal governments, or for 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 November 10, 2014, CMS published a final rule with comment period on the CY 2015 OPPS and ASC programs which included the interim APC assignments and status indicators of new or replacement Healthcare Common Procedure Coding System codes. 79 Fed. Reg. 66,770. On February 24, 2015, CMS published a correction notice. 80 Fed. Reg. 9,629. On July 8, 2015, CMS published a proposed rule on the CY 2015 OPPS and ASC programs. 80 Fed. Reg. 39,200. CMS received approximately 38 comments and 670 comments on these items, respectively.

CMS also found good cause to waive notice and comment rulemaking requirements under section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)) for these revisions because CMS states that the revisions were simply technical corrections that brought § 405.1835 of the Board appeals regulations into full conformity with section 1878(a)(1)(B) of the Act, and maintained consistency between § 405.1811 of the contractor hearing officer appeals regulations and § 405.1835 of the Board appeals regulations. CMS states that the revisions did not represent changes in policy, nor did they have a substantive effect, and the public interest was best served by timely correction of these technical errors. Comments on the final rule will be accepted through December 29, 2015.

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

CMS determined that the final rule with comment period will not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, CMS stated, there was no need for review by the Office of Management and Budget under the authority of PRA.

Statutory authorization for the rule

CMS promulgated this final rule with comment period under the authority of sections 205, 1102, 1812(d), 1814(b), 1815, 1815(a), 1833, 1833(a), (i), (n), 1833(t), 1834, 1861(v), 1871, 1872, 1878, 1881, 1883, 1886, and 1893 of the Social Security Act. 42 U.S.C. §§ 405, 1302,

1395d(d), 1395f(b), 1395g, 1395g(a), 1395l, 1395l(a), (i), (n), 1395l(t), 1395m, 1395x(v), 1395hh, 1395ii, 1395oo, 1395rr, 1395tt, 1395ww, and 1395ddd.

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

CMS determined that the final rule with comment period is economically significant under the Order and is a major rule. Therefore, it has been reviewed by the Office of Management and Budget.

Executive Order No. 13,132 (Federalism)

CMS determined that this final rule with comment period will not have a substantial direct effect on state, local, or tribal governments, preempt state law, or otherwise have a federalism implication.