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November 24, 2014

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

The Honorable Fred Upton
Chairman
The Honorable Henry 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 and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Physician-Owned Hospitals: Data Sources for Expansion Exception; Physician Certification of Inpatient Hospital Services; Medicare Advantage Organizations and Part D Sponsors: CMS-Identified Overpayments Associated with Submitted Payment Data*

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 and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Physician-Owned Hospitals: Data Sources for Expansion Exception; Physician Certification of Inpatient Hospital Services; Medicare Advantage Organizations and Part D Sponsors: CMS-Identified Overpayments Associated with Submitted Payment Data" (RIN: 0938-AS15). We received the rule on October 31, 2014. It was published in the *Federal Register* as a final rule with comment period on November 10, 2014. 79 Fed. Reg. 66,770.

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 calendar year (CY) 2015 to implement applicable statutory requirements and changes

arising from CMS's continuing experience with these systems. In this rule, CMS describes the changes to the amounts and factors used to determine the payment rates for Medicare services paid under OPPTS and those paid under the ASC payment system. In addition, it updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program. Further, this rule makes changes to the data sources permitted for expansion requests for physician-owned hospitals under the physician self-referral regulations; changes to the underlying authority for the requirement of an admission order for all hospital inpatient admissions and changes to require physician certification for hospital inpatient admissions only for long-stay cases and outlier cases; and changes to establish a formal process, including a three-level appeals process, to recoup overpayments that result from the submission of erroneous payment data by Medicare Advantage (MA) organizations and Part D sponsors in the limited circumstances in which the organization or sponsor fails to correct these data.

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 time of January 1, 2015. The rule was received on October 31, 2014, and was published in the *Federal Register* on November 10, 2014. 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 because of the timing of the release of the new Healthcare Common Procedure Coding System (HCPCS) codes in this rule, it was impractical for CMS to provide prior notice and solicit comment on these codes and the payments assigned to them in advance of publication of the final rule that implements OPPTS and the ASC payment system. CMS believes it would have been contrary to the public interest to delay establishment of payment amounts for these codes. Therefore, CMS found good cause to waive the notice of proposed rulemaking for the establishment of payment amounts for certain HCPCS codes.

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: Annie Lamb
Regulations Coordinator
Department of Health and Human Services

REPORT UNDER 5 U.S.C. § 801(a)(2)(A) ON A MAJOR RULE
ISSUED BY THEDEPARTMENT OF HEALTH AND HUMAN SERVICES,
CENTERS FOR MEDICARE & MEDICAID SERVICES
ENTITLED

"MEDICARE AND MEDICAID PROGRAMS; HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEMS AND QUALITY REPORTING PROGRAMS; PHYSICIAN-OWNED HOSPITALS: DATA SOURCES FOR EXPANSION EXCEPTION; PHYSICIAN CERTIFICATION OF INPATIENT HOSPITAL SERVICES; MEDICARE ADVANTAGE ORGANIZATIONS AND PART D SPONSORS: CMS-IDENTIFIED OVERPAYMENTS ASSOCIATED WITH SUBMITTED PAYMENT DATA"
(RIN: 0938-AS15)

(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 estimates 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) 2015) will increase total Outpatient Prospective Payment System (OPPS) payments by 2.2 percent in CY 2015. 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, including essential access community hospitals; and the payment adjustment for cancer hospitals will not increase OPPS payments because these changes to OPPS are budget neutral. However, these updates will change the distribution of payments within the budget neutral system. CMS estimates that the total change in payments between CY 2014 and CY 2015, considering all payments, including 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 increase total estimated OPPS payments by 2.3 percent. CMS estimates 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 2015 compared to CY 2014 to be approximately \$236 million.

In the accounting statement accompanying this final rule with comment period, CMS estimates that the CY 2015 hospital OPD fee schedule increase in this rule will result in annualized monetized transfers of \$900 million from the federal government to outpatient hospitals and other providers receiving payment under hospital OPPS. CMS also estimates that the CY 2015 update to the ASC payment system will result in annualized monetized transfers of \$42 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 estimates that this final rule with comment period may have a significant impact on approximately 2,006 hospitals with voluntary ownership and approximately 709 small rural

hospitals. 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 December 10, 2013, CMS published a final rule on the CY 2014 OPps and ASC programs, which included the interim APC assignments and status indicators of new or replacement HCPCS codes. 78 Fed. Reg. 74,826. On July 14, 2014, CMS published a proposed rule on the CY 2015 OPps and ASC programs. 79 Fed. Reg. 40,915. CMS received 490 comments and 719 comments on these items, respectively.

CMS also found good cause to waive the notice of proposed rulemaking for the establishment of payment amounts for selected HCPCS codes. CMS determined that it was impracticable for it to provide prior notice and solicit comment on these codes and the payments assigned to them in advance of publication of the final rule that implements OPps and the ASC payment system. However, CMS also determined that it was imperative that these coding changes be timely accounted for and recognized under OPps and ASC payment system because services represented by these codes will be provided to Medicare beneficiaries in hospital outpatient departments and ASCs during the calendar year in which they become effective. If CMS did not assign payment amounts to new codes on an interim basis, it concluded that it would not be able to pay for these services during the initial calendar year in which the codes become effective. For these reasons, CMS believes it would be contrary to the public interest to delay establishment of payment amounts for these codes.

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

CMS determined that this final rule with comment period contains information collection requirements under the Act. CMS estimated the financial burden of these requirements for the CY 2017 payment determination and subsequent years, including, among other provisions, (1) \$4.2 million for all hospitals for requirements associated with the Hospital Outpatient Quality Reporting (OQR), (2) approximately \$96.9 million for chart-abstracted measures, (3) \$3,208,203 for the National Healthcare Safety Network healthcare-associated infection measure, (4) \$119,070 for web-based submission of these measures, and (5) \$180,000 for OQR program validation. CMS also estimated that changes to three measures will result in a reduction in financial burden of \$23.8 million for the CY 2016 payment determination from CMS's original estimate of \$76.8 million.

Statutory authorization for the rule

CMS promulgated this final rule with comment period under the authority of sections 1102, 1860D-1 through 1860D-42, 1871, and 1877 of the Social Security Act. 42 U.S.C. §§ 1302, 1395w-101 through 1395w-152, 1395hh, and 1395nn.

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

CMS determined that this final rule with comment period is economically significant under the Order and therefore 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.