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September 5, 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 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 Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2015 Rates; Quality Reporting Requirements for Specific Providers; Reasonable Compensation Equivalents for Physician Services in Excluded Hospitals and Certain Teaching Hospitals; Provider Administrative Appeals and Judicial Review; Enforcement Provisions for Organ Transplant Centers; and Electronic Health Record (EHR) Incentive Program*

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 Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2015 Rates; Quality Reporting Requirements for Specific Providers; Reasonable Compensation Equivalents for Physician Services in Excluded Hospitals and Certain Teaching Hospitals; Provider Administrative Appeals and Judicial Review; Enforcement Provisions for Organ Transplant Centers; and Electronic Health Record (EHR) Incentive Program" (RINs: 0938-AS11; 0938-AR12; 0938-AR53). We received the rule on August 4, 2014. It was published in the *Federal Register* as a final rule on August 22, 2014. 79 Fed. Reg. 49,854.

The final rule revises the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals to implement changes arising from CMS's continuing experience with these systems. Some of these changes implement certain statutory provisions contained in the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 (collectively known as the Affordable Care Act), the Protecting Access to Medicare Act of 2014, and other legislation. This rule also updates the rate-of-increase limits for certain hospitals excluded from the IPPS that are paid on a reasonable cost basis subject to these limits. In addition, this rule updates the payment policies and the annual payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs) and implementing certain statutory changes to the LTCH PPS under the Affordable Care Act and the Pathway for Sustainable Growth Rate Reform Act of 2013 and the Protecting Access to Medicare Act of 2014. With this rule, CMS is making a number of changes relating to direct graduate medical education (GME) and indirect medical education (IME) payments. Specifically, this rule establishes new requirements or revises requirements for quality reporting by specific providers (acute care hospitals, PPS-exempt cancer hospitals, and LTCHs) that are participating in Medicare.

The final rule updates policies relating to the Hospital Value-Based Purchasing Program, the Hospital Readmissions Reduction Program, and the Hospital-Acquired Condition Reduction Program. In addition, the rule makes technical corrections to the regulations governing provider administrative appeals and judicial review; updates the reasonable compensation equivalent limits, and revising the methodology for determining such limits, for services furnished by physicians to certain teaching hospitals and hospitals excluded from the IPPS; makes regulatory revisions to broaden the specified uses of Medicare Advantage risk adjustment data and to specify the conditions for release of such risk adjustment data to entities outside of CMS; and makes changes to the enforcement procedures for organ transplant centers. Further, this rule aligns the reporting and submission timelines for clinical quality measures for the Medicare EHR Incentive Program for eligible hospitals and critical access hospitals (CAHs) with the reporting and submission timelines for the Hospital Inpatient Quality Reporting Program. In addition, with this rule CMS is providing guidance and clarification of certain policies for eligible hospitals and CAHs such as CMS's policy for reporting zero denominators on clinical quality measures and CMS's policy for case threshold exemptions. Finally, this rule finalizes two interim final rules with comment period relating to criteria for disproportionate share hospital uncompensated care payments and extensions of temporary changes to the payment adjustment for low-volume hospitals and of the Medicare-Dependent, Small Rural Hospital (MDH) Program.

The Congressional Review Act 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. U.S.C. 801(a)(3)(A). This final rule has a stated effective date of October 1, 2014. Under the rule's stated applicability dates, certain provisions of the rule are applicable to appeals based on untimely contractor determinations that are pending or were filed on or after August 21, 2008. Certain other provisions of this rule have a stated applicability date of January 1, 2015, and other provisions have a stated applicability date of July 1, 2015. The rule was received on August 4, 2014, and published in the *Federal Register* on August 22, 2014. Therefore, to the extent the rule purports to be effective prior to October 21, 2014, this final rule does not have the required 60-day delay in effective date.

The 60-day delay in effective date can be waived, however, if the agency finds for good cause that notice and public procedures thereon are 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). For two provisions of this final rule CMS found such good cause. For the provisions of the rule concerning technical changes to section 405.1835 of title 42, *Code of Federal Regulations*, and corresponding amendments to section 405.1811 of the same title, CMS found it unnecessary to undertake notice-and-comment rulemaking because these revisions are simply technical corrections that bring section 405.1835 into conformity statute, and maintain consistency between section 405.1811 and section 405.1835. According to CMS, the revisions do not represent changes in policy, nor do they have a substantive effect, and the public interest would be best served by timely correction of these technical errors. Therefore, CMS found good cause to waive notice and comment procedures in that instance.

Second, CMS found the timeframes were extremely compressed and processing issues were complicated for developing the provisions of this rule concerning the Hospital IPPS for Acute Care Hospitals and the LTCH PPS. These provisions concern the fiscal year payment system. CMS found it would be contrary to the public interest to delay the effective date of the payment system portions of this rule and specified that those portions of the rule will be effective October 1, 2014. Therefore, the 60-day delay requirement does not apply to these provisions of the final rule for which CMS found good cause to waive the requirement.

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
Department of Health and Human Services

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 INPATIENT PROSPECTIVE PAYMENT SYSTEMS
FOR ACUTE CARE HOSPITALS AND THE LONG-TERM CARE HOSPITAL
PROSPECTIVE PAYMENT SYSTEM AND FISCAL YEAR 2015 RATES; QUALITY
REPORTING REQUIREMENTS FOR SPECIFIC PROVIDERS; REASONABLE
COMPENSATION EQUIVALENTS FOR PHYSICIAN SERVICES IN EXCLUDED HOSPITALS
AND CERTAIN TEACHING HOSPITALS; PROVIDER ADMINISTRATIVE APPEALS AND
JUDICIAL REVIEW; ENFORCEMENT PROVISIONS FOR ORGAN TRANSPLANT CENTERS;
AND ELECTRONIC HEALTH RECORD (EHR) INCENTIVE PROGRAM"
(RINs: 0938-AS11; 0938-AR12; 0938-AR53)

(i) Cost-benefit analysis

The Centers for Medicare & Medicaid Services (CMS) estimates that the provisions of this final rule concerning acute care hospitals will result in annualized monetary transfers of \$756 million from inpatient prospective payment system (IPPS) Medicare providers to the federal government; i.e., they will save the federal government an estimated \$756 million. CMS estimates that the provisions of this final rule concerning long-term care hospitals (LTCHs) will result in annualized monetary transfers from the federal government to LTCH Medicare providers of \$178 million; i.e., they will cost the federal government an estimated \$178 million. CMS also estimates that the costs to LTCHs associated with the data for the LTCH Quality Reporting Program at \$4.7 million.

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

For purposes of the Act, CMS considers all hospitals and other providers and suppliers to be small entities. CMS included in the final rule a regulatory impact analysis which discussed the need for the final rule, the objectives of the IPPS, the limitation of its analysis, hospitals included and excluded from the IPPS, quantitative effect of the policy changes under the IPPS for operating costs, effect of other policy changes, and alternatives considered, among other topics.

(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 will 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 May 5, 2014, CMS published a proposed rule on changes to the Medicare IPPS for operating costs and for capital-related costs of acute care hospitals for fiscal year 2015.

79 Fed. Reg. 27,978. The proposed rule also set forth proposed changes relating to payments for IME and GME costs and payments to certain hospitals that continue to be excluded from the IPPS and paid on a reasonable cost basis. In addition, in the proposed rule, CMS set forth proposed changes to the payment rates, factors, and other payment rate policies under the LTCH PPS for FY 2015. CMS received approximately 653 timely pieces of correspondence containing multiple comments on the May 5, 2014, proposed rule. CMS responded to the in-scope comments in the final rule.

However, for the provisions concerning the Hospital IPPS for Acute Care Hospitals and the LTCH PPS, CMS found good cause to waive the 30-day delay in effective date under the Act. CMS found the timeframes for developing annual rules are extremely compressed and the processing issues complicated. Further, these provisions concern the fiscal year payment system. CMS found it would be contrary to the public interest to delay the effective date of the payment system portions of this rule and specified that those portions of the rule will be effective October 1, 2014.

Additionally, for the provisions of the rule concerning technical changes to section 405.1835 of title 42, *Code of Federal Regulations*, and corresponding amendments to section 405.1811 of the same title, CMS found it unnecessary to undertake notice-and-comment rulemaking because these revisions are simply technical corrections that bring section 405.1835 into conformity statute, and maintain consistency between section 405.1811 and section 405.1835. According to CMS, the revisions do not represent changes in policy, nor do they have a substantive effect, and the public interest would be best served by timely correction of these technical errors. Therefore, CMS found good cause to waive notice and comment procedures.

CMS also published two interim final rules with comment period on October 13, 2013, and March 18, 2014. 78 Fed. Reg. 61,191; 79 Fed. Reg. 15,022. CMS received 12 timely pieces of correspondence and 4 timely pieces of correspondence on the interim final rules, respectively. CMS responded to the comments and finalized the interim rules in this final rule.

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

CMS determined that this final rule contains information collection requirements under the Act. CMS discussed information collection requirements under the Act in connection to 10 regulatory provisions. In all 10 cases, CMS concluded that the information collection requirement was already approved under an existing Office of Management and Budget (OMB) control number, imposed no new burden or reduced an existing burden, exempt from review under the Act, or contained in the updated information request portion of the final rule.

Statutory authorization for the rule

CMS promulgated this final rule under the authority of sections 1814, 1820, 1834, 1866, and 1886 of the Social Security Act. 42 U.S.C. §§ 1395f, 1395i-4, 1395m, 1395cc, 1395ww.

Executive Order Nos. 12,866 and 13,563 (Regulatory Planning and Review)

CMS estimates that the changes for fiscal year 2015 acute care hospital operating and capital payments will redistribute amounts in excess of \$100 million to acute care hospitals. In accordance with the Order, OMB reviewed this final rule.