U.S. GOVERNMENT ACCOUNTABILITY OFFICE

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Washington, DC 20548

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September 3, 2013

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 Waxman
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Dave Camp
Chairman
The Honorable Sander 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 2014 Rates; Quality Reporting Requirements for Specific Providers; Hospital Conditions of Participation; Payment Policies Related to Patient Status*

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 2014 Rates; Quality Reporting Requirements for Specific Providers; Hospital Conditions of Participation; Payment Policies Related to Patient Status" (RINs: 0938-AR53; 0938-AR73). We received the rule on August 2, 2013. It was published in the *Federal Register* as a final rule on August 19, 2013. 78 Fed. Reg. 50,496.

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 the 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) and other legislation. These changes will be applicable to discharges occurring on or after

October 1, 2013, unless otherwise specified in the final rule. CMS is also updating the rate-of-increase limits for certain hospitals excluded from the IPPS that are paid on a reasonable cost basis subject to these limits. The updated rate-of-increase limits will be effective for cost reporting periods beginning on or after October 1, 2013. CMS is also updating 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 that were applied to the LTCH PPS by the Affordable Care Act. Generally, these updates and statutory changes will be applicable to discharges occurring on or after October 1, 2013, unless otherwise specified in this final rule. In addition, CMS is making a number of changes relating to direct graduate medical education (GME) and indirect medical education (IME) payments. CMS is establishing new requirements or has revised requirements for quality reporting by specific providers (acute care hospitals, PPS-exempt cancer hospitals, LTCHs, and inpatient psychiatric facilities (IPFs)) that are participating in Medicare. CMS is updating policies relating to the Hospital Value-Based Purchasing (VBP) Program and the Hospital Readmissions Reduction Program. In addition, CMS is revising the conditions of participation (CoPs) for hospitals relating to the administration of vaccines by nursing staff as well as the CoPs for critical access hospitals relating to the provision of acute care inpatient services. Additionally, CMS is finalizing proposals issued in two separate proposed rules that included payment policies related to patient status: payment of Medicare Part B inpatient services and admission and medical review criteria for payment of hospital inpatient services under Medicare Part A.

The final rule has an effective date of October 1, 2013. 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 August 2, 2013, but it was not published in the *Federal Register* until August 19, 2013. Therefore, the final rule 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, with the exception of the 60-day delay in effective date requirement.

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 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 2014 RATES; QUALITY REPORTING REQUIREMENTS FOR SPECIFIC PROVIDERS; HOSPITAL CONDITIONS OF PARTICIPATION; PAYMENT POLICIES RELATED TO PATIENT STATUS"
(RINs: 0938-AR53; 0938-AR73)

(i) Cost-benefit analysis

CMS included an economic analysis, which included a regulatory impact analysis of the final rule. CMS estimates that the changes for FY 2014 acute care hospital operating and capital payments will redistribute amounts in excess of $100 million to acute care hospitals. According to CMS, the applicable percentage increase to the IPPS rates required by the statute, in conjunction with other payment changes in the final rule, will result in an estimated $498 million increase in FY 2014 operating payments (or 0.5 percent change) and an estimated $134 million increase in FY 2014 capital payments (or 1.6 percent change). CMS notes that these changes are relative to payments made in FY 2013. CMS also included the impact analysis of the capital payments in the final rule. In addition, CMS states that LTCHs are expected to experience an increase in payments by $72 million in FY 2014 relative to FY 2013.

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

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, CMS states that small entities include small businesses, nonprofit organizations, and small government jurisdictions. CMS estimates that most hospitals and most other providers and suppliers are small entities as that term is used in the RFA. CMS notes that the great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the Small Business Administration's definition of a small business (having revenues of less than $7.5 million to $34.5 million in any 1 year). Additionally, for purposes of the RFA, CMS explains that all hospitals and other providers and suppliers are considered to be small entities, but individuals and states are not included in the definition of a small entity. CMS believes that the provisions of this final rule relating to acute care hospitals would have a significant impact on small entities. Because CMS lacks data on individual hospital receipts, it cannot determine the number of small proprietary LTCHs. Therefore, CMS is assuming that all LTCHs are considered small entities for purposes of its analysis. CMS states that Medicare fiscal intermediaries and Medicare Administrative Contractors are not considered to be small entities. Because CMS acknowledges that many of the affected entities are small entities, the analysis discussed in the final rule constitutes its regulatory flexibility analysis. In the FY 2014 IPPS/LTCH PPS proposed rule, CMS solicited public comments on its estimates and analysis of the impact of its proposals

on those small entities. Any public comments that CMS received and its responses are presented in the final rule.

(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 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 10, 2013, CMS published a proposed rule in the *Federal Register* entitled, "Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Fiscal Year 2014 Rates; Quality Reporting Requirements for Specific Providers; Hospital Conditions of Participation." 78 Fed. Reg. 27,486. CMS received approximately 721 timely pieces of correspondence containing multiple comments on the FY 2014 IPPS/LTCH PPS proposed rule. CMS notes that some public comments were outside of the scope of the proposed rule and are not addressed with policy responses in the final rule. CMS states that summaries of the public comments that are within the scope of the proposed rule and its responses to those public comments are set forth in the various sections of the final rule under the appropriate heading.

Additionally, on March 18, 2013, CMS issued a proposed rule entitled, "Medicare Program; Part B Inpatient Billing in Hospitals." 78 Fed. Reg. 16,632. CMS received 392 timely pieces of correspondence in response to this proposed rule. CMS states that it summarized and responded to these public comments and discussed its final policies after taking into consideration the public comments received.

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

All LTCHs will be required to collect data using the LTCH CARE Data Set (Version 2.01). The LTCH CARE Data Set was approved on June 10, 2013, by the Office of Management and Budget in accordance with the PRA; the OMB Control Number is 0938-1163.

With regard to the proposed payment of Medicare Part B inpatient services, CMS states that the medical recordkeeping requirement associated with the services billed on Part B inpatient claims during the inpatient stay is exempt from the PRA in accordance with 5 C.F.R. § 1320.3(b)(2). According to CMS, the same holds for recordkeeping associated with the services billed on a Part B outpatient claim for services provided in the 3-day payment window prior to the inpatient admission. CMS solicited public comment on each of these issues for applicable sections of the Part B Inpatient Billing proposed rule that contained information collection requirements (ICRs). CMS believes that the time, effort, and financial resources necessary to comply with the medical recordkeeping requirements would be incurred by persons in the normal course of their activities and, therefore, considered to be usual and customary business practices. With regard to the appeals of proposed payment of Medicare Part B inpatient services, CMS states that the appeals information collection activity is exempt from the requirements of the PRA because it is associated with an administrative action (5 C.F.R. §§ 1320.4(a)(2) and (c)).

CMS notes that it did not receive any public comments on these medical recordkeeping requirements or appeals information collection activity. Additionally, CMS states that the finalized aforementioned provisions do not impose any new or revised reporting or recordkeeping requirements and would not impose any new or revised burden estimates.

Statutory authorization for the rule

CMS states that it is making changes to the Medicare IPPS, to the LTCH PPS, and to other related payment methodologies and programs for FY 2014 and subsequent fiscal years under various statutory authorities. Those authorities include, but are not limited to sections 1814(l); 1820; 1834(g); 1886(a)(4); 1886(b)(3)(B)(viii); 1886(d); 1886(g); 1866(k); 1886(o); and 1886(r) of the Social Security Act (the Act); sections 1886(p) as added by section 3008 of the Affordable Care Act; 1886(q) as added by section 3025 and amended by section 10309 of the Affordable Care Act; 1886(s)(4) as added by section 3401(f) and amended by 10322(a) of the Affordable Care Act; sections 123(a) and (c) of Public Law 106-113; and section 307(b)(1) of Public Law 106-554 (as codified under section 1886(m)(1) of the Act, as added by section 3005 of the Affordable Care).

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

CMS's final rule policy on Part B inpatient payment has been designated as an "economically" significant rule, and accordingly, the final rule policy has been reviewed by the Office of Management and Budget. CMS has prepared a regulatory impact analysis that, to the best of its ability, presents the costs and benefits of its final policy.

Executive Order No. 13,132 (Federalism)

CMS has examined the provisions of the final rule policy and determined that it will not have a substantial direct effect on state, local, or tribal governments, preempt state law, or otherwise have a federalism implication, with the exception of Medicaid expenditures, which will increase for services furnished in governmental hospitals (including state and local governmental hospitals).