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United States Government Accountability Office
Washington, DC 20548

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December 12, 2007

The Honorable Max Baucus
Chairman
The Honorable Charles E. Grassley
Ranking Minority Member
Committee on Finance
United States Senate

The Honorable John D. Dingell
Chairman
The Honorable Joe Barton
Ranking Minority Member
Committee on Energy and Commerce
House of Representatives

The Honorable Charles Rangel
Chairman
The Honorable Jim McCrery
Ranking Minority Member
Committee on Ways and Means
House of Representatives

Subject: *Department of Health and Human Services, Centers for Medicare and Medicaid Services: Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates, the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates, the Hospital Inpatient Prospective Payment System and FY 2008 Payment Rates; and Payments for Graduate Medical Education for Affiliated Teaching Hospitals in Certain Emergency Situations Medicare and Medicaid Programs: Hospital Conditions of Participation; Necessary Provider Designations of Critical Access Hospitals*

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 and Medicaid Services (CMS), entitled “Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates, the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates, the Hospital Inpatient Prospective Payment System and FY 2008 Payment Rates; and Payments for Graduate Medical Education for Affiliated Teaching Hospitals in

Certain Emergency Situations Medicare and Medicaid Programs: Hospital Conditions of Participation; Necessary Provider Designations of Critical Access Hospitals” (RIN: 0938-AO71; RIN: 0938-AO70; RIN: 0938-AO35). We received the rule on November 1, 2007. It was published in the *Federal Register* as a final rule on November 27, 2007. 72 Fed. Reg. 66,580.

The final rule with comment period revises the Medicare hospital outpatient prospective payment system to implement applicable statutory requirements and changes arising from CMS’s continuing experience with the system, including changes to the amounts and factors used to determine Medicare’s payments. The final rule with comment period sets forth the applicable relative payment weights and amounts for services furnished in Ambulatory Surgical Centers (ASCs) and other pertinent rate setting information for the 2008 ASC payment system. The final rule also includes changes made to the 2008 hospital inpatient provider payment system final rule as required by the enactment of the TMA, Abstinence Education, and QI Programs Extension Act of 2007. Pub.L. No. 110-90, 121 Stat. 984. Finally, CMS has included an interim final rule with comment period modifying the regulations relating to graduate medical education payments made to teaching hospitals that have Medicare affiliation agreements for certain emergency situations.

The final rule has an announced effective date of January 1, 2008. 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. 5 U.S.C. 801(a)(3)(A). The rule was received by Congress on November 2, 2007, and by our Office on November 1, 2007, but was not published in the *Federal Register* until November 27, 2007. Therefore, the final rule does not have the required 60-day delay in its effective date.

Enclosed is our assessment of the 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 indicates that, with the exception of the delay in the rule’s effective date, CMS complied with the applicable requirements.

If you have any questions about this report, please contact Michael R. Volpe, Assistant General Counsel, at (202) 512-8236. The official responsible for GAO evaluation work relating to the subject matter of the rule is Marjorie Kanof, Managing Director, Health Care. Ms. Kanof can be reached at (202) 512-7114.

signed

Robert J. Cramer
Associate General Counsel

Enclosure

cc: Ann Stallion
Program Manager
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 AND MEDICAID SERVICES
ENTITLED

"MEDICARE PROGRAM: CHANGES TO THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM AND CY 2008 PAYMENT RATES, THE AMBULATORY SURGICAL CENTER PAYMENT SYSTEM AND CY 2008 PAYMENT RATES, THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEM AND FY 2008 PAYMENT RATES; AND PAYMENTS FOR GRADUATE MEDICAL EDUCATION FOR AFFILIATED TEACHING HOSPITALS IN CERTAIN EMERGENCY SITUATIONS MEDICARE AND MEDICAID PROGRAMS: HOSPITAL CONDITIONS OF PARTICIPATION; NECESSARY PROVIDER DESIGNATIONS OF CRITICAL ACCESS HOSPITALS"
(RIN: 0938-AO71; RIN: 0938-AO70; RIN: 0938-AO35)

(i) Cost-benefit analysis

CMS estimates that the changes made by the final rule changing the outpatient prospective payment system (OPPS) payment rates will increase Medicare expenditures for calendar year 2008 over the expenditures for calendar year 2007 by \$3.4 billion. The changes made to the Ambulatory Surgical Center (ASC) payment system are expected to have no net effect on Medicare expenditures in calendar year 2008.

CMS estimates that the changes in inpatient prospective payment system (IPPS) payment rates will increase Medicare payments to IPPS providers for calendar year 2008 over the expenditures for calendar year 2007 by \$4.635 billion.

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

CMS has prepared a Final Regulatory Flexibility Analysis of the impact of the final rule regarding changes to the ASC payment system and the OPPS payment rates on hospitals considered to be small entities and also on small rural hospitals. It found that almost all classes of hospitals will experience positive updates in OPPS payments in calendar year 2008, and that the impact on ASC's will vary depending on the patient mix and procedures offered by the individual ASC.

CMS found that the changes to the IPPS payment rates did not require a regulatory flexibility analysis because CMS had waived notice-and-comment rulemaking for those provisions.

CMS found that the changes to the graduate medical education (GME) regulations impacting emergency Medicare GME affiliated groups would not have a significant impact on affected hospitals nor would it affect a substantial number of small entities.

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

CMS has determined that none of the rules will have an effect on state, local, or tribal governments or on the private sector of more than the \$120 million threshold.

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

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

On August 2, 2007, CMS published in the *Federal Register* a proposed rule for the calendar year 2008 OPPI/ASC to implement statutory requirements and changes arising from continuing experience with both systems. 72 Fed. Reg. 42,628. CMS received approximately 2,180 comments and responded to those comments in the final rule.

CMS waived notice-and-comment rulemaking and the 30-day delay with respect to the adjusted IPPS payment factors, rates, and thresholds, because the corrections to the factors were required by section 7 of Public Law 110-90 and delay would be contrary to the public interest. CMS also waived notice-and-comment rulemaking and the 30-day delay for substantive changes made to the FY 2008 IPPS final rule. CMS made the changes retroactive to October 1, 2007, because the final rule was not consistent with the plain meaning of the Social Security Act, and it would be contrary to the public interest for CMS policy not to be consistent with the plain meaning of the statute.

CMS waived notice-and-comment rulemaking and the 30-day delay with respect to Medicare GME affiliation agreement provisions and made the provisions effective retroactively to August 29, 2005. The provisions respond to the needs of hospitals and GME programs affected by Hurricanes Katrina and Rita, and therefore a delay would be contrary to the public interest.

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

The final rule with comment period and the interim final rule with comment period contain collections of information subject to review by the Office of Management and Budget (OMB) under the Act. CMS has submitted the required information to OMB for its review, and the collection requirements will not take effect until approved by OMB. CMS expects the total burden for all hospitals for the CY 2009

updates to be 921,000 hours per year. Other proposed requirements involve collections subject to the Act; however, CMS states that the burdens are exempt as defined in 5 C.F.R. 1320.3(b)(2) because persons would incur the time, effort, and financial resources necessary to comply with the requirement in the normal course of their activities.

Statutory authorization for the rule

The final rule with comment period revising the Medicare hospital OPPS and the ASC payment system is issued under the authority of sections 1832 and 1833 of the Social Security Act.

The final rule making changes to IPPS payment rates is issued under the authority of section 7 of the TMA, Abstinence Education, and QI Programs Extension Act of 2007, Public Law 110-90, September 29, 2007, 121 Stat. 984.

The interim final rule with comment period relating to GME payments made to teaching hospitals that have Medicare affiliation agreements for certain emergency situations is issued under the authority of sections 1135 and 1886 of the Social Security Act.

Executive Order No. 12,866

The rule was reviewed by the Office of Management and Budget under the order. The final rule with comment period relating to changes to the OPPS and ASC payment system was found to be an economically significant rule under the order, as was the final rule relating to changes to the IPPS. The interim rule with comment period relating to the Medicare GME affiliation provisions for teaching hospitals in certain emergency situations was determined not to be a major rule under the order because the costs to the Medicare program under the provisions would be negligible.

Executive Order No. 13,132 (Federalism)

CMS has determined that the rules do not have federalism implications as defined in Executive Order No. 13,132.