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September 1, 2006

The Honorable Michael B. Enzi
Chairman
The Honorable Edward M. Kennedy
Ranking Minority Member
Committee on Health, Education, Labor, and Pensions
United States Senate

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

The Honorable William M. Thomas
Chairman
The Honorable Charles B. Rangel
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 Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Fiscal Year 2007 Occupational Mix Adjustment to Wage Index; Health Care Infrastructure Improvement Program; Selection Criteria of Loan Program for Qualifying Hospitals Engaged in Cancer-Related Health Care and Forgiveness of Indebtedness; and Exclusion of Vendor Purchases Made Under the Competitive Acquisition Program (CAP) for Outpatient Drugs and Biologicals Under Part B for the Purpose of Calculating the Average Sales Price (ASP)*

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 Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Fiscal Year 2007 Occupational Mix Adjustment to Wage Index; Health Care Infrastructure Improvement Program; Selection Criteria of Loan Program for Qualifying Hospitals Engaged in Cancer-Related Health Care and Forgiveness of Indebtedness; and Exclusion of Vendor Purchases Made Under the Competitive Acquisition Program (CAP) for Outpatient Drugs and Biologicals Under Part B for the Purpose of Calculating the Average Sales Price (ASP)” (RINs: 0938-AO12, 0938-AO03, 0938-AN93, 0938-AN58). We received the rule on August 1, 2006. It was published in the Federal Register as “final rules and interim final rule with comment period” on August 18, 2006. 71 Fed. Reg. 47870.

The final rule revises the Medicare hospital inpatient prospective payment systems for operating and capital-related costs to implement changes arising from CMS’s continuing experience with these systems and to implement a number of changes made by the Deficit Reduction Act of 2005 (Pub. L. 109-171). Among other changes, as noted above, the final rule finalizes policy documents relating to the implementation of the Health Care Infrastructure Improvement Program, a hospital loan program for cancer research.

The rule has an announced effective date of October 1, 2006, with the exception of the portion of the rule regarding the calculation of the average sale price of drugs, which CMS has made effective on August 18, 2006, the date of the rule’s publication in the Federal Register. 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 rule was received by Congress on August 1, 2006, and was published in the Federal Register on August 18, 2006. Therefore, the portions of the rule for which comments were received do not have the required 60-day delay. The portion of the rule that CMS made effective on August 18, 2006, does not require the 60-day delay because the CRA does not require the delay where an agency for “good cause finds (and incorporates the finding and a brief statement of reasons therefore in the rule issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.” 5 U.S.C. 808(2).

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, the CMS complied with the applicable requirements.

If you have any questions about this report, please contact James W. Vickers, Assistant General Counsel, at (202) 512-8210. 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) 512-7101.

signed

Kathleen E. Wannisky
Managing Associate General Counsel

Enclosure

cc: Ann Stallion
Regulations Coordinator
Department of Health and
Human Services

ENCLOSURE

ANALYSIS UNDER 5 U.S.C. § 801(a)(1)(B)(i)-(iv) OF 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 INPATIENT
PROSPECTIVE PAYMENT SYSTEMS AND FISCAL YEAR 2007 RATES; FISCAL
YEAR 2007 OCCUPATIONAL MIX ADJUSTMENT TO WAGE INDEX; HEALTH CARE
INFRASTRUCTURE IMPROVEMENT PROGRAM; SELECTION CRITERIA OF LOAN
PROGRAM FOR QUALIFYING HOSPITALS ENGAGED IN CANCER-RELATED
HEALTH CARE AND FORGIVENESS OF INDEBTEDNESS; AND EXCLUSION OF
VENDOR PURCHASES MADE UNDER THE COMPETITIVE ACQUISITION
PROGRAM (CAP) FOR OUTPATIENT DRUGS AND BIOLOGICALS UNDER PART B
FOR THE PURPOSE OF CALCULATING THE AVERAGE SALES PRICE (ASP)"
(RINS: 0938-AO12, 0938-AO03, 0938-AN93, 0938-AN58)

(i) Cost-benefit analysis

CMS states that the market basket update to the inpatient prospective payment systems, in conjunction with the other payment changes made in the rule, will result in an increase of approximately \$3.4 billion in fiscal year operating and capital payments. The \$142 million in funds for the loan program for cancer center costs under the Health Care Infrastructure Improvement is appropriated specifically for the loan program and not more than \$2 million may be used for the administration of the program.

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

CMS has determined that the final rule will have a significant economic impact on a substantial number of small entities and has, therefore, prepared a Final Regulatory Flexibility Analysis.

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

The final rule does not contain either an intergovernmental or private sector mandate, as defined in title II, of more than \$120 million in any one year.

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

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

The final rule was issued using the notice and comment procedures found at 5 U.S.C. 553. CMS published numerous Notices of Proposed Rulemaking covering the various items contained in the final rule. On May 17, 2006, a proposed rule was published in the Federal Register dealing with the operating costs, capital-related costs, and the occupational mix. 71 Fed. Reg. 28644. In response, CMS received over 2,300 comments. On September 30, 2005 (70 Fed. Reg. 57368 and 57376) and on November 21, 2005 (70 Fed. Reg. 70748), three proposed rules dealing with loan program and loan forgiveness under the infrastructure improvement program and the calculation of the average sales price of drugs, respectively, were published. The comments received under these proposed rules are discussed in the preamble.

In addition, CMS has found “good cause” to forgo notice and comment regarding the revision of the term “unit” in calculating the average sale price of drugs and has issued that rule as an interim rule with a request for comments because of its need to become effective immediately to allow proper calculations.

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

The final rule contains information collections that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. The preamble to the final rule contains the required information that has been forwarded to OMB, including the annual burden of each collection.

Statutory authorization for the rule

The final rule is promulgated under the authority found in sections 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh) and section 124 of the Pub. L. 106-113 (113 Stat. 1501A-332).

Executive Order No. 12866

The final rule was reviewed by OMB and found to be an “economically significant” regulatory action under the order.

Executive Order No. 13132 (Federalism)

CMS notes that the final rule does not have federalism implications under the order.