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December 6, 2005

The Honorable Charles E. Grassley
Chairman
The Honorable Max Baucus
Ranking Minority Member
Committee on Finance
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
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; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 and Certain Provisions Related to the Competitive Acquisition Program of Outpatient Drugs and Biologicals Under Part B*

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; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 and Certain Provisions Related to the Competitive Acquisition Program of Outpatient Drugs and Biologicals Under Part B” (RIN: 0938-AN84 and RIN 0938-AN58). We received the rule on November 2, 2005. It was published in the Federal Register as a “final rule with comment” on November 21, 2005. 70 Fed. Reg. 70116.

The final rule refines the resource-based practice expense relative value units and makes other changes to Medicare Part B payment policy.

The final rule has an announced effective date of January 1, 2006. 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 4, 2005, and was published in the Federal Register on November 21, 2005. Therefore, the 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 effective date, 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

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; REVISIONS TO PAYMENT POLICIES
UNDER THE PHYSICIAN FEE SCHEDULE FOR CALENDAR YEAR 2006
AND CERTAIN PROVISIONS RELATED TO THE COMPETITIVE ACQUISITION
PROGRAM OF OUTPATIENT DRUGS AND BIOLOGICALS UNDER PART B"
(RIN: 0938-AN84 AND 0938-AN58)

(i) Cost-benefit analysis

CMS prepared a Regulatory Impact Analysis that discusses the costs and benefits of the various changes made to the physician fee schedule, including the change in payments for various procedures. CMS estimates the net impact of the final rule will be a decrease in expenditures of \$2.668 billion from calendar year 2005 to calendar year 2006.

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

CMS prepared a Final Regulatory Flexibility Analysis in connection with the final rule, which complies with the requirements of the Act. The analysis discusses the impact on beneficiaries and on physicians, both by specialty and geographic location.

(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 mandate, as defined in title II, of more than \$110 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.

A portion of the final rule was issued using the notice and comment procedures found at 5 U.S.C. 553. On August 8, 2005, CMS issued a Notice of Proposed Rulemaking in the Federal Register. 70 Fed. Reg. 45764. In response, CMS received approximately 15,000 comments; the major ones are discussed in the preamble to the final rule.

In addition, CMS found “good cause” to waive the notice of proposed rulemaking for the portion of the rule concerning the national drug coding system which is updated in the fall of each year, thereby making it impracticable to solicit comments in advance of the final rule. However, CMS is providing a 60-day comment period regarding the portion of the final rule not covered by the August proposed rule.

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. However, all of the collections have been approved by OMB previously and given OMB Control Nos. 0938-0296 and 0938-0921.

Statutory authorization for the rule

The final rule is promulgated under the authority found in sections 1102, 1861, 1862(a), 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 1302, 1395x, 1395y(a), 1395hh, 1395kk, 1395rr, and 1395ww(k)), and section 353 of the Public Health Service Act (42 U.S.C. 263a).

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 has determined that the final rule does not have federalism implications under the order.