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December 4, 2008

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 B. 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: Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; E-Prescribing Exemption for Computer-Generated Facsimile Transmissions; and Payment for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)*

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: Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; E-Prescribing Exemption for Computer-Generated Facsimile Transmissions; and Payment for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)” (RINs: 0938-AP18, 0938-AN14). We received the rule on October 31, 2008. It was published in the *Federal Register* as a “final rule with comment period” on November 19, 2008. 73 Fed. Reg. 69,726.

The final rule with comment period implements changes to the physician fee schedule and other Medicare Part B payment policies to reflect changes in medical practice and the relative value of services. It also finalizes the calendar year (CY) 2008 interim relative value units (RVUs) and issues interim RVUs for CY 2009. As required by statute, the final rule also announces that the physician fee schedule update is 1.1 percent for CY 2009, the preliminary estimate for the sustainable growth rate for CY 2009 is 7.4 percent, and the conversion factor for CY 2009 is \$36.0666. The final rule also implements certain provisions of the Medicare Improvements for Patients and Providers Act of 2008, Pub. L. No. 110-275, 122 Stat. 2494 (July 15, 2008).

The final rule is effective on January 1, 2009, except for amendments to § 410.62 and § 411.351, which are effective July 1, 2009. 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 October 31, 2008, but it was not published in the *Federal Register* until November 18, 2008. 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 or wish to contact GAO officials responsible for the evaluation work relating to the subject matter of the rule, please contact Michael R. Volpe, Assistant General Counsel, at (202) 512-8236.

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: PAYMENT POLICIES UNDER THE PHYSICIAN FEE  
SCHEDULE AND OTHER REVISIONS TO PART B FOR CY 2009;  
E-PRESCRIBING EXEMPTION FOR COMPUTER-GENERATED FACSIMILE  
TRANSMISSIONS; AND PAYMENT FOR CERTAIN DURABLE MEDICAL  
EQUIPMENT, PROSTHETICS, ORTHOTICS, AND SUPPLIES (DMEPOS)"  
(RINS: 0938-AP18, 0938-AN14)

(i) Cost-benefit analysis

CMS performed a cost-benefit analysis of the final rule. CMS estimates that the final rule will increase expenditures for CY 2009 over the expenditures for CY 2008 by \$3.0 billion.

(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 for this final rule as required by the Act.

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

CMS concluded that the final rule does not contain either an intergovernmental or private sector mandate, as defined in Title II, of more than \$130 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.*

CMS promulgated this final rule using the notice and comment procedures found in the Administrative Procedure Act, 5 U.S.C. § 553. CMS published a proposed rule in the *Federal Register* on July 7, 2008, "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; and Revisions to the Amendment of the E-Prescribing Exemption for Computer Generated Facsimile Transmissions." 73 Fed. Reg. 38,502. CMS received approximately 4,100 timely public comments. These included comments from individual physicians, health care workers, professional associations, manufacturers,

and Members of Congress. The majority of the comments addressed proposals related to independent diagnostic testing facilities, anti-markup, prohibition concerning providers of sleep tests, and the general impact of the proposed rule on specific specialties. CMS responded to the issues raised in the comments in the final rule.

CMS finds good cause to waive the notice of proposed rulemaking for the interim RVUs for selected procedure codes and to establish these codes on an interim final basis. CMS is providing a 60-day comment period for these provisions. CMS also finds good cause to waive the notice of proposed rulemaking for the misvalued codes identified in Table 26, and to revise RVUs for these codes on an interim final basis. CMS is providing a 60-day comment period for these provisions.

The Medicare Improvements for Patients and Providers Act of 2008, Pub. L. No. 110-275, 122 Stat. 2494 (July 15, 2008) (MIPPA), was enacted after publication of the proposed rule. Therefore, there was no discussion in the proposed rule of the new incentive program that is included in the final rule. However, CMS states that many of the requirements under MIPPA with respect to this incentive program are self-implementing. CMS also explains that MIPPA authorizes CMS to implement certain aspects of the incentive program by program instruction or otherwise. Although MIPPA was not enacted until after publication of the proposed rule, CMS received some comments on this new incentive program. CMS responded to those comments in the final rule. Moreover, CMS finds good cause to waive notice and comment rulemaking for requirements that effectuate the self-implementing provisions of the MIPPA. CMS also finds good cause to waive notice and comment rulemaking for those requirements that are not self-implementing.

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

The final rule contains collections of information subject to review by the Office of Management and Budget under the Act. CMS is requesting comments on the information collections in this final rule with comment period.

Statutory authorization for the rule

The final rule is promulgated pursuant to the authority in 42 U.S.C. §§ 263a, 273, 1302, 1320b, 1395d(d), 1395f(b), 1395(g), 1395i-3, 1395l(a), 1395m, 1395w-152, 1395x, 1395y(a), 1395aa(m), 1395cc, 1395ff, 1395hh, 1395kk, 1395nn, 1395rr, 1395tt, 1395ww(k), 1395ddd, and section 124 of Pub. L. No. 106-133, 113 Stat. 1501A-332.

Executive Order No. 12,866

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

Executive Order No. 13,132 (Federalism)

CMS determined that the e-prescribing portions of this final rule present a potential federalism implication. According to CMS, no state categorically bars e-prescribing, but the scope and substance of state laws varies widely among the states. CMS notes that in recent years many states have actively legislated in this area. CMS concluded that should a state law be contrary to the Part D e-prescribing program, the Medicare and Medicaid Act provides for preemption of that state law. CMS concludes in the final rule that states would not incur any direct costs as a result of this rule. 73 Fed. Reg. 69,919.