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December 13, 2010

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

The Honorable Henry A. Waxman  
Chairman  
The Honorable Joe L. Barton  
Ranking Member  
Committee on Energy and Commerce  
House of Representatives

The Honorable Sander M. Levin  
Acting Chairman  
The Honorable Dave Camp  
Ranking Member  
Committee on Ways and Means  
House of Representatives

Subject: *Department of Health and Human Services, Centers for Medicare & Medicaid Services: Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011*

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; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B For CY 2011” (RIN: 0938-AP79). We received the rule on November 2, 2010. It was published in the *Federal Register* as a final rule with comment period on November 29, 2010. 75 Fed. Reg. 73,170.

This final rule with comment period addresses changes to the physician fee schedule and other Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice and the relative value of services. It finalizes the calendar year (CY) 2010 interim relative value units (RVUs) and issues

interim RVUs for new and revised procedure codes for CY 2011. It also addresses, implements, or discusses certain provisions of both the Affordable Care Act (ACA) and the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). In addition, this final rule with comment period discusses payments under the Ambulance Fee Schedule (AFS), the Ambulatory Surgical Center (ASC) payment system, and the Clinical Laboratory Fee Schedule (CLFS), payments to end-stage renal disease (ESRD) facilities, and payments for Part B drugs. Finally, this final rule with comment period also includes a discussion regarding the Chiropractic Services Demonstration program, the Competitive Bidding Program for durable medical equipment, prosthetics, orthotics, and supplies (CBP DMEPOS), and provider and supplier enrollment issues associated with air ambulances.

The final rule has an effective date of January 1, 2011. 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). However, notwithstanding the 60-day delay requirement, any rule that an agency for good cause finds that notice and public comment are impracticable, unnecessary, or contrary to the public interest is to take effect when the promulgating agency so determines. 5 U.S.C. §§ 553(d)(3), 808(2). In this regard, CMS believes it has good cause to forego the notice and comment procedures because the statute establishes the time period for which the premium rates will apply and the formulas used to calculate the Part B premiums are statutorily directed, and therefore no 60-day delay is required under the CRA.

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.

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: Ann Stallion  
Program Manager, Department of  
Health and Human Services

ENCLOSURE

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; PAYMENT POLICIES UNDER THE  
PHYSICIAN FEE SCHEDULE AND OTHER REVISIONS  
TO PART B FOR CY 2011"  
(RIN: 0938-AP79)

(i) Cost-benefit analysis

CMS prepared a cost-benefit analysis of the final rule. CMS estimates that the final rule will result in a decrease in expenditures of \$17.6 billion for physician fee schedule (PFS) conversion factor update. CMS estimates an increase in expenditures of \$1.97 billion for Affordable Care Act provisions.

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

CMS concluded that this final rule will have a significant impact on a substantial number of small entities, because the great majority of hospitals and most other health care providers are small entities, either by being nonprofit organizations or by meeting the Small Business Administration definition of a small business. Accordingly, CMS prepared a regulatory flexibility analysis for the rule. CMS also stated that the final rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

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

CMS determined that this final rule will not mandate any requirements for state, local, or tribal governments, in the aggregate, or expenditure of \$135 million or more by the private sector.

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

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

On July 13, 2010, CMS published a notice of proposed rulemaking for the PFS in the *Federal Register*. 75 Fed. Reg. 40,040. CMS received approximately 8,500 timely pieces of correspondence from the public. CMS responded to the comments in the

final rule. 75 Fed. Reg. 73,170. CMS found good cause to waive notice of proposed rulemaking for the interim RVUs for selected procedure codes.

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

The final rule contains information collection requirements under the Act. CMS estimates that the two new information collection requirements will result in a total annual burden of 196,509 hours and cost \$11,584,380 annually.

The final rule will require that physicians' offices develop a disclosure form when referrals are made to providers of MRI, computed tomography or positron emission tomography in which the physician has an interest, and include a list of at least five other suppliers of the service within a 25 mile radius, if possible. CMS estimates that 71,000 physicians will be required to develop a standard form, for a total annual burden of 71,000 hours, and comply with the requirements, for a total annual burden of 125,433 hours.

The final rule also contains requirements for the appeals process for termination of competitive bidding contracts for durable medical equipments, prosthetics, orthotics, and supplies (DMEPOS) suppliers. The total estimated burden associated with the remedy procedures, appeals, and termination notices in the case of an unsuccessful appeal is 76 hours annually and \$5,700 annually.

#### Statutory authorization for the rule

CMS states that the final rule is promulgated pursuant to sections 1102, 1812(d), 1814(b), 1815, 1833(a),(i), and (n), 1834, 1860D-1 through 1860D-42, 1861, 1862(a), 1871, 1874, 1877, 1881, 1883, 1886, and 1893 of the Social Security Act (42 U.S.C. §§ 1302, 1395d(d), 1395f(b), 1395g, 1395l(a),(i) and (n), 1395m, 1395w-101 through 1395w-152, 1395x, 1395y(a), 1395hh, 1395kk, 1395nn, 1395rr, 1395tt, 1395ww, and 1395ddd); and section 124 of Public Law 106-133 (113 Stat. 1501A-332) and section 353 of the Public Health Service Act (42 U.S.C. § 263a).

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

CMS determined that this rule is an economically significant rule under Executive Order 12,866 and prepared a regulatory impact analysis that presents the costs and benefits of the rulemaking. The final rule was reviewed by the Office of Management and Budget.

#### Executive Order No. 13,132 (Federalism)

CMS determined that this final rule would not have any substantial direct effect on state or local governments, preempt states, or otherwise have federalism implications.