



United States Government Accountability Office
Washington, DC 20548

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December 13, 2011

The Honorable Max Baucus
Chairman
The Honorable Orrin G. Hatch
Ranking Member
Committee on Finance
United States Senate

The Honorable Fred Upton
Chairman
The Honorable Henry A. Waxman
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Dave Camp
Chairman
The Honorable Sander M. Levin
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, Five-Year Review of Work Relative Value Units, Clinical Laboratory Fee Schedule: Signature on Requisition, and Other Revisions to Part B for CY 2012*

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, Five-Year Review of Work Relative Value Units, Clinical Laboratory Fee Schedule: Signature on Requisition, and Other Revisions to Part B for CY 2012" (RINs: 0938-AQ25; 0938-AQ00). We received the rule on November 2, 2011. It was published in the *Federal Register* as a final rule with comment period on November 28, 2011. 76 Fed. Reg. 73,026.

This final rule with comment period addresses changes to the physician fee schedule and other Medicare Part B payment policies. CMS is making these changes to ensure that its payment systems are updated to reflect changes in medical practice and the relative value of services. The rule also addresses, implements, or discusses certain statutory provisions including provisions of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively known as the Affordable Care Act) and the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008. In addition, this final rule with comment period discusses payments for Part B drugs; Clinical Laboratory Fee Schedule; Signature on Requisition; Physician Quality Reporting System; the Electronic Prescribing (eRx) Incentive Program; the Physician Resource-Use Feedback Program and the value modifier; productivity adjustment for ambulatory surgical center payment system and the ambulance, clinical laboratory, and durable medical equipment prosthetics orthotics and supplies fee schedules; and other Part B related issues.

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). This final rule with comment period was received on November 2, 2011, and published in the *Federal Register* on November 28, 2011. The final rule has an effective date of January 1, 2012.¹ Therefore, those provisions of the rule for which the stated effective date is January 1, 2012, do not have the required 60-day delay in effective date. 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). CMS states that if it finds such good cause, it can waive the 60-day delay requirement. CMS did in fact find good cause to waive the notice of proposed rulemaking for the interim relative value units (RVUs) for selected procedure codes and with respect to select misvalued codes and to revise RVUs for those codes on an interim final basis.

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.

¹The 3-day payment window policy provisions of the rule are to be implemented by July 1, 2012.

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

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, FIVE-YEAR REVIEW OF
WORK RELATIVE VALUE UNITS, CLINICAL LABORATORY
FEE SCHEDULE: SIGNATURE ON REQUISITION,
AND OTHER REVISIONS TO PART B FOR CY 2012"
(RINS: 0938-AQ25; 0938-AQ00)

(i) Cost-benefit analysis

Centers for Medicare & Medicaid Services (CMS) discussed the costs and benefits of this final rule with comment period. CMS estimates that the calendar year (CY) 2012 annualized monetized transfers will decrease by \$19.2 billion for the physician fee schedule (PFS) update. This estimate includes the estimated CY 2012 incurred benefit impact associated with the estimated CY 2012 PFS conversion factor update based on a mid-session review of the fiscal year 2012 President's Budget.

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

CMS determined that many of the entities affected by this final rule with comment period are small entities and therefore CMS conducted a Final Regulatory Flexibility Act analysis. This analysis included alternatives CMS considered for the various final policies in this rule. In addition, CMS determined that this rule will 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 the final rule with comment period is not anticipated to impose any costs on state, local, or tribal governments in the aggregate, or on the private sector, of \$100 million (\$136 million adjusted for inflation) respectively.

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

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

CMS found good cause to waive the notice of proposed rulemaking for the interim relative value units (RVUs) for selected procedure codes and to establish RVUs for these codes on an interim basis. CMS also found good cause to waive notice and comment procedures with respect to select misvalued codes and to revise RVUs for these codes on an interim final basis. CMS provided a 60-day public comment period for these items.

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

CMS determined that this final rule with comment period contains an information collection requirement under the Act. CMS's estimated hour burden for the initial health risk assessment (HRA) is 256,000 total hours. However, CMS determined that, for purposes review and approval by the Office of Management and Budget (OMB), the average annual burden which accounts both the initial HRA and subsequent HRAs is 200,000. In addition, this final rule also makes reference to several other associated information collection requirements that are not discussed in the regulation text. CMS discusses these, some of which have received approval from the Office of Management and Budget, in the final rule preamble.

Statutory authorization for the rule

CMS promulgated this final rule with comment period under the authority of sections 1102, 1834, 1871, 1881(b)(1), and 1893 of the Social Security Act. 42 U.S.C. §§ 1302, 1395m, 1395hh, 1395rr(b)(1), 1395ddd.

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

CMS determined that the final rule with comment period is economically significant under the Order, and the rule has been reviewed by OMB.

Executive Order No. 13,132 (Federalism)

CMS determined that the final rule with comment period will not have a substantial direct effect on state or local government, preempt states, or otherwise have a federalism implication.