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December 3, 2012

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; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013*

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, entitled "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013" (RIN: 0938-AR11). We received the rule on November 2, 2012. It was published in the *Federal Register* as a final rule with comment period on November 16, 2012. 77 Fed. Reg. 68,892.

The final rule with comment period addresses changes to the physician fee schedule, payments for Part B drugs, and other Medicare Part B payment policies to ensure that CMS's payment systems are updated to reflect changes in medical practice and the relative value of services. It also implements provisions of the Affordable Care Act by establishing a face-to-face encounter as a condition of payment for certain durable medical equipment (DME) items. In addition, it implements statutory changes regarding the termination of non-random prepayment review.

The rule has an effective date of January 1, 2013. 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, an agency can waive the delay in effective date if it finds, for good cause, that the delay is impracticable, unnecessary, or contrary to the public interest. 5 U.S.C. § 808(2). CMS incorporated a statement of finding such good cause and provided the reasons in the final rule with comment period.

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

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; REVISIONS TO PAYMENT POLICIES
UNDER THE PHYSICIAN FEE SCHEDULE, DME FACE-TO-FACE
ENCOUNTERS, ELIMINATION OF THE REQUIREMENT FOR
TERMINATION OF NON-RANDOM PREPAYMENT COMPLEX
MEDICAL REVIEW AND OTHER REVISIONS TO PART B FOR CY 2013"
(RIN: 0938-AR11)

(i) Cost-benefit analysis

CMS performed a cost-benefit analysis in conjunction with the final rule with comment period. The statute requires that CMS establish by regulation each year payment amounts for all physicians' services, adjusted to reflect the variations in the costs of providing services in different geographic areas. The statute also requires that annual adjustments to the relative value units (RVUs) not cause annual estimated expenditures to differ by more than \$20 million from what they would have been had the adjustments not been made. If adjustments to RVUs would cause expenditures to change by more than \$20 million, CMS must make adjustments to preserve budget neutrality.

The largest payment increase for primary care specialties overall will result from a new payment for managing a beneficiary's care when the beneficiary is discharged from an inpatient hospital, a skilled nursing facility (SNF), an outpatient hospital observation, partial hospitalization services, or a community mental health center. Payments to primary care specialties also will increase due to redistributions from changes in payments for services furnished by other specialties. Because of the budget-neutral nature of this system, decreases in payments for one service result in increases in payments in others.

Payments to primary care specialties are also impacted by the completion of the 4-year transition to new practice expense (PE) RVUs using the new Physician Practice Information Survey (PPIS) data that was adopted in the calendar year (CY) 2010 Physician Fee Schedule (PFS) final rule with comment period. Several types of providers are projected to see decreases in Medicare PFS payments, mainly as a result of the potentially misvalued codes initiative. CMS has received numerous new codes with new values and revised codes with new values for CY 2013 as a result of CMS's ongoing misvalued codes initiative, an effort to improve payment accuracy. Many of the new and revised codes that CMS valued on an interim basis

for CY 2013 originated with the potentially misvalued codes initiative. Reductions for pathology, neurology, and independent laboratories are a result of the misvalued code initiative. In the case of independent laboratories, CMS noted that independent laboratories receive the majority of the Medicare revenue from the Clinical Lab Fee Schedule, which is unaffected by the misvalued code initiative. Radiation therapy centers will see an overall decrease of 9 percent primarily as a result of the PPIIS transition discussed above and a change in the interest rate assumption used to calculate PE. Radiation oncology sees a 7 percent decrease for the same reasons as radiation therapy centers.

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

CMS estimated that the final rule with comment period may have a significant impact on a substantial number of small entities. As authorized by 5 U.S.C. 605(a), CMS included the information required for its regulatory flexibility analysis as part of its regulatory impact analysis. CMS certified that the final rule with comment period will not have a significant impact on 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 would have no consequential spending effect on state, local, or tribal governments, or on the private sector.

(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 final rule with comment period. CMS found that because of the late publication of the resource-based Relative Value Scale Update Committee (RUC) recommendations, it would be impracticable for CMS to solicit public comment prior to the final rule with comment period. CMS also found good cause to waive the 30-day delay in effective date required by the Administrative Procedure Act, 5 U.S.C. § 553(d)(3).

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

The final rule with comment period contains information collection requirements subject to the Paperwork Reduction Act. The final rule with comment period requires that a physician must have documented and communicated to a durable medical equipment (DME) supplier that the physician or physician assistant (PA), nurse practitioner (NP), or clinical nurse specialist (CNS) has had a face-to-face encounter with the beneficiary no more than 6 months before the order is written.

CMS estimated that the physician documentation burden to review and document when a PA, NP, or CNS performed the face-to-face encounter in year 1 would be nearly 83,333 hours and a total of 483,333 hours over 5 years. The associated cost in year 1 is estimated at nearly \$9.8 million and over 5 years has associated costs of nearly \$57.03 million based on the growth rate of the Medicare population. The increase is slightly more than five-fold because the number of Medicare beneficiaries would increase over time. The average annual burden over 5 years for 580,000 claims (2,900,000/5) is 96,667 hours at a cost of \$11,406,667. CMS assumed it will take 3 minutes for a PA, NP, or CNS to prepare the medical record for the review of the face-to-face encounter. For a total of 25,000 hours at a cost of about \$1.4 million in year 1 and nearly 145,000 hours over 5 years at a cost of nearly \$8 million based on the growth rate of the Medicare population. The average annual burden over 5 years for 580,000 claims (2,900,000/5) is 29,000 hours at a cost of \$1,595,000.

The final rule also contains information collection requirements related to the Physician Quality Reporting System (PQRS). CMS estimated that the average amount per eligible professional earning an incentive in 2013 and 2014 would be \$539. Therefore, CMS estimated that it would distribute approximately \$162 million ($\$539 \times 300,000$ eligible professionals) and \$216 million ($\$539 \times 400,000$ eligible professionals) in incentive payments in 2013 and 2014, respectively. CMS believes these incentive payments will help offset the cost to eligible professionals participating in PQRS for the applicable year. CMS notes that, beginning in 2015, incentive payments for satisfactory reporting in PQRS will cease and payment adjustments for not satisfactorily reporting will commence. The total burden associated with participating in PQRS is the time and effort associated with indicating intent to participate in PQRS, if applicable, and submitting PQRS quality measures data. CMS estimated that the burden for an individual eligible professional would be \$354 and \$3,256 for a group practice.

Statutory authorization for the rule

The final rule with comment period is authorized by sections 1102, 1106, 1138, 1834, 1860D–1 through 1860D–42, 1871, 1881, 1881(b)(l), 1893, and 1899 of the Social Security Act (42 U.S.C. §§ 1302, 1306, 1320b–8, 1395m, 1395w–101 through 1395w–152, 1395hh, and 1395ddd, 1395rr(b)(l)) and section 371 of the Public Health Service Act (42 U.S.C. 273).

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

CMS determined that the final rule with comment period is economically significant under the Executive Order. CMS prepared a regulatory impact analysis to accompany the final rule with comment period.

Executive Order No. 13,132 (Federalism)

CMS determined that the final rule with comment period does not impose any costs on state or local governments, and therefore does not have federalism implications.