



441 G St. N.W.  
Washington, DC 20548

B-327566

November 25, 2015

The Honorable Orrin G. Hatch  
Chairman  
The Honorable Ron Wyden  
Ranking Member  
Committee on Finance  
United States Senate

The Honorable Fred Upton  
Chairman  
The Honorable Frank Pallone, Jr.  
Ranking Member  
Committee on Energy and Commerce  
House of Representatives

The Honorable Kevin Brady  
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 and Other Revisions to Part B for CY 2016*

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; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016" (RIN: 0938-AS40). We received the rule on October 30, 2015. It was published in the *Federal Register* as a final rule with comment period on November 16, 2015. 80 Fed. Reg. 70,886.

The final rule with comment period addresses changes to the physician fee schedule and other Medicare Part B payment policies to ensure that the CMS payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute.

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). The final rule with comment period has an announced effective date of January 1, 2016, except the definition of "ownership or investment interest" in

§ 411.362(a), which has an effective date of January 1, 2017. We received the rule on October 30, 2015, and it was published in the *Federal Register* on November 16, 2015. Therefore, the final rule does not have the required 60-day delay in effective date for the provisions identified with an effective date of January 1, 2016. The 60-day delay in effective date can be waived, however, if the agency finds for good cause that the delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the findings and its reasons in the rule issued. CMS found good cause to waive the notice of proposed rulemaking and the notice and comment procedures for the final rule with comment period with respect to the misvalued codes and to revise relative value units for these codes on an interim final basis. CMS provided a 60-day public 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  
Deputy Director, ODRM  
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 AND  
OTHER REVISIONS TO PART B FOR CY 2016"  
(RINs: 0938-AS40)

(i) Cost-benefit analysis

The Centers for Medicare & Medicaid Services (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; CMS must make adjustments to preserve budget neutrality.

CMS provided a table in the rule accompanied with an explanation that showed the payment impact by Medicare specialty. To the extent that there are year-to-year changes in the volume and mix of services provided by physicians, CMS noted that the actual impact on total Medicare revenues will be different from those shown in table. CMS's estimates of changes in Medicare revenues for Physician Fee Schedule (PFS) services compare payment rates for CY 2015 with payment rates for CY 2016 using CY 2014 Medicare utilization as the basis for the comparison. The payment impacts reflect averages for each specialty based on Medicare utilization. The payment impact for an individual physician could vary from the average and would depend on the mix of services the practitioner furnishes. As stated by CMS, the average change in total revenues would be less than the impact displayed in the table because practitioners and other entities furnish services to both Medicare and non-Medicare patients and specialties may receive substantial Medicare revenues for services that are not paid under PFS.

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

CMS determined that the final rule will have an economically significant impact on a substantial number of small entities. Because approximately 95 percent of the practitioners, other providers and suppliers covered by the final rule with comment period are considered to be small entities, CMS incorporated the cost-benefit analysis discussed above to meet the requirements of the Regulatory Flexibility Act, as authorized by 5 U.S.C. § 605(a).

Section 1102(b) of the Social Security Act requires CMS to perform a regulatory impact analysis if a rule may have a significant economic impact on the operations of a substantial number of small rural hospitals. CMS certified that the final rule with comment period 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 would impose no mandates 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 and incorporated a statement of the finding and its reasons. CMS did, however, provide a 60-day public comment period. Specifically, CMS found good cause to waive the notice of the proposed rulemaking for the RVU codes changed by the American Medical Association's (AMA's) annual fall update, and for the interim RVUs for selected procedure codes. CMS found that it is in the public interest to implement revised RVUs for codes that were identified to be misvalued and that have been reviewed and reevaluated by AMA's Specialty Society Relative (Value) Update Committee on an interim final basis for CY 2016.

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

The final rule with comment period contains information collection requirements as defined under the Paperwork Reduction Act. CMS has submitted a copy of the final rule with comment period to the Office of Management and Budget (OMB) for review of its information collection and recordkeeping requirements, and such requirements are not effective until they have been approved by OMB.

The final rule with comment period contains information collection requirements (ICRs) which CMS described and also summarized in a table in the rule. These include:

- an ICR which is carried over from the CY 2016 proposed rule regarding 42 C.F.R. part 405, subpart D governing the submission of opt-out affidavits;
- an ICR for clinics that bill as if they were provider-based to an Indian Health Service hospital as of April 7, 2000, but which are now tribally-operated clinics under statute and which may seek certification as a grandfathered tribal federally qualified health center (FQHC);
- an ICR regarding the payment for rural health clinics and FQHC services under § 405.2462(g)(3);
- an ICR regarding exceptions to the referral prohibition related to compensation arrangements under § 411.357;
- an ICR regarding the physician quality reporting system under § 414.90;
- an ICR regarding appropriate use criteria for advanced diagnostic imaging services under § 414.94(c)(1) and (2);
- an ICR regarding the comprehensive primary care initiative and the Medicare Electronic Health Record Incentive Program, which CMS stated is exempt from PRA in accordance with section 1115A(d)(3) of the Social Security Act; and
- an ICR regarding the Medicare Shared Savings Program, which CMS stated is exempt from PRA in accordance with section 3022 of the Patient Protection and Affordable Care Act.

### Statutory authorization for the rule

The final rule with comment period is authorized by sections 205(a), 1102, 1106, 1834, 1860D-1 through D-42, 1861, 1862(a), 1862(m), 1869, 1871, 1874, 1877, 1881, 1881(b)(1), 1886(k), 1893, 1886(k), and 1899 of the Social Security Act (42 U.S.C. 405(a), 1302, 1306, 1395m, 1395w-101 through 1395w-152, 1395x, 1395y(a), 1395y(m), 42 U.S.C. 1395b-3, 1395ff, 1395hh, 1395kk, 1395nn, 1395rr, 1395rr(b)(1), 1395ddd, 1395ww(k), 1395jjj, 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 the final rule with comment period is economically significant under the Executive Order. Accordingly, the final rule with comment period was reviewed by the Office of Management and Budget.

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

CMS determined that because the final rule with comment period does not impose any costs on state or local governments, the requirements of the Executive Order are not applicable.