U.S. GOVERNMENT ACCOUNTABILITY OFFICE
441 G St. N.W.
Washington, DC 20548

B-326413

November 25, 2014

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

The Honorable Fred Upton
Chairman
The Honorable Henry 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, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015*

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, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015" (RIN: 0938-AS12). We received the rule on October 31, 2014. It was published in the *Federal Register* as a final rule with comment period on November 13, 2014. 79 Fed. Reg. 67,548.

The final rule with comment period addresses changes to the physician fee schedule and other Medicare Part B payment policies to ensure that the 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, 2015, except for certain amendments which are

effective on October 31, 2014. We received the rule on October 31, 2014, and it was published in the *Federal Register* on November 13, 2014. 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, 2015. 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.

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

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; REVISIONS TO PAYMENT POLICIES
UNDER THE PHYSICIAN FEE SCHEDULE, CLINICAL LABORATORY
FEE SCHEDULE, ACCESS TO IDENTIFIABLE DATA FOR THE
CENTER FOR MEDICARE AND MEDICAID INNOVATION MODELS
& OTHER REVISIONS TO PART B FOR CY 2015"
(RIN: 0938-AS12)

(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; 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, the actual impact on total Medicare revenues will be different from those shown in table. CMS estimates of changes in Medicare revenues for Physician Fee Schedule (PFS) services compare payment rates for CY 2014 with payment rates for CY 2015 using CY 2013 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 physician furnishes. The average change in total revenues would be less than the impact displayed in the table because physicians furnish services to both Medicare and non-Medicare patients and specialties may receive substantial Medicare revenues for services that are not paid under the 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 Special Society Relative (Value) Update Committee (RUC) on an interim final basis for CY 2015. CMS waived notice and comment procedures for the federally qualified health center prospective payment system rates and adjustments, because such changes merely provide technical corrections to the regulations, without making any substantive changes. Finally, CMS found good cause to waive the notice-and-comment procedure as contrary to the public interest for the revisions to the Electronic Health Record Incentive Program, as it found that a delay would interfere with the ability of eligible professionals and eligible hospitals to request a hardship exception as detailed in the final rule with comment period.

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 related to the report of payments or other transfers of value and physician ownership and investment interests. CMS determined that these requirements would require 1,150 manufacturers to each spend 1 hour annually reporting and 0.5 hour on system upgrades, for a total annual burden of 1,150 hours on reporting and a cost of $30,349, and a total annual burden of 575 hours on system upgrades and a cost of $27,341. CMS further determined that these requirements would require 420 group purchasing organizations to each spend 1 hour annually reporting and 0.5 hour on system upgrades, for a total annual burden of 420 hours on reporting and a cost of $11,084, and a total annual burden of 210 hours on system upgrades and a cost of $9,986.

The final rule with comment period also contains information collection requirements related to the Physician Quality Reporting System. CMS determined that the changes related to the start-up for first-time participants would apply to 164,000 respondents and result in a total annual burden of 820,000 hours and a total cost of $13.120 million. CMS determined that the changes related to the claims-based reporting mechanism would apply to 250,000 respondents and result in a total annual burden of 1,306,025 hours and a total cost of $107.090 million. CMS determined that the changes related to the qualified registry-based and qualified clinical data

registry-based reporting mechanisms would apply to 1650,000 respondents and result in a total annual burden of 13,750 hours and have no set costs. Finally, CMS determined that the changes related to group practices using the group practice reporting option web interface would apply to 200 respondents and result in a total annual burden of 17,000 hours and a total cost of $1.334 million.

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.