U.S. GOVERNMENT ACCOUNTABILITY OFFICE
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Washington, DC 20548

B-325384

December 23, 2013

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, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014*

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 & Other Revisions to Part B for CY 2014" (RIN: 0938-AR56). We received the rule on December 6, 2013. It was published in the *Federal Register* as a final rule with comment period on December 10, 2013. 78 Fed. Reg. 74,230.

The final rule with comment period addresses changes to the physician fee schedule, clinical laboratory fee schedule, and other Medicare Part B payment policies to ensure that CMS payment systems are updated to reflect changes in medical practice and the relative value of services. This final rule with comment period also includes a discussion in the Supplementary Information regarding various programs.

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, 2014, except for certain other amendments which are effective on January 1, 2015, and other policies specified under certain identified preamble sections which are applicable on January 27, 2014. We received the rule on December 6, 2013, and it was published in the *Federal Register* on December 10, 2013. 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, 2014, or January 27, 2014.

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. In that regard, CMS noted that due to the lapse in appropriations and the statutory requirements governing the system, CMS found it contrary to the public interest to delay the effective dates of the Medicare Physician Fee Schedule (MPFS) portions of this final rule. CMS found good cause to waive the notice of proposed rulemaking and the notice and comment procedures for certain interim procedure codes identified. CMS found good cause to waive notice and comment procedures with respect to the misvalued codes and to revise Relative Value Units (RVU) for these codes on an interim final basis. CMS found that it would be contrary to the public interest to delay the effective date of the Physician Quality Reporting System (PQRS), value-based payment modifier, Electronic Health Record (EHR) incentive program, and Medicare Shared Savings provisions of this final rule. Lastly, CMS incorporated a statement of its findings along with its reasons that a delayed effective date is both impracticable and contrary to the public interest, and waived the delay in the effective date of this final rule, but clarified that the delayed effective date is not waived for other provisions in this final rule with comment period, and that those policies will be effective on January 27, 2014. Consequently, to the extent that there are portions of this final rule that have a stated effective date of January 1, 2014, or January 27, 2014, and the agency has not found good cause, CMS is not in compliance with the 60-day requirement.

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 with the exception of the 60-day delay in effective date as discussed above.

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; REVISIONS TO PAYMENT POLICIES
UNDER THE PHYSICIAN FEE SCHEDULE, CLINICAL LABORATORY FEE
SCHEDULE & OTHER REVISIONS TO PART B FOR CY 2014"
(RIN: 0938-AR56)

(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 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 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 2013 with payment rates for CY 2014 using CY 2012 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.

The most widespread specialty impacts of the RVU changes are generally related to the following major factors. The first factor is due to CMS's rescaling of the RVUs to match the weights assigned to work, Practice Expense (PE), and Malpractice (MP) in the revised Medicare Economic Impact. A conversion factor (CF) adjustment is also made to assure budget neutrality for this adjustment in RVUs. The second factor involves service-level changes to RVUs for new, revised, and misvalued services. In addition, a number of other changes contribute to the impacts shown in the table. Other factors include a statutory change that requires CMS to use a 90 percent equipment utilization rate rather than the previously used 75 percent for expensive diagnostic imaging equipment, updates to direct practice expense inputs for ultrasound services, and adjustments to time for some services. The table displayed the estimated CY 2014 combined impact on total allowed charges by specialty of all the RVU changes. These impacts range from an increase of 12 percent for chiropractors to a decrease of 10 percent for diagnostic testing facilities. Again, these impacts are estimated prior to the application of the negative CY 2014 CF update applicable under the Act.

(ii) Agency actions relevant to the Regulatory Flexibility Act (RFA), 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 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 provided a 60-day public comment period. Specifically, CMS found good cause to waive the notice of the proposed rulemaking for the interim RVUs for selected procedure codes identified and to establish RVUs for these codes on an interim final basis. CMS found good cause to waive notice and comment procedures with respect to the misvalued codes and to revise RVUs for these codes on an interim final basis. CMS finalized the MPFS in this CY 2014 final rule with comment period and found good cause to waive the 60-day delay in effective date, in order to adhere to the statutory requirements that an adjusted CF apply to services furnished on or after January 1, 2014, and that budget neutrality be maintained. CMS found that it would be contrary to the public interest to delay the effective date of the Physician Quality Reporting System (PQRS), value-based payment modifier, Electronic Health Record (EHR) incentive program, and Medicare Shared Savings provisions of this final rule. CMS noted that the waiver of the delayed effective date only applies to the provisions that were adopted in this final rule with comment period, but that the delayed effective date is not waived for other provisions of this final rule with comment period, and those policies will be effective on January 27, 2014.

Paperwork Reduction Act (PRA), 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 a collection regarding medical services coverage decisions that relate to health care technology. CMS noted that over the past 18 years, there have been approximately 4000 Investigational Device Exemption (IDE) studies approved that are potentially coverable by Medicare, averaging to about 222 per year. If the sponsor requests a second review, the documents will have to be sent again. CMS estimated that this may happen 5–8 percent of the time. Adding another 8 percent brings the total estimate to approximately 240 requests per year. Accordingly, CMS estimated that it will take 1 to 2 hours for an executive administrative assistant in a medical device company to prepare the required information. CMS estimated that for 240 requests per year, that the total time to be expended by all potential study sponsors is estimated to be between 240 to 480 hours. CMS estimated the cost to be between $7.822–$15,643 per study, for 222 potential IDE study sponsors plus a potential 19 additional submissions. If the average time of a study is

2 years, the annualized cost is $3,911–$15,643 years applications or $16.30–$39.59 per study. The higher figure is used for the burden calculation in the PRA submission to the Office of Management and Budget (OMB). The preceding requirements and burden estimates will be submitted to OMB under OCN 0938-New (CMS–10511).

The final rule also contains information collection requirements related to the Physician Quality Reporting System (PQRS). CMS stated that although the sections contain information collection requirements regarding the input process and the endorsement of consensus-based quality measures, this rule did not revise any of the information collection requirements or burden estimates that are associated with those provisions. The burden estimates for participating in the PQRS in 2014 are subject to OMB review/approval under OCN 0938–1059. (CMS–10276). Based on information drawn from the 2011 Reporting Experience and CMS's participation estimate, CMS believes that, out of the 400,000 eligible professionals it expects to participate in the PQRS in 2014, the PQRS will distribute 2014 incentives to approximately 270,000 eligible professionals (27 percent of 1 million eligible professionals). At $1,059 per eligible professional, the PQRS will distribute approximately $286 million in incentive payments for 2014. CMS believes these incentive payments will help offset the cost eligible professionals may undertake for participating in the PQRS for the applicable year. CMS notes that the total burden associated with participating in the PQRS is the time and effort associated with indicating intent to participate in the PQRS, if applicable, and submitting PQRS quality measures data. CMS estimated that the burden for an individual eligible professional would be $432 and $3,160 for a group practice.

The final rule with comment period also contains an information collection requirement related to the Medicare Electronic Health Record (EHR) Incentive Program which provides incentive payments to eligible professionals, eligible hospitals, and Critical Access Hospitals that demonstrate meaningful use of certified EHR technology. CMS believes any burden or impact associated with this rule's changes to the EHR Incentive Program are already absorbed by OCN 0938–1158 and are not subject to additional OMB review under the authority of the PRA.

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), 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), 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. 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.