



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

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December 20, 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 and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Hospital Value-Based Purchasing Program; Organ Procurement Organizations; Quality Improvement Organizations; Electronic Health Records (EHR) Incentive Program; Provider Reimbursement Determinations and Appeals*

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 and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Hospital Value-Based Purchasing Program; Organ Procurement Organizations; Quality Improvement Organizations; Electronic Health Records (EHR) Incentive Program; Provider Reimbursement Determinations and Appeals” (RIN: 0938-AR54). 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. 74,826.

The final rule with comment period revises the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for CY 2014 to implement applicable statutory requirements and changes arising from CMS’s continuing experience with these systems. In this final rule with comment period, CMS describes the changes to the amounts and factors used to determine the payment rates for

Medicare services paid under OPSS and those paid under the ASC payment system. In addition, this final rule with comment period updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program, the ASC Quality Reporting (ASCQR) Program, and the Hospital Value-Based Purchasing (VBP) Program. In the final rules in this document, CMS is also finalizing changes to the conditions for coverage (CfCs) for organ procurement organizations (OPOs); revisions to the Quality Improvement Organization (QIO) regulations; changes to the Medicare fee-for-service Electronic Health Record (EHR) Incentive Program; and changes relating to provider reimbursement determinations and appeals.

The final rules in the document are effective on January 1, 2014, with the exception of 42 C.F.R. §§ 412.167, 486.316; 486.318; 475.1; 475.100 to 475.107; 495.4 and 495.104, which are effective on January 27, 2014. The implementation date for the policies relating to comprehensive Ambulatory Payment Classification (APC) groups is January 1, 2015.

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, notwithstanding the 60-day delay requirement, any rule that an agency for good cause finds that notice and public procedures are impractical, unnecessary, or contrary to the public interest is to take effect when the promulgating agency so determines. §§ 553(d)(3), 808(2). Accordingly, CMS believes it has good cause for making the final rules effective as stated. CMS believes it would be contrary to the public interest to delay the effective date of the OPSS and ASC payment systems portions, including the Hospital OQR Program and the ASCQR Program parts of the final rule with comment period because these are calendar year payment systems. CMS typically issues the OPSS/ASC payment systems final rule with comment period by November 1 of each year to both comply with the requirement to annually review and update these payment systems and ensure that the payment policies for these systems are effective on January 1, the first day of the calendar year to which the policies are intended to apply, but was delayed by the federal government shutdown which lasted from October 1, 2013, through October 16, 2013. The Hospital OQR Program and the ASCQR Program are intended to align with OPSS and the ASC payment system, respectively.

CMS also believes it would be contrary to the public interest to delay the effective date of the Hospital VBP Program performance and baseline period because these policies are being finalized in this document solely because CMS inadvertently neglected to propose and finalize them in the FY 2014 IPPS/LTCH PPS proposed and final rules. These policies are intended to align with the previously finalized performance and baseline periods for other measures included in the FY 2016 Hospital VBP Program, with January 1, 2014, being the start date of reporting. In addition, a delay in effective date would be contrary to the public interest in ensuring that payments under the IPPS to hospitals in FY 2016 properly and completely reflect their performance on quality measures in 2014.

CMS also believes that it would be contrary to the public interest to delay the effective date of the revisions to the provider reimbursement determinations and appeals reopening rule under 42 C.F.R. § 405.1885 because it has determined that applying these revisions to currently pending cost reports, appeals, and reopenings is in the public interest in finality of payment amounts and necessary to comply with the requirements of sections 1878 and 1886 of the Social Security Act (the Act). If the effective date of this final rule with comment period and final rules mentioned above in this document is delayed by 60 days, the OPSS and ASC payment system policies (including the Hospital OQR and the ASCQR Program policies), the Hospital VBP Program performance and baseline period policies, and the revisions to the provider reimbursement determinations and appeals regulations at 42 C.F.R. § 405.1885, adopted in this

final rule with comment period and final rules, will not be effective as of the beginning of the payment year. CMS notes that its waiver of the delayed effective date only applies to the OPPS and ASC payment system policies (including the Hospital OQR and the ASCQR Program policies), the Hospital VBP Program performance and baseline period policies, and the revisions to the provider reimbursement determinations and appeals regulations at 42 C.F.R. § 405.1885, that are adopted in this final rule with comment period and in the applicable final rules.

The delayed effective date for all other policies in the final rules in this document was not waived for good cause, and these policies will be effective on January 27, 2014. These policies do not have the required 60-day delay in effective date.

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 requirement for certain provisions.

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 AND MEDICAID PROGRAMS: HOSPITAL OUTPATIENT PROSPECTIVE
PAYMENT AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEMS AND
QUALITY REPORTING PROGRAMS; HOSPITAL VALUE-BASED PURCHASING
PROGRAM; ORGAN PROCUREMENT ORGANIZATIONS; QUALITY IMPROVEMENT
ORGANIZATIONS; ELECTRONIC HEALTH RECORDS (EHR) INCENTIVE
PROGRAM; PROVIDER REIMBURSEMENT DETERMINATIONS AND APPEALS"
(RIN: 0938-AR54)

(i) Cost-benefit analysis

CMS summarized the costs and benefits of the final rule with comment period. CMS estimates that the effects of the final OPPS payment provisions will result in expenditures exceeding \$100 million in any 1 year. CMS further estimates that the total increase from the changes in this final rule with comment period in federal government expenditures under the OPPS for CY 2014 compared to CY 2013 will be approximately \$600 million. Taking into account its estimated changes in enrollment, utilization, and case-mix, CMS estimates that the OPPS expenditures for CY 2014 will be approximately \$4.372 billion higher relative to expenditures in CY 2013. Because this final rule with comment period is economically significant as measured by the \$100 million threshold, CMS prepared a regulatory impact analysis that, to the best of its ability, presents its costs and benefits.

CMS estimates that the update to the conversion factor and other adjustments (not including the effects of outlier payments, the pass-through estimates, and the application of the frontier state wage adjustment for CY 2014) will increase total OPPS payments by 1.7 percent in CY 2014. CMS states that the changes to the APC weights, the changes to the wage indices, the continuation of a payment adjustment for rural sole community hospitals, including essential access community hospitals, and the payment adjustment for cancer hospitals will not increase OPPS payments because these changes to the OPPS are budget neutral. However, these updates will change the distribution of payments within the budget neutral system. CMS estimates that the total change in payments between CY 2013 and CY 2014, considering all payments, including changes in estimated total outlier payments, pass-through payments, and the application of the frontier state wage adjustment outside of budget neutrality, in addition to the application of the OPD fee schedule increase factor after all adjustments required by sections 1833(t)(3)(F), 1833(t)(3)(G), and 1833(t)(17) of the Act, will increase total estimated OPPS payments by 1.8 percent.

CMS estimates the total increase (from changes to the ASC provisions in this final rule with comment period as well as from enrollment, utilization, and case-mix changes) in expenditures under the ASC payment system for CY 2014 compared to CY 2013 to be approximately \$143 million. Because the provisions for the ASC payment system are part of a final rule that is economically significant as measured by the \$100 million threshold, CMS prepared a regulatory impact analysis of the changes to the ASC payment system that, to the best of its ability, presents the costs and benefits of this portion of the final rule with comment period.

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

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, CMS estimates that most hospitals, ASCs, and CMHCs are small entities as that term is used in the RFA. For purposes of the RFA, most hospitals are considered small businesses according to the Small Business Administration's size standards with total revenues of \$35.5 million or less in any single year. CMS states that most ASCs and most CMHCs are considered small businesses with total revenues of \$10 million or less in any single year. CMS estimates that this final rule with comment period may have a significant impact on approximately 2,040 hospitals with voluntary ownership.

In addition, section 1102(b) of the Act requires CMS to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, CMS defines a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has 100 or fewer beds. CMS estimates that this final rule with comment period may have a significant impact on approximately 709 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

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately \$141 million. CMS states that the final rule with comment period does not mandate any requirements for state, local, or tribal governments, or for 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 published two proposed rules related to OPPS/ASC payment systems. CMS states that it received approximately 2,677 timely pieces of correspondence on the CY 2014 OPPS/ASC proposed rule that appeared in the *Federal Register* on July 19, 2013, 78 Fed. Reg. 43,534, and the correcting document published in the *Federal Register* on September 6, 2013, 78 Fed. Reg. 54,842. CMS states that the final rule with comment period refers to the corrected information wherever applicable. CMS notes that it received some public comments that were outside the scope of the proposed rule and that are not addressed in this final rule with comment period. CMS notes that summaries of the public comments to the proposed rule and the correcting document that are within the scope of the proposed rule and its responses are set forth in the various sections of the final rule with comment period under the appropriate subject-matter headings. Additionally, CMS received approximately 27 timely pieces of correspondence on the CY 2013 OPPS/ASC final rule with comment period that appeared in the *Federal Register* on November 15, 2012, 77 Fed. Reg. 68,210, some of which contained comments on the interim APC assignments and/or status indicators of healthcare common procedure coding system codes identified with comment indicator "NI" in Addenda B, AA, and BB to that final rule. CMS notes that summaries of these public comments on topics that were open to comment and its responses to them are set forth in various sections of this final rule with comment period under the appropriate subject-matter headings.

In the CY 2014 OPPTS/ASC proposed rule CMS solicited public comments on various issues. 78 Fed. Reg. 43,684. CMS discussed its proposal to modify the outcome measures requirement for OPOs set forth at § 486.318. CMS states that currently, OPOs are required to meet all three outcome measures in that section or they are automatically decertified. CMS proposed to modify that requirement so that OPOs will meet the outcome measures requirement if they meet two out of the three outcome measures. Based on its experience with OPOs and historical data concerning how many OPOs typically fail to meet one of the outcome measures, CMS believes that there would be about five OPOs that would fail to meet one of the outcome measures. CMS's proposal would result in those five OPOs meeting the outcome measures requirement and not being automatically de-certified. Therefore, CMS explains that these five OPOs would not have to perform the ICRs under this section, which would be the time and resources needed to go through the appeals process in an attempt to secure a reversal of the decertification. While CMS does not have a reliable estimate on how much these OPOs would save due to the numerous unknown variables, they are confident that these OPOs would sustain a significantly positive effect from not being automatically de-certified as is currently required under the OPO CfCs. In addition, under 5 C.F.R. § 1320.3(c), a "collection of information" does not include requirements imposed on fewer than 10 entities. Therefore, CMS states that the requirements of this section are not subject to the PRA.

Additionally, CMS proposed to revise 42 C.F.R. § 495.4 to provide a special method for making hospital-based determinations for 2013 only in the cases of those EPs who reassign their benefits to Method II CAHs. CMS also proposed a minor clarification to the regulations at § 495.104(c)(2) concerning the cost reporting period to be used in determining final EHR payments for hospitals. CMS refers readers to the Stage 1, 75 Fed. Reg. 44,517 through 44,544, and Stage 2, 77 Fed. Reg. 54,125 through 54,135, final rules for the Medicare EHR Incentive Program for the discussions of the burden of the information collection requirements of the Medicare Fee-for-Service EHR Incentive Program. CMS states that its proposals in the proposed rule did not modify or increase the information collection requirements of the program in any way. After reviewing the public comments it received on the proposed rule, CMS is finalizing its proposals discussed in the final rule with comment period. CMS states that these final policies do not modify or increase the information collection requirements of the Medicare Fee-for-Service EHR Incentive Program in any way.

CMS also discussed associated information collections that are not specified in the regulatory text.

Statutory authorization for the rule

CMS states that the final rule with comment period is authorized by section 1833(i) and (t) of the Social Security Act.

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

CMS states that the final rule with comment period has been designated as an economically significant rule. Accordingly, the final rule with comment period has been reviewed by the Office of Management and Budget.

Executive Order No. 13,132 (Federalism)

CMS states that it examined the OPPTS and ASC provisions included in this final rule with comment period in accordance with the Order, and determined that they will not have a substantial direct effect on state, local, or tribal governments, preempt state law, or otherwise have a federalism implication.