U.S. GOVERNMENT ACCOUNTABILITY OFFICE
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B-328571

November 28, 2016

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: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; Electronic Health Record (EHR) Incentive Programs; Payment to Nonexcepted Off-Campus Provider-Based Department of a Hospital; Hospital Value-Based Purchasing (VBP) Program; Establishment of Payment Rates Under the Medicare Physician Fee Schedule for Nonexcepted Items and Services Furnished by an Off-Campus Provider-Based Department of a Hospital*

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: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; Electronic Health Record (EHR) Incentive Programs; Payment to Nonexcepted Off-Campus Provider-Based Department of a Hospital; Hospital Value-Based Purchasing (VBP) Program; Establishment of Payment Rates Under the Medicare Physician Fee Schedule for Nonexcepted Items and Services Furnished by an Off-Campus Provider-Based Department of a Hospital" (RIN: 0938-AS82). We received the rule on November 2, 2016. It was published in the *Federal Register* as a final rule with comment period and interim final rule with comment period on November 14, 2016. 81 Fed. Reg. 79,562.

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 calendar year 2017 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 OPPS 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 and the ASC Quality Reporting (ASCQR) Program. Further, in this final rule with comment period, CMS is making changes to tolerance thresholds for clinical outcomes for solid organ transplant programs; to Organ Procurement Organizations definitions, outcome measures, and organ transport documentation; and to the Medicare and Medicaid Electronic Health Record Incentive Programs. The rule also removes the Hospital Consumer Assessment of Healthcare Providers and Systems Pain Management dimension from the Hospital Value-Based Purchasing (VBP) Program. In addition, the rule implements section 603 of the Bipartisan Budget Act of 2015 relating to payment for certain items and services furnished by certain off-campus provider-based departments of a provider. The final rule with comment period also includes an interim final rule with comment period to establish the Medicare Physician Fee Schedule payment rates for the nonexcepted items and services billed by a nonexcepted off-campus provider-based department of a hospital in accordance with the provisions of section 603.

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). This final rule has a stated effective date of January 1, 2017. The rule was received on November 3, 2016, and was published in the *Federal Register* on November 14, 2016. Therefore, the final rule does not have the required 60-day delay in its effective date.

The 60-day delay in effective date can be waived, however, if the agencies find for good cause that delay is impracticable, unnecessary, or contrary to the public interest, and the agencies incorporate a statement of the findings and their reasons in the rule issued. 5 U.S.C. § 553(d)(3), 808(2). For two aspects of this rule, CMS stated that it found good cause. Regarding CMS's proposed policy on billing and payment for nonexcepted items and services, CMS found good cause to waive the notice of proposed rulemaking and to issue that portion of this rule as a final rule on an interim basis subject to public comment. Additionally, CMS found good cause to waive the notice of proposed rulemaking for the establishment of payment amounts for selected Healthcare Common Procedure Coding System (HCPCS) codes. For other aspects of this final rule, CMS did not claim good cause.

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, other than the 60-day delay requirement, 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: Agnes Thomas
Regulations Coordinator
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: HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEMS AND QUALITY REPORTING PROGRAMS; ORGAN PROCUREMENT ORGANIZATION REPORTING AND COMMUNICATION; TRANSPLANT OUTCOME MEASURES AND DOCUMENTATION REQUIREMENTS; ELECTRONIC HEALTH RECORD (EHR) INCENTIVE PROGRAMS; PAYMENT TO NONEXCEPTED OFF-CAMPUS PROVIDER-BASED DEPARTMENT OF A HOSPITAL; HOSPITAL VALUE-BASED PURCHASING (VBP) PROGRAM; ESTABLISHMENT OF PAYMENT RATES UNDER THE MEDICARE PHYSICIAN FEE SCHEDULE FOR NONEXCEPTED ITEMS AND SERVICES FURNISHED BY AN OFF-CAMPUS PROVIDER-BASED DEPARTMENT OF A HOSPITAL"
(RIN: 0938-AS82)

(i) Cost-benefit analysis

The Centers for Medicare and Medicaid Services (CMS) estimate that the policies in this final rule with comment period will result in a 1.7 percent overall increase in outpatient prospective payment system (OPPS) payments to providers. CMS estimates that total OPPS payments for calendar year (CY) 2017, including beneficiary cost-sharing, to the approximate 3,906 facilities paid under OPPS (including general acute care hospitals, children's hospitals, cancer hospitals, and community mental health centers (CMHCs)) will increase by approximately $773 million compared to CY 2016 payments, excluding CMS's estimated changes in enrollment, utilization, and case-mix. CMS estimated the isolated impact of its OPPS policies on CMHCs because CMHCs are only paid for partial hospitalization services under OPPS. Continuing the provider-specific structure that CMS adopted beginning in CY 2011 and basing payment fully on the type of provider furnishing the service, it estimates a 15.0 percent decrease in CY 2017 payments to CMHCs relative to their CY 2016 payments. CMS estimates that its update of the wage indexes based on the FY 2017 IPPS final rule wage indexes results in no change for urban hospitals and a 0.3 percent increase for rural hospitals under OPPS. CMS estimates that, for most hospitals, the application of the hospital Outpatient Department (OPD) fee schedule increase factor of 1.65 percent to the conversion factor for CY 2017 will mitigate the impacts of the budget neutrality adjustments. As a result of the OPD fee schedule increase factor and other budget neutrality adjustments, the agency estimates that rural and urban hospitals will experience increases of approximately 1.7 percent for urban hospitals and 2.2 percent for rural hospitals. According to CMS's estimates, the percentage change in estimated total payments by specialty groups under the CY 2017 payment rates compared to estimated CY 2016 payment rates ranges between 12 percent for cardiovascular system procedures and −15 percent for hemic and lymphatic system procedures. CMS estimates that this rule's implementation of section 603 of the Bipartisan Budget Act of 2015 will reduce Medicare Part B expenditures by approximately $50 million in CY 2017, relative to a baseline where section 603 was not implemented in CY 2017. CMS estimates that estimated hospital OPPS transfers from CY 2016 to CY 2017 associated with the CY 2017 hospital outpatient OPD fee schedule increase will be $773 million from the federal government to outpatient hospitals and other providers who receive payment under the hospital OPPS.

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

CMS provided a regulatory flexibility analysis for this final rule with comment period. CMS discussed the need for this rule, its effects, and alternatives considered. CMS also estimated that this final rule with comment period will increase payments to small rural hospitals by less than 3 percent and therefore determined it should not have a significant impact on approximately 639 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 this 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.

On July 14, 2016, CMS published a proposed rule. 81 Fed. Reg. 45,603. CMS addressed comments received in the final rule.

Commenters raised specific concerns with CMS proposing the "applicable payment system" to be the Medical Physician Fee Schedule (MPFS), proposing to make no payment to the hospital, and proposing to make payment only to the physician or practitioner under MPFS for the services they furnish. After consideration of the public comments, CMS determined that establishing MPFS as the applicable payment system for nonexcepted items and services furnished by nonexcepted off-campus provider-based departments (PBDs) without simultaneously implementing billing mechanisms to enable hospitals to bill and be paid under MPFS may result in a number of negative consequences, such as implications under the physician self-referral and anti-kickback statutes and existing "incident to" regulations, thereby possibly leading to an inability for either the physician or the hospital to bill for certain nonexcepted items and services, and potentially, in effect, failing to fully implement the statutory language providing for payment for nonexcepted items and services under the applicable payment system. In addition, the public comments raised concerns that if CMS chose to finalize the payment proposal without modification, those final policies could result in possible access to care issues for Medicare beneficiaries in CY 2017. Commenters suggested that many nonexcepted off-campus PBDs would have chosen to cease operations rather than attempting to navigate the issues and resolve concerns raised in public comments, and that some of these may have been in otherwise underserved areas. After considering the gravity of concerns raised in public comments on CMS's proposed policy on billing and payment for nonexcepted items and services, CMS concluded that it is not feasible to finalize the policy it proposed for CY 2017, and for which it provided detailed notice and an opportunity to comment in the CY 2017 OPPS/ASC proposed rule. At the same time CMS determined the law requires that payment shall be made for these nonexcepted items and services under the applicable payment system other than OPPS beginning January 1, 2017. As such, because of the potential implications of finalizing some of CMS's proposed policies related to payment for nonexcepted items and services furnished by nonexcepted off-campus PBDs on hospitals, physicians, and beneficiaries, and the statutory requirement that payment shall be made for these items and services under the applicable payment system other than OPPS beginning January 1, 2017, CMS found that it would be impracticable and contrary to the public interest to undergo notice and comment procedures before finalizing, on an interim basis subject to public comment, a payment policy for these items and services for CY 2017. Therefore, CMS found good cause to waive the notice of proposed rulemaking and to issue this portion of the final rule as an interim basis subject to public comment. CMS is providing a 60-day public comment period.

Additionally, CMS found good cause to waive the notice of proposed rulemaking for the establishment of payment amounts for selected Healthcare Common Procedure Coding System (HCPCS) codes. CMS utilizes HCPCS codes for Medicare payment purposes. HCPCS is a national coding system comprised of Level I codes (current procedural terminology--CPT--codes) and Level II codes that are intended to provide uniformity to coding procedures, services, and supplies across all types of medical providers and suppliers. CPT codes are copyrighted by American Medical Association (AMA) and consist of several categories, including Category I codes which are 5-digit numeric codes, and Category III codes which are temporary codes to track emerging technology, services, and procedures. AMA issues an annual update of the CPT code set each fall, with January 1 as the effective date for implementing the updated CPT codes. The HCPCS codes, including both CPT codes and Level II codes, are similarly updated annually on a calendar year basis. Annual Level II coding changes are not available to the public until the fall immediately preceding the annual January update of the OPPS and the ASC payment system. Because

of the timing of the release of these new codes, CMS determined it was impracticable for it to provide prior notice and solicit comment on the Level II codes and the payments assigned to them in advance of publication of the final rule that implements OPPS and the ASC payment system. However, CMS considers it imperative that these coding changes be accounted for and recognized timely under OPPS and ASC payment system for payment because services represented by these codes will be provided to Medicare beneficiaries in hospital outpatient departments and ASCs during the calendar year in which they become effective. According to CMS, regulations require that HCPCS codes be used to report health care services, including services paid under OPPS and the ASC payment system. CMS assigned interim payment amounts and status indicators to any new codes according to its assessment of the most appropriate APC based on clinical and resource homogeneity with other procedures and services in the APC. If CMS did not assign payment amounts to new codes on an interim basis, the alternative according to CMS would be to not pay for these services during the initial calendar year in which the codes become effective. Therefore CMS believes it would be contrary to the public interest to delay establishment of payment amounts for these codes.

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

CMS discussed the applicability of the Act to various provisions of this final rule with comment period. For instance, CMS notes that the information collection requirements of the Hospital Outpatient Quality Reporting (OQR) Program are currently approved under Office of Management and Budget (OMB) Control Number 0938-1109. CMS expects the relevant provisions of this final rule to this previously approved collection will have no additional burden or are excluded from review as they are collection activities conducted during an administrative action such as reconsideration. CMS also notes that the information collection requirements associated with the five newly adopted Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) survey-based measures are currently approved under OMB Control Number 0938-1240.

To better align the Ambulatory Surgical Center Quality Reporting Program with its other quality reporting and value-based purchasing programs, CMS updated its burden calculation methodology to standardize elements within its burden calculation. Specifically, CMS is finalizing its proposals to utilize: (1) a standard estimate of the time required for abstracting chart data for measures based on historical data from other quality reporting programs; and (2) a standard hourly labor cost for chart abstraction activities.

Statutory authorization for the rule

CMS promulgated this final rule under the authority of sections 1102, 1128l, 1138, 1833(t), 1864, 1865, 1871, 1875, and 1881(b)(2) of the Social Security Act and section 371 of the Public Health Service Act. 42 U.S.C. §§ 273, 1302, 1320a-7j, 1320b-8, 1395aa, 1395bb, 1395hh, 1395l(t), 1395ll, 1395hh, 1395rr(b)(1).

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

CMS determined that this final rule with comment period is economically significant under the Order, and it was reviewed by OMB.

Executive Order No. 13,132 (Federalism)

CMS determined that this final rule with comment period will not have a substantial direct effect on state, local, or tribal governments, preempt state law, or otherwise have a federalism implication.