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

B-328371

September 6, 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 Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2017 Rates; Quality Reporting Requirements for Specific Providers; Graduate Medical Education; Hospital Notification Procedures Applicable to Beneficiaries Receiving Observation Services; Technical Changes Relating to Costs to Organizations and Medicare Cost Reports; Finalization of Interim Final Rules With Comment Period on LTCH PPS Payments for Severe Wounds, Modifications of Limitations on Redesignation by the Medicare Geographic Classification Review Board, and Extensions of Payments to MDHs and Low-Volume Hospitals*

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 Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2017 Rates; Quality Reporting Requirements for Specific Providers; Graduate Medical Education; Hospital Notification Procedures Applicable to Beneficiaries Receiving Observation Services; Technical Changes Relating to Costs to Organizations and Medicare Cost Reports; Finalization of Interim Final Rules With Comment Period on LTCH PPS Payments for Severe Wounds, Modifications of Limitations on Redesignation by the Medicare Geographic Classification Review Board, and Extensions of Payments to MDHs and Low-Volume Hospitals" (RINs: 0938-AS77, 0938-AS88, 0938-AS41).

We received the rule on August 5, 2016. It was published in the *Federal Register* as a final rule on August 22, 2016. 81 Fed. Reg. 56,762.

The final rule revises the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals to implement changes arising from CMS's continuing experience with these systems for FY 2017. Some of these changes will implement certain statutory provisions contained in the Pathway for Sustainable Growth Reform Act of 2013, the Improving Medicare Post-Acute Care Transformation Act of 2014, the Notice of Observation Treatment and Implications for Care Eligibility Act of 2015, and other legislation. CMS also is providing the estimated market basket update to apply to the rate-of-increase limits for certain hospitals excluded from the IPPS that are paid on a reasonable cost basis subject to these limits for FY 2017. CMS updates the payment policies and the annual payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs) for FY 2017. In addition, CMS is making changes relating to direct graduate medical education (GME) and indirect medical education payments; establishing new requirements or revising existing requirements for quality reporting by specific Medicare providers (acute care hospitals, PPS-exempt cancer hospitals, LTCHs, and inpatient psychiatric facilities), including related provisions for eligible hospitals and critical access hospitals (CAHs) participating in the Electronic Health Record Incentive Program; updating policies relating to the Hospital Value-Based Purchasing Program, the Hospital Readmissions Reduction Program, and the Hospital-Acquired Condition Reduction Program; implementing statutory provisions that require hospitals and CAHs to furnish notification to Medicare beneficiaries, including Medicare Advantage enrollees, when the beneficiaries receive outpatient observation services for more than 24 hours; announcing the implementation of the Frontier Community Health Integration Project Demonstration; and making technical corrections and changes to regulations relating to costs to related organizations and Medicare cost reports; CMS is providing notice of the closure of three teaching hospitals and the opportunity to apply for available GME resident slots under section 5506 of the Affordable Care Act. CMS is finalizing the provisions of interim final rules with comment period that relate to a temporary exception for certain wound care discharges from the application of the site neutral payment rate under the LTCH PPS for certain LTCHs; application of two judicial decisions relating to modifications of limitations on redesignation by the Medicare Geographic Classification Review Board; and legislative extensions of the Medicare-dependent, small rural hospital program and changes to the payment adjustment for low-volume hospitals.

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 October 1, 2016. The rule was received by GAO on August 5, 2016, and was published in the *Federal Register* on August 22, 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). CMS noted that, in the April 21, 2016, interim final rule with comment period (IFC), it found good cause for waiving notice-and-comment rulemaking and the 60-day delay in effective date, given the decisions of the courts of appeals and the public interest in consistent application of a federal policy nationwide. CMS stated that revising the regulation text at § 412.230(a)(5)(ii) and removing the regulation text at § 412.230(a)(5)(iii) through an IFC and subsequent final rule rather than through the normal notice-and-comment rulemaking cycle

and waiving the 60-day delay of effective date would ensure a uniform national reclassification policy. According to CMS, by reason of the court decisions, this policy has already been effective since July 23, 2015, in the Third Circuit and February 4, 2016, in the Second Circuit. Absent such a policy, the wage index for acute care hospitals paid under the IPPS would have remained confusingly inconsistent across jurisdictions. Even though CMS waived notice of proposed rulemaking requirements and issued the provisions on an interim basis with subsequent issuance of a final rule, CMS states that it 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: 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 INPATIENT PROSPECTIVE PAYMENT SYSTEMS FOR ACUTE CARE HOSPITALS AND THE LONG-TERM CARE HOSPITAL PROSPECTIVE PAYMENT SYSTEM AND POLICY CHANGES AND FISCAL YEAR 2017 RATES; QUALITY REPORTING REQUIREMENTS FOR SPECIFIC PROVIDERS; GRADUATE MEDICAL EDUCATION; HOSPITAL NOTIFICATION PROCEDURES APPLICABLE TO BENEFICIARIES RECEIVING OBSERVATION SERVICES; TECHNICAL CHANGES RELATING TO COSTS TO ORGANIZATIONS AND MEDICARE COST REPORTS; FINALIZATION OF INTERIM FINAL RULES WITH COMMENT PERIOD ON LTCH PPS PAYMENTS FOR SEVERE WOUNDS, MODIFICATIONS OF LIMITATIONS ON REDESIGNATION BY THE MEDICARE GEOGRAPHIC CLASSIFICATION REVIEW BOARD, AND EXTENSIONS OF PAYMENTS TO MDHS AND LOW-VOLUME HOSPITALS"
(RINs: 0938-AS77, 0938-AS88, 0938-AS41)

(i) Cost-benefit analysis

The Centers for Medicare & Medicaid Services (CMS) included an economic analyses appendix with this final rule. According to CMS, the applicable percentage increase to the inpatient prospective payment systems (IPPS) rates required by the statute, in conjunction with other payment changes in this final rule, will result in an estimated $987 million increase in fiscal year (FY) 2017 operating payments (or 0.9 percent change) and an estimated $66 million increase in FY 2017 capital payments (or 0.8 percent change). In addition, long term care hospitals (LTCHs) are expected to experience a decrease in payments by $363 million in FY 2017 relative to FY 2016.

CMS states that its operating impact estimate includes the −1.5 percent documentation and coding adjustment applied to the IPPS standardized amount and which represents part of the recoupment required under section 631 of the American Taxpayer Relief Act of 2012 (ATRA) Pub. L. 112-240 (Jan. 2, 2013). In addition, CMS's operating payment impact estimate includes the 1.65 percent hospital update to the standardized amount (which includes the estimated 2.7 percent market basket update less 0.3 percentage points for the multifactor productivity adjustment and less 0.75 percentage point required under the Patient Protection and Affordable Care Act). CMS's operating payment impact estimate also includes an adjustment of (1/0.998) to permanently remove the −0.2 percent reduction and a 1.006 temporary adjustment to address the effects of the 0.2 percent reduction in effect for FYs 2014 through 2016 as a result of a 2-midnight policy which was explained the final rule. According to CMS, the estimates of IPPS operating payments to acute care hospitals do not reflect any changes in hospital admissions or real case-mix intensity, which will also affect overall payment changes.

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

CMS estimates that most hospitals and most other providers and suppliers are small entities as that term is used in the Act. CMS believes that the provisions of this final rule relating to acute care hospitals would have a significant impact on small entities. Further, CMS assumes all LTCHs are considered small entities. CMS also stated that Medicare Administrative Contractors are not considered to be small entities. CMS discussed the need for this rule, the objectives of IPPS, limitations of its analysis, quantitative effects of the policy changes under IPPS for operating costs, the effects of other changes in this rule, and alternatives considered, among other topics.

(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 will not mandate any requirements for state, local, or tribal governments, nor will it affect private sector costs.

(iv) Other relevant information or requirements under acts and executive orders

Administrative Procedure Act, 5 U.S.C. §§ 551 et seq.

On April 27, 2016, CMS published a proposed rule in the *Federal Register*, which set forth proposed payment and policy changes to the Medicare IPPS for FY 2017 operating costs and for capital-related costs of acute care hospitals and certain hospitals and hospital units that are excluded from IPPS, including proposed changes relating to payments for IME and direct GME to certain hospitals that continue to be excluded from the IPPS and paid on a reasonable cost basis. In addition, CMS set forth proposed changes to the payment rates, factors, and other payment and policy-related changes to programs associated with payment rate policies under the LTCH prospective payment system (PPS) for FY 2017. 81 Fed. Reg. 24,946.

On April 21, 2016, CMS published an interim final rule with comment period (April 2016 IFC) in the *Federal Register* that addressed provisions relating to (1) a temporary exception to the site neutral payment rate under the LTCH PPS for certain severe wound discharges from certain LTCHs, and (2) application of two judicial decisions relating to modifications of the limitations on redesignation by the Medicare Geographic Classification Review Board (MGCRB). 81 Fed. Reg. 23,428. CMS states that on the temporary exception to the site neutral payment rate under the LTCH for certain severe wound discharges from certain LTCHs, it received 22 timely pieces of correspondence. In response to the section of the interim final rule with comment period on modification of limitations on redesignation by the MGCRB, it received seven timely pieces of correspondence.

On August 17, 2015, CMS published an interim final rule with comment period (August 2015 IFC) that appeared in the *Federal Register* as part of the FY 2017 IPPS/LTCH PPS final rule. CMS addressed the legislative extensions relating to the payment adjustment for low-volume hospitals and the MDH program (CMS-rule 1632-IFC). 80 Fed. Reg. 49,594. In response to this interim final rule with comment period, CMS received 14 timely pieces of correspondence. However, all of the correspondence included public comments that were outside the scope of the provisions of the interim final rule with comment period. CMS states that it is finalizing this interim final rule with comment. CMS noted that some of these public comments were outside of the scope of the proposed rule. CMS responded to comments within the scope of the proposed rule in the final rule.

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

According to CMS, the August 2015 IFC and this final rule do not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget (OMB) under the authority of the Paperwork Reduction Act of 1995. However, in the April 2016 IFC (81 Fed. Reg. 23,435), CMS stated that it had requested an emergency review of an information collection. In compliance with the requirement of section 3506(c)(2)(A) of PRA, CMS submitted the following for emergency review to OMB. CMS requested an emergency review and approval under 5 CFR 1320.13(a)(2)(i) of the implementing regulations of PRA in order to implement the provisions of section 231 of Public Law 114-113 as expeditiously as possible. CMS stated that public harm was reasonably likely to ensue if the normal clearance procedures were followed because the approval of this information collection is essential to ensuring that otherwise qualifying grandfathered urban hospital-within-hospitals (HwHs) are not unduly delayed in attempting to obtain relief provided by the temporary exception by applying to be treated as rural before the temporary exception expires on December 31, 2016.

CMS stated in the April 2016 IFC that, for the purposes of implementing subparagraph (E) of section 1886(m)(6) of the Act as provided by Public Law 114-113, CMS revised the regulations at § 412.522(b)(2)(ii)(B)(2) to utilize the same administrative mechanisms used in the existing rural reclassification process for urban subsection (d) hospitals under § 412.103. CMS also stated that it will allow grandfathered LTCH HwHs (previously defined in that IFC) to apply to their CMS regional office for treatment as being located in a rural area for the sole purpose of qualifying for this temporary exception from the application of the site neutral payment rate.

CMS stated in the April 2016 IFC that, for urban subsection (d) hospitals, and now temporarily LTCHs, it implemented the rural reclassification provision in the regulations at § 412.103. In general, the provisions of § 412.103 provides that a hospital located in an urban area may be reclassified as a rural hospital if it submits an application in accordance with the established criteria. The hospital must also meet certain conditions, which include being located in a rural census tract of a metropolitan statistical area, or in an area designated by any law or regulation of the state as a rural area, or designated as a rural hospital by state law or regulation. Paragraph (b) of § 412.103 sets forth application requirements for a hospital seeking reclassification as rural under that section, which includes a written application mailed to the CMS regional office that contains an explanation of how the hospital meets the condition that constitutes the request for reclassification, including data and documentation necessary to support the request. As provided in paragraphs (c) and (d) of § 412.103, the CMS regional office reviews the application and notifies the hospital of its approval or disapproval of the request within 60 days of the filing date, and a hospital that satisfies any of the criteria set forth § 412.103(a) is considered as being located in the rural area of the state in which the hospital is located as of that filing date.

CMS noted in the April 21, 2016, IFC that this policy only allows grandfathered LTCH HwHs to apply for this reclassification, and the rural treatment will only extend to this temporary exception for certain wound care discharges from the site neutral payment rate (meaning a grandfathered HwH LTCH will not be treated as rural for any other reason, including, but not limited to, the 25-percent threshold policy and wage index policies). CMS also noted that the any rural treatment under § 412.103 for a grandfathered HwH LTCH expires at the same time as this temporary provision (that is, December 31, 2016).

In the April 2016 IFC (81 FR 23,436), CMS estimated that each application will require 2.5 hours of work from each LTCH. Based on the current information it had received from the Medicare Administrative Contractors (MACs), out of the approximately 120 current LTCHs that existed in 1995, which is a necessary but not sufficient condition to be a grandfathered HwH, there are approximately 5 hospitals that currently meet the criteria of being a grandfathered HwH and would not be precluded from submitting an application. CMS noted that as the MACs continue to update the list of grandfathered HwH that the number of potential applicants could increase. Because it is possible that the number of applicants could rise to 10 or more, in an abundance of caution, CMS treated this information collection as being subject to PRA. Therefore, CMS estimated that the aggregate number of hours associated with this request across all currently estimated eligible hospitals will be 12.5. CMS estimated a current, average salary of $29 per hour (based on the Bureau of Labor Statistics Current Population Survey, plus 100 percent for fringe benefits ($58 per hour)). Therefore, CMS estimated the total one-time costs associated with this request will be $725 (12.5 hours × $58 per hour).

In the April 2016 IFC, CMS stated that written comments and recommendations from the public would be considered for this emergency information collection request if received by April 28, 2016. CMS requested OMB review and approval of this information collection request by May 5, 2016, with a 180-day approval period. CMS states that it gave two access websites and a telephone number in the IFC where the public could obtain copies of a supporting statement and any related forms for the proposed collection(s). CMS states that it did not receive any public comments in response to this information collection request and, therefore, are finalizing it as it was set forth in the April 2016 IFC, without modification. OMB approved the Emergency PRA package on May 9, 2016, for the aforementioned burden, which is under OMB control number 0938-0907.

Statutory authorization for the rule

CMS stated that it promulgated the final rule under the authority of sections 1814, 1820, 1834, 1866, 1886, and 1899B of the Social Security Act, sections 123 of the Balanced Budget Refinement Act (Pub. L. No. 106-113), section 307 of the Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Benefits Improvement and Protection Act of 2000, Pub. L. No. 106-554, (BIPA), and pursuant to changes under the American Taxpayer Relief Act of 2012 (ATRA) Pub. L. 112-240 (Jan. 2, 2013), the Pathway for SGR Reform Act of 2013, Pub. L. No. 113-67 (Dec. 26, 2013), the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act), Pub. L. No. 113-185 (Oct. 6, 2014), the Medicare Access and CHIP Reauthorization Act of 2015, Pub. L. No. 114-10 (April 16, 2015), the Consolidated Appropriations Act, 2016, Pub. L. No. 114-113, (Dec. 18, 2015), and the Notice of Observation Treatment and Implication for Care Eligibility Act (the NOTICE Act), Pub. L. No. 114-42, (August 6, 2015).

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

CMS estimated that the final changes for FY 2017 acute care hospital operating and capital payments will redistribute amounts in excess of $100 million to acute care hospitals. The applicable percentage increase to the IPPS rates required by the statute, in conjunction with other payment changes in this final rule, will result in an estimated $987 million increase in FY 2017 operating payments (or 0.9 percent change) and an estimated $66 million increase in FY 2017 capital payments (or 0.8 percent change). These changes are relative to payments made in FY 2016. In addition, LTCHs are expected to experience a decrease in payments by $363 million in FY 2017 relative to FY 2016. In accordance with the provisions of Executive Order 12,866, the final rule was reviewed by the Office of Management and Budget.

Executive Order No. 13,132 (Federalism)

According to CMS, because the final rule does not impose any costs on state or local governments, the requirements of Executive Order 13,132 are not applicable.