



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

B-331594

November 26, 2019

The Honorable Chuck Grassley
Chairman
The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate

The Honorable Frank Pallone, Jr.
Chairman
The Honorable Greg Walden
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Richard Neal
Chairman
The Honorable Kevin Brady
Ranking Member
Committee on Ways and Means
House of Representatives

Subject: *Department of Health and Human Services, Centers for Medicare & Medicaid Services: Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Revisions of Organ Procurement Organizations Conditions of Coverage; Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Changes to Grandfathered Children’s Hospitals-Within-Hospitals; Notice of Closure of Two Teaching Hospitals and Opportunity To Apply for Available Slots*

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: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Revisions of Organ Procurement Organizations Conditions of Coverage; Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Changes to Grandfathered Children’s Hospitals-Within-Hospitals; Notice of Closure of Two Teaching Hospitals and Opportunity To Apply for Available Slots” (RIN: 0938-AT74). We received the rule on November 5, 2019. It was published in the *Federal Register* as a final rule with comment period on November 12, 2019. 84 Fed. Reg. 61142. The effective date of the rule is January 1, 2020.

The final rule revises the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for Calendar Year 2020 based on CMS's continuing experience with these systems. The final rule 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. Also, the final rule updates and refines the requirements for the Hospital Outpatient Quality Reporting Program and the ASC Quality Reporting Program. The final rule also establishes a process and requirements for prior authorization for certain covered outpatient department services; revises the conditions for coverage of organ procurement organizations; revises the regulations to allow grandfathered children's hospitals-within-hospitals to increase the number of beds without resulting in the loss of grandfathered status; and provides notice of the closure of two teaching hospitals and the opportunity to apply for available slots for purposes of indirect medical education and direct graduate medical education payments.

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 was received by both Houses of Congress on November 5, 2019. 165 Cong. Rec. S6446 (daily ed. Nov. 6, 2019); 165 Cong. Rec. H8782 (daily ed. November 12, 2019). The final rule was published in the *Federal Register* on November 12, 2019. 84 Fed. Reg. 61142. The final rule has an effective date of January 1, 2020. Therefore, the final rule does not have the required 60-day delay in its 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. 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 Janet Temko-Blinder, Assistant General Counsel, at (202) 512-7104.

signed

Shirley A. Jones
Managing Associate General Counsel

Enclosure

cc: Calvin E. Dukes II
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: CHANGES TO HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEMS AND QUALITY REPORTING PROGRAMS; REVISIONS OF ORGAN PROCUREMENT ORGANIZATIONS CONDITIONS OF COVERAGE; PRIOR AUTHORIZATION PROCESS AND REQUIREMENTS FOR CERTAIN COVERED OUTPATIENT DEPARTMENT SERVICES; POTENTIAL CHANGES TO THE LABORATORY DATE OF SERVICE POLICY; CHANGES TO GRANDFATHERED CHILDREN’S HOSPITALS-WITHIN-HOSPITALS; NOTICE OF CLOSURE OF TWO TEACHING HOSPITALS AND OPPORTUNITY TO APPLY FOR AVAILABLE SLOTS”
(RIN: 0938-AT74)

(i) Cost-benefit analysis

The Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) estimated that under this final rule transfers from the federal government to hospitals and other providers who receive payment under the hospital outpatient prospective payment systems would amount to \$1,210 million. CMS further estimated transfers from the federal government to Medicare providers and suppliers through the ambulatory surgical center payment system would amount to \$100 million.

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

CMS determined the final rule will not have a significant impact on a substantial number of small entities. CMS also stated the final rule should not have a significant economic impact on approximately 609 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 stated the final rule 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 a notice of proposed rulemaking on August 9, 2019. 84 Fed. Reg. 39398. CMS received 3400 timely pieces of correspondence on the final rule. CMS opened another comment period on the rule which ends December 2, 2019.

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

CMS determined the final rule contains information collection requirements (ICRs) subject to the Act. The ICRs are associated with control numbers 0938-1109; 0938-1270; and a new ICR that is under development and will be submitted to the Office of Management and Budget (OMB) for approval. CMS estimated the total burden cost of the ICR to be \$1.58 million and the total cost for regulatory familiarization to be \$3.37 million.

Statutory authorization for the rule

CMS promulgated the final rule pursuant to sections 263a, 273, 495, 1302, 1302b-12, 1320b-8, 1395l, 1395m, 1395x, 1395y, 1395ff, 1395hh, 1395kk, 1395rr, 1395ww, and 1395ddd of title 42, United States Code.

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

CMS determined the final rule to be economically significant and submitted it to OMB for review.

Executive Order No. 13,132 (Federalism)

CMS determined the final rule will not have a substantial effect on state, local, or tribal governments, preempt state law, or otherwise have a federalism implication.