U.S. GOVERNMENT ACCOUNTABILITY OFFICE

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Washington, DC 20548

B-334822

December 7, 2022

The Honorable Ron Wyden
Chairman
The Honorable Mike Crapo
Ranking Member
Committee on Finance
United States Senate

The Honorable Frank Pallone, Jr.
Chairman
The Honorable Cathy McMorris Rodgers
Republican Leader
Committee on Energy and Commerce
House of Representatives

The Honorable Richard Neal
Chairman
The Honorable Kevin Brady
Republican Leader
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 Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating; COVID-19*

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 Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating; COVID-19" (RIN: 0938-AU82). We received the rule on November 7, 2022. It was published in the *Federal Register* as a final rule with comment period on November 23, 2022. 87 Fed. Reg. 71748. The effective date is January 1, 2023.

The final rule, according to CMS, revises the Medicare Hospital Outpatient Prospective Payment System (OPPS) and the Medicare Ambulatory Surgical Center (ASC) Payment

System for calendar year 2023 based on continuing experience with the systems. CMS explained that the rule describes changes to the amounts and factors used to determine payment rates for Medicare services paid under the OPPS and those paid under the ASC Payment System. Also, CMS stated the rule updates and refines the requirements for the Hospital Outpatient Quality Reporting Program, the ASC Quality Reporting Program, and the Rural Emergency Hospital Quality Reporting (REH) Program. Additionally, CMS stated the rule updates the requirements for Organ Acquisition, REHs, Prior Authorization, and Overall Hospital Quality Star Rating.

Further, CMS stated the rule establishes a new provider type for REHs, and finalizes proposals regarding payment policy, quality measures, and enrollment policy for REHs. Additionally, CMS noted it is finalizing the conditions of participation that REHs must meet in order to participate in the Medicare and Medicaid programs. CMS explained that the rule finalizes changes to the Critical Access Hospitals (CAHs) conditions of participation for the location and distance requirements, patient's rights requirements, and flexibilities for CAHs that are part of a larger health system. Finally, CMS stated that it is finalizing as implemented a number of provisions included in the COVID-19 interim final rules with comment period.

The Congressional Review Act 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 the House of Representatives and the Senate on November 7, 2022. 168 Cong. Rec. H8493 (daily ed. Nov. 14, 2022); 168 Cong. Rec. S6776 (daily ed. Nov. 17, 2022). The rule was published in the *Federal Register* on November 23, 2022. 87 Fed. Reg. 71748. The rule has a stated effective date of January 1, 2023. Therefore, based on the date of publication, 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 Shari Brewster, Assistant General Counsel, at (202) 512-6398.

Shirley A. Jones
Managing Associate General Counsel

Enclosure

cc: Calvin E. Dukes II
Regulations Coordinator
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: HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEMS AND QUALITY REPORTING PROGRAMS; ORGAN ACQUISITION; RURAL EMERGENCY HOSPITALS: PAYMENT POLICIES, CONDITIONS OF PARTICIPATION, PROVIDER ENROLLMENT, PHYSICIAN SELF-REFERRAL; NEW SERVICE CATEGORY FOR HOSPITAL OUTPATIENT DEPARTMENT PRIOR AUTHORIZATION PROCESS; OVERALL HOSPITAL QUALITY STAR RATING; COVID-19"
(RIN: 0938-AU82)

(i) Cost-benefit analysis

The Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) estimated the costs and benefits of this final rule. CMS estimated that the Hospital Outpatient Prospective Payment System (OPPS) transfers from calendar year 2022 to calendar year 2023 associated with the calendar year 2023 Hospital Outpatient Department fee schedule increase will be $2.53 billion per year from the federal government to outpatient hospitals and other providers who receive payment under the Hospital OPPS. CMS estimated costs in calendar year 2023 of -$11,688,943 million, and regulatory familiarization costs of $17.204 million. Additionally, CMS estimated economic cost impacts of the rule on the private sector, Medicare, and the total economic impact to the health sector for years one, five, and ten, respectively.

CMS stated there will be quantifiable benefits due to an expected reduction in the unnecessary utilization of the new Medicare outpatient department service category subject to prior authorization. CMS stated it is difficult to project the exact decrease in unnecessary utilization.

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

CMS determined that this final rule will not have a significant impact on a substantial number of small entities. CMS further determined that the rule should not have a significant impact on the approximately 549 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 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 27, 2022, CMS published a proposed rule. 87 Fed. Reg. 44502. CMS received approximately 1,599 timely pieces of correspondence on the proposed rule from individuals, elected officials, providers and suppliers, practitioners, and advocacy groups. CMS responded to the comments in this final rule.

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

CMS stated that this final rule contains information collection requirements subject to PRA for the Hospital Outpatient Quality Reporting Program (Office of Management and Budget (OMB) Control Number 0938-1109); Ambulatory Surgical Center Quality Reporting Program (OMB Control Number 0938-1270); Addition of a New Service Category for Hospital Outpatient Department Prior Authorization Process (OMB Control Number 0938-1368); Payment Adjustments for Domestic NIOSH-Approved Surgical N95 Respirators (CMS-10821); Rural Emergency Hospital Provider Enrollment Requirements (OMB Control Number 0938-0685); and Rural Emergency Hospitals and Critical Access Hospitals Conditions of Participation (OMB Control Number 0938-1043). CMS provided estimates of associated burdens in the final rule.

Statutory authorization for the rule

CMS promulgated this final rule pursuant to sections 263a, 405(a), 1302, 1320b-12, 1395(hh), 1395d(d), 1395f(b), 1395g, 1395i-3, 1395l(a), (i), (n) and (t), 1395m, 1395w-101 through 1395w-152, 1395x, 1395x(v), 1395x(kkk), 1395y(a), 1395aa(m), 1395cc, 1395ff, 1395hh, 1395kk, 1395nn, 1395rr, 1395tt, 1395ww, 1395ww(k), and 1395ddd of title 42, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

CMS stated that this final rule is economically significant under the Order and has been reviewed by OMB.

Executive Order No. 13132 (Federalism)

CMS determined that this final rule will not have a substantial direct effect on state, local, or tribal governments, preempt state law, or otherwise have a federalism implication. Further, CMS determined that the rule should not have a significant effect on small rural hospitals.