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December 5, 2023

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

The Honorable Cathy McMorris Rodgers
Chair
The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Jason Smith
Chairman
The Honorable Richard Neal
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; Quality Reporting Programs; Payment for Intensive Outpatient Services in Hospital Outpatient Departments, Community Mental Health Centers, Rural Health Clinics, Federally Qualified Health Centers, and Opioid Treatment Programs; Hospital Price Transparency; Changes to Community Mental Health Centers Conditions of Participation, Changes to the Inpatient Prospective Payment System Medicare Code Editor; Rural Emergency Hospital Conditions of Participation Technical Correction*

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; Quality Reporting Programs; Payment for Intensive Outpatient Services in Hospital Outpatient Departments, Community Mental Health Centers, Rural Health Clinics, Federally Qualified Health Centers, and Opioid Treatment Programs; Hospital Price Transparency; Changes to Community Mental Health Centers Conditions of Participation, Changes to the Inpatient Prospective Payment System Medicare Code Editor; Rural Emergency Hospital Conditions of Participation Technical Correction” (RIN: 0938-AV09). We received the rule on November 1, 2023. It was published in the *Federal*

Register as a final rule on November 22, 2023. 88 Fed. Reg. 81540. The stated effective date is January 1, 2024.

CMS states that the final rule revises the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for calendar year 2024. CMS further states that the final rule: (1) describes changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment system; (2) updates and refines the requirements for the Hospital Outpatient Quality Reporting (OOR) Program, the ASC Quality Reporting (ASCQR) Program, and the Rural Emergency Hospital Quality Reporting (REHQR) Program; (3) establishes a payment for certain intensive outpatient (IOP) services under Medicare, beginning January 1, 2024; (4) updates and refines requirements for hospitals to make public their standard charge information and enforcement of hospital price transparency; (5) finalizes changes to the Community Mental Health Centers (CMHC) Conditions of Participation (CoPs) to provide requirements for furnishing IOP services; (6) finalizes the proposed personnel qualifications for Mental Health Counselors (MHC) and Marriage and Family Therapists; (7) removes discussion of the Inpatient Prospective Payment System (IPPS) Medicare Code Editor (MCE) from the annual IPPS rulemakings, beginning with the fiscal year 2025 rulemaking; and (8) makes a technical correction to the Rural Emergency Hospital (REH) CoPs under the standard for the designation and certification of REHs.

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 *Congressional Record* does not yet reflect receipt by the Senate or House of Representatives, but CMS provided documentation showing receipt by both houses on November 1, 2023. Email from Regulations Coordinator, CMS, to CRA Rules, GAO, *Subject: Official Submission - RIN 0938-AV09* (Nov. 1, 2023). The rule was published in the *Federal Register* on November 22, 2023, and it has a stated effective date of January 1, 2024. 88 Fed. Reg. 81540. 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 Shari Brewster, Assistant General Counsel, at (202) 512-6398.



Shirley A. Jones
Managing Associate General Counsel

Enclosure

cc: Calvin E. Dukes II
Regulations Coordinator
Centers for Medicare & Medicaid Services
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; QUALITY REPORTING
PROGRAMS; PAYMENT FOR INTENSIVE OUTPATIENT SERVICES IN HOSPITAL
OUTPATIENT DEPARTMENTS, COMMUNITY MENTAL HEALTH CENTERS,
RURAL HEALTH CLINICS, FEDERALLY QUALIFIED HEALTH CENTERS,
AND OPIOID TREATMENT PROGRAMS; HOSPITAL PRICE TRANSPARENCY;
CHANGES TO COMMUNITY MENTAL HEALTH CENTERS
CONDITIONS OF PARTICIPATION, CHANGES TO THE INPATIENT PROSPECTIVE
PAYMENT SYSTEM MEDICARE CODE EDITOR; RURAL EMERGENCY HOSPITAL
CONDITIONS OF PARTICIPATION TECHNICAL CORRECTION”
(RIN: 0938-AV09)

(i) Cost-benefit analysis

The Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) analyzed the costs and benefits of this final rule. CMS’s analysis included discussion of the impacts of outpatient prospective payment system (OPPS) changes, the impacts of updated wage indexes, the impacts of the rural adjustment and cancer hospital payment adjustment, the impacts of the outpatient department (OPD) fee schedule increase factor, the impacts of the final ambulatory surgical center (ASC) payment update, and the impacts of hospital prices transparency.

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

CMS certified that the final rule will have a significant economic impact on a substantial number of small entities by causing a change in such entities’ revenue of more than 3 to 5 percent. CMS also estimated that the final rule will increase payments to small rural hospitals by approximately 5 percent, therefore having what CMS deems to be a negligible impact on approximately 554 small rural hospitals. CMS stated that it provided a regulatory flexibility analysis and regulatory impact analysis through the preamble of the final rule.

(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 the final rule will not impose any mandate that will result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of more than \$177 million in any one year.

(iv) Agency actions relevant to the Administrative Pay-As-You-Go-Act of 2023, Pub. L. No. 118-5, div. B, title III, 137 Stat 31 (June 3, 2023)

Section 270 of the Administrative Pay-As-You-Go-Act of 2023 amended 5 U.S.C. § 801(a)(2)(A) to require GAO to assess agency compliance with the Act, which establishes requirements for administrative actions that affect direct spending, in GAO’s major rule reports. In guidance to Executive Branch agencies, issued on September 1, 2023, the Office of Management and Budget (OMB) instructed that agencies should include a statement explaining that either: “the Act does not apply to this rule because it does not increase direct spending; the Act does not apply to this rule because it meets one of the Act’s exemptions (and specifying the relevant exemption); the OMB Director granted a waiver of the Act’s requirements pursuant to section 265(a)(1) or (2) of the Act; or the agency has submitted a notice or written opinion to the OMB Director as required by section 263(a) or (b) of the Act” in their submissions of rules to GAO under the Congressional Review Act. OMB, *Memorandum for the Heads of Executive Departments and Agencies*, Subject: Guidance for Implementation of the Administrative Pay-As-You-Go Act of 2023, M-23-21 (Sept. 1, 2023), at 11–12. OMB also states that directives in the memorandum that supplement the requirements in the Act do not apply to proposed rules that have already been submitted to the Office of Information and Regulatory Affairs, however agencies must comply with any applicable requirements of the Act before finalizing such rules.

The final rule does not discuss the Act. However, in its submission to us, CMS stated that “this Act does not apply to this rule because it meets one of the Act’s exemptions, the direct spending is less than \$100 million in any given year during such 10-year period.”

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

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

On July 31, 2023, CMS published a proposed rule. 88 Fed. Reg. 49552. CMS stated that it received approximately 3,777 timely pieces of correspondence regarding the proposed rule from individuals, elected officials, providers and suppliers, practitioners, manufacturers, and advocacy groups. CMS responded to comments in the final rule.

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

CMS determined that the final rule contains information collection requirements under the Act. CMS provided the below burden estimates with respect to the final rule.

Change to Hospital Outpatient Quality Reporting (OQR) Program Information Collection Burden (OMB Control Number 0938-1109):

Calendar Year 2027: increase of 16,193 hours and total cost estimate of \$344,131.
Calendar Year 2028: increase of 16,472 hours and total cost estimate of \$358,683.
Calendar Year 2029: increase of 18,427 hours and total cost estimate of \$460,531.
Calendar Year 2030: increase of 67,283 hours and total cost estimate of \$1,507,424.
Calendar Year 2031: increase of 67,562 hours and total cost estimate of \$1,521,976.
Calendar Year 2032: increase of 67,842 hours and total cost estimate of \$1,536,526.

Change to Ambulatory Surgical Center Quality Reporting (ASCQR) Program Information Collection Burden (OMB Control Number 0938-1270):

Calendar Year 2027: increase of 74 hours and total cost estimate of \$1,524.
Calendar Year 2028: increase of 77 hours and total cost estimate of \$1,706.
Calendar Year 2029: increase of 81 hours and total cost estimate of \$1,889.
Calendar Year 2030: increase of 295 hours and total cost estimate of \$6,323.
Calendar Year 2031: increase of 298 hours and total cost estimate of \$6,497.
Calendar Year 2032: increase of 302 hours and total cost estimate of \$6,670.

Change to Rural Emergency Hospital Quality Reporting (REHQR) Program Information Collection Burden (CMS requesting OMB authorization for a new information collection request):

Calendar Year 2024: increase of 9,101 hours and total cost estimate of \$474,344.

Information Collection Requirements Related to Hospital Price Transparency (CMS requesting OMB review and approval under OMB Control Number 0938-1369): total one-time burden estimate for the first year of 120 hours per hospital with an initial one-time national burden of \$75,147,235.80; estimated ongoing annual national burden of 383,292 hours with an annual national cost of \$32,370,571.

Statutory authorization for the rule

CMS promulgated the final rule pursuant to sections 263a, 300gg-18, 405(a), 1302, 1320b-12, 1395i-3, 1395l(t), 1395m, 1395x, 1395y(a), 1395aa(m), 1395cc, 1395ff, 1395hh, 1395kk, 1395rr, 1395ww(k), and 1395ddd of title 42, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

CMS stated that OMB's Office of Information and Regulatory Affairs (OIRA) determined that the final rule is significant pursuant to the Order. Accordingly, CMS provided a regulatory impact analysis. CMS estimated that the total increase in federal government expenditures under the OPSS for calendar year (CY) 2024, compared to CY 2023, due to the changes to the OPSS in the final rule, will be approximately \$2.2 billion. CMS further estimated that the OPSS expenditures, including beneficiary cost-sharing, for CY 2024, will be approximately \$88.9 billion, which is approximately \$6.0 billion higher than estimated OPSS expenditures in CY 2023. Additionally, CMS estimated that the total increase in Medicare expenditures (not including beneficiary cost-sharing) under the Medicare ASC payment system for CY 2024 compared to CY 2023, will be approximately \$207 million.

Executive Order No. 13132 (Federalism)

CMS determined that the OPSS and ASC provisions included in the final rule will not have a substantial direct effect on state, local, or tribal governments, preempt state law, or otherwise have a federalism implication.