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December 12, 2024

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 and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs, including the Hospital Inpatient Quality Reporting Program; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information; Medicaid and CHIP Continuous Eligibility; Medicaid Clinic Services Four Walls Exceptions; Individuals Currently or Formerly in Custody of Penal Authorities; Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals; and All-Inclusive Rate Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities*

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 and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs, including the Hospital Inpatient Quality Reporting Program; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information; Medicaid and CHIP Continuous Eligibility; Medicaid Clinic Services Four Walls Exceptions; Individuals Currently or Formerly in Custody of Penal Authorities; Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals; and All-Inclusive Rate Add-On Payment for High-Cost Drugs Provided by Indian

Health Service and Tribal Facilities” (RIN: 0938-AV35). We received the rule on November 6, 2024. It was published in the *Federal Register* on November 27, 2024. 89 Fed. Reg. 93912. The stated effective date of the rule is January 1, 2025.

According to CMS, this rule revises the Medicare Hospital Outpatient Prospective Payment System (OPPS) and the Medicare Ambulatory Surgical Center (ASC) payment system for calendar year 2025 based on CMS’s continuing experience with these systems. CMS stated that it described 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. CMS also stated that the rule updates the requirements for the Hospital Outpatient Quality Reporting Program, Rural Emergency Hospital Quality Reporting Program, ASC Quality Reporting Program, and Hospital Inpatient Quality Reporting Program.

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 House of Representatives received the rule on November 6, 2024. 170 Cong. Rec. H5975 (daily ed. Nov. 13, 2024). The Senate received the rule on November 7, 2024. 170 Cong. Rec. S6525 (daily ed. Nov. 12, 2024). The rule was published in the *Federal Register* on November 27, 2024. 89 Fed. Reg. 93912. The stated effective date of the rule is January 1, 2025. Therefore, the stated effective date is less than 60 days from the date of publication in the *Federal Register*.

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 Charlie McKiver, Assistant General Counsel, at (202) 512-5992.



Shirley A. Jones
Managing Associate General Counsel

Enclosure

cc: Christina Kang
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 AND MEDICAID PROGRAMS: HOSPITAL OUTPATIENT
PROSPECTIVE PAYMENT AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEMS;
QUALITY REPORTING PROGRAMS, INCLUDING THE HOSPITAL INPATIENT QUALITY
REPORTING PROGRAM; HEALTH AND SAFETY STANDARDS FOR OBSTETRICAL
SERVICES IN HOSPITALS AND CRITICAL ACCESS HOSPITALS; PRIOR AUTHORIZATION;
REQUESTS FOR INFORMATION; MEDICAID AND CHIP CONTINUOUS ELIGIBILITY;
MEDICAID CLINIC SERVICES FOUR WALLS EXCEPTIONS; INDIVIDUALS CURRENTLY
OR FORMERLY IN CUSTODY OF PENAL AUTHORITIES; REVISION TO MEDICARE
SPECIAL ENROLLMENT PERIOD FOR FORMERLY INCARCERATED INDIVIDUALS;
AND ALL-INCLUSIVE RATE ADD-ON PAYMENT FOR HIGH-COST DRUGS
PROVIDED BY INDIAN HEALTH SERVICE AND TRIBAL FACILITIES”
(RIN: 0938-AV35)

(i) Cost-benefit analysis

The Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS) conducted detailed economic analyses for this rule. See 89 Fed. Reg. 94550 (Nov. 27, 2024). CMS provided tables summarizing the estimated impact of the rule on aggregate payments for selected procedures in dollars and in percent change. See 89 Fed. Reg. 94558–94559.

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

According to CMS, the Secretary of HHS has certified that this rule will have a significant economic impact on a substantial number of small entities. 89 Fed. Reg. 94585.

(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 rule does not mandate any requirements for state, local, or tribal governments. 89 Fed. Reg. 94585. CMS stated that for the private sector facilities, the regulatory impact analysis, together with the remainder of the preamble, constitutes the analysis required under the Act. *Id.*

(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.

CMS did not discuss the Act in this rule. In its submission to us, CMS stated that it provided a statement on the Act as a separate document. However, CMS did not provide such a document to us.

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

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

On July 22, 2024, CMS published a proposed rule. 89 Fed. Reg. 59186. CMS stated that it received approximately 3,500 timely pieces of correspondence on the proposed rule. 89 Fed. Reg. 93921. CMS responded to comments in this rule.

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

CMS determined that this rule contains information collection requirements under PRA that were previously submitted to OMB for approval under various OMB control numbers. See 89 Fed. Reg. 94522–94548.

Statutory authorization for the rule

CMS promulgated this rule pursuant to sections 1395hh and 1302 of title 42, United States Code, and section 1833 of the Social Security Act.

Executive Order No. 12866 (Regulatory Planning and Review)

The Office of Information and Regulatory Affairs determined that this rule is significant under the Order. CMS stated that OMB has reviewed the rule. 89 Fed. Reg. 94550.

Executive Order No. 13132 (Federalism)

CMS determined that this rule does not have federalism implications. See 89 Fed. Reg. 94585.