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

B-336637

September 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 and the Children's Health Insurance 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 2025 Rates; Quality Programs Requirements; and Other Policy Changes

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 and the Children's Health Insurance 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 2025 Rates; Quality Programs Requirements; and Other Policy Changes" (RIN: 0938-AV34). We received the rule on August 2, 2024. It was published in the *Federal Register* on August 28, 2024. 89 Fed. Reg. 68986. With the exception of instruction 2 (§ 405.1845), instruction 29 (§ 482.42(e)) and instruction 31 (§ 485.640(d)), the stated effective date of the rule is October 1, 2024. The regulation at § 405.1845 is effective January 1, 2025. The regulations at §§ 482.42(e) and 485.640(d) are effective on November 1, 2024.

According to CMS, this rule revises the Medicare hospital inpatient prospective payment systems for operating and capital-related costs of acute care hospitals; makes changes relating

to Medicare graduate medical education for teaching hospitals; updates the payment policies and the annual payment rates for the Medicare prospective payment system for inpatient hospital services provided by long-term care hospitals; and makes other policy-related changes.

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 Senate received the rule on July 31, 2024. 170 Cong. Rec. S5768 (daily ed. Aug. 1, 2024). The House of Representatives received the rule on August 2, 2024. 170 Cong. Rec. H5005 (daily ed. Aug. 23, 2024). The rule was published in the *Federal Register* on August 28, 2024. 89 Fed. Reg. 68986. With the exception of two regulations that will be effective November 1, 2024, and one regulation that will be effective January 1, 2025, the rule has a stated effective date of October 1, 2024. Therefore, the stated effective date is less than 60 days from the publication 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 Charlie McKiver, Assistant General Counsel, at (202) 512-5992.

Shirley A. Jones

Managing Associate General Counsel

Enclosure

cc: Calvin E. Dukes II

Regulations Coordinator

Department of Health and Human Services

Page 2 B-336637

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 AND THE CHILDREN'S HEALTH INSURANCE 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 2025 RATES; QUALITY PROGRAMS REQUIREMENTS; AND OTHER POLICY CHANGES" (RIN: 0938-AV34)

(i) Cost-benefit analysis

The Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS) prepared an analysis of the costs and benefits for this rule. See 89 Fed. Reg. 68986, 68993–94 (Aug. 28, 2024).

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

CMS stated that the Secretary of HHS has certified that this rule would have a significant economic impact on a substantial number of small entities. See 89 Fed. Reg. at 70042. CMS also stated that the rule would affect payments to a substantial number of small rural hospitals, as well as other classes of hospitals, and the effects on some hospitals may be significant. *Id.* at 69994.

(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 will not impose any mandates on state, local, or tribal governments, in the aggregate, or on the private sector, of \$100 million or more, adjusted annually for inflation, in any one year. See 89 Fed. Reg. at 70043.

(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*

Page 3 B-336637

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 discussed the Act in the rule. However, we identified no such discussion in the rule.

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

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

On May 2, 2024, CMS issued a proposed rule. 89 Fed. Reg. 35934. CMS stated that it received comments from various interested parties. 89 Fed. Reg. 69626. CMS summarized and responded to comments in the rule. *Id.* CMS noted that it did not address comments received with respect to provisions of the proposed rule that CMS is not finalizing at this time. *Id.*

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

CMS determined that this rule contains information collection requirements under the Act. *See* 89 Fed. Reg. 69891–69909.

Statutory authorization for the rule

CMS promulgated this rule pursuant to sections 1302 and 1395hh of title 42 of the United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

CMS stated that this rule is economically significant under the Order and that OMB has reviewed the rule. See 89 Fed. Reg. 69994.

Executive Order No. 13132 (Federalism)

CMS determined that this rule would not have a substantial direct effect on state or local governments, preempt states, or otherwise have a federalism implication. See 89 Fed. Reg. 70043.

Page 4 B-336637