U.S. GOVERNMENT ACCOUNTABILITY OFFICE

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December 5, 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 and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs To Provide Refunds With Respect to Discarded Amounts; and COVID-19 Interim Final Rules*

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; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs To Provide Refunds With Respect to Discarded Amounts; and COVID-19 Interim Final Rules" (RINs: 0938-AU81, 0938-AU95, 0938-AU31, 0938-AU32) (final rule). We received the final rule on November 3, 2022. It was published in the *Federal Register*, as a final rule and interim final rules, on November 18, 2022. 87 Fed. Reg. 69404. The stated effective date of the final rule is January 1, 2023.

According to CMS, this final rule addresses changes to the Physician Fee Schedule; other changes to Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice, relative value of services, and changes in the statute; Medicare Shared Savings Program requirements; updates to the Quality Payment Program; Medicare coverage of opioid use disorder services furnished by opioid treatment programs; updates to certain Medicare and Medicaid provider enrollment policies, including for skilled nursing facilities; updates to conditions of payment for durable medical equipment, prosthetics, orthotics, and supplies fee schedule suppliers; healthcare common procedural coding system level II coding and payment for wound care management products; electronic prescribing for controlled substances for a covered Part D drug under a prescription drug plan or an MA-PD plan under the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (SUPPORT Act);[1] updates to the Medicare Ground Ambulance Data Collection System; provisions under the Infrastructure Investment and Jobs Act; and finalizes the calendar year 2022 Methadone Payment Exception for Opioid Treatment Programs interim final rule with comment period. CMS stated that it is also finalizing, as implemented, a few provisions included in the Coronavirus Disease 2019 interim final rules with comment period.

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). This final rule was published in the *Federal Register* on November 18, 2022. 87 Fed. Reg. 69404. The Congressional Record does not reflect the date of receipt by either House of Congress. The stated effective date of the final rule is January 1, 2023. 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
Department of Health and Human Services

[1] Pub. L. No. 115-271, 132 Stat 3894 (Oct. 24, 2018).

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 AND MEDICAID PROGRAMS; CY 2023 PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE AND OTHER CHANGES TO PART B PAYMENT AND COVERAGE POLICIES; MEDICARE SHARED SAVINGS PROGRAM REQUIREMENTS; IMPLEMENTING REQUIREMENTS FOR MANUFACTURERS OF CERTAIN SINGLE-DOSE CONTAINER OR SINGLE-USE PACKAGE DRUGS TO PROVIDE REFUNDS WITH RESPECT TO DISCARDED AMOUNTS; AND COVID-19 INTERIM FINAL RULES"
(RINS: 0938-AU81, 0938-AU95, 0938-AU31, 0938-AU32)

(i) Cost-benefit analysis

The Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS) provided an accounting statement, which includes estimates of calendar year 2023, annualized monetized transfers. For the Physician Fee Schedule Conversion Factor update, CMS estimates a decrease in expenditures of $2.2 billion from the federal government to physicians, other practitioners, providers, and suppliers who receive payment under Medicare. CMS also estimates a decrease of $0.6 billion in transfers of beneficiary cost coinsurance from beneficiaries to the federal government. Lastly, CMS provided primary estimates that show a decrease of $1,139 million in transfers from the federal government to accountable care organizations at a 7 percent discount rate and $1,197 million at a 3 percent discount rate for calendar years 2023 through 2024.

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

CMS stated that the analysis and discussion provided in the regulatory impact analysis for this final rule, as well as analysis provided elsewhere in the final rule, is intended to comply with the requirements of the RFA. The analysis includes 1) a statement of need; 2) overall impact; 3) changes in relative value unit impacts; 4) changes related to telehealth services; 5) other provisions of the regulation; 6) alternatives considered; 7) impact on beneficiaries; 8) estimating regulatory familiarization costs; 9) accounting statement; and 10) conclusion. Additionally, the Secretary of HHS certified that the final rule will not have a significant impact on the operations of a substantial number of 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 will impose no mandates on state, local, or tribal governments or on 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 29, 2022, CMS released a proposed rule. 87 Fed. Reg. 45860. CMS addressed comments relevant to the topics discussed throughout the various sections of the preamble in the final rule.

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

CMS determined that this final rule contains information collection requirements (ICRs) under the PRA. CMS stated that it will submit ICR changes to the Office of Management and Budget (OMB) for review. CMS prepared a summary of the annual burden estimates for changes made by this final rule. The ICRs included in the summary of annual burden estimates for changes include: "Registration, Attestation, Dispute Resolution and Correction, Assumptions Document and Data Retention Requirements for Open Payments" (OMB Control Number 0938-1237); "Dispute Resolution for Discarded Drug Refunds" (OMB Control Number 0938-NEW (CMS-10835)); "Manufacturer Submission of Average Sales Price (ASP) Data for Medicare Part B Drugs and Biological and Supporting Regulations" (OMB Control Number 0938-0921); "CMS Medicare Part D E-Prescribing Tools in 42 CFR 423.128(d)(1) and 423.160" (OMB Control Number 0938-1396); and "Quality Payment Program/Merit-Based Incentive Payment System (MIPS)" (OMB Control Number 0938-1314). According to CMS, the final rule will decrease total annual burden hours by 635,999.33 hours and decrease total cost by $71,741,739.

Statutory authorization for the rule

CMS promulgated this final rule pursuant to sections 263a, 405, 1302, 1306, 1320b-12, 1395m, 1395x, 1395w-101 through 1395w-152, 1395y, 1395ff, 1395hh, 1395kk, 1395nn, 1395rr, 1395ww, 1395ddd, and 1395jjj of title 42, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

CMS determined that this final rule is economically significant under the Order. CMS stated that it, in accordance with the Order, prepared a regulatory impact analysis that presents the costs and benefits of the rulemaking.

Executive Order No. 13132 (Federalism)

CMS determined that this final rule does not impose any costs on state or local governments, and, therefore, the requirements of the Order are not applicable.