



441 G St. N.W.
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May 19, 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
Ranking Member
Committee on Ways and Means
House of Representatives

Subject: *Department of Health and Human Services, Centers for Medicare & Medicaid Services: Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency*

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; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency” (RINs: 0938-AU30, 0938-AU31, and 0938-AU33). We received the rule on May 5, 2022. It was published in the *Federal Register* as a final rule on May 9, 2022. 87 Fed. Reg. 27704. The effective date is June 28, 2022, except for amendatory instructions 27 and 36 (regarding the definition of “negotiated price” at §§ 423.100 and 423.2305), which are effective January 1, 2024.

According to CMS, the final rule revises the Medicare Advantage program and Medicare Prescription Drug Benefit program regulations to implement changes related to marketing and

communications, past performance, Star Ratings, network adequacy, medical loss ratio reporting, special requirements during disasters or public emergencies, and pharmacy price concessions. CMS stated this final rule will also revise regulations related to dual eligible special needs plans, other special needs plans, and cost contract plans. Finally, CMS stated the final rule finalizes certain Star Ratings provisions that were included in two prior interim final rules.

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 final rule was published in the *Federal Register* on May 9, 2022. 87 Fed. Reg. 27704. The final rule has a stated effective date of June 28, 2022. Therefore, based on the date of publication, the final rule does not have the required 60-day delay in its effective date, except for amendatory instructions 27 and 36 (regarding the definition of “negotiated price” at §§ 423.100 and 423.2305), which are effective January 1, 2024.

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.

A handwritten signature in cursive script that reads "Shirley A. Jones".

Shirley A. Jones
Managing Associate General Counsel

Enclosure

cc: Calvin E. Dukes II
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 PROGRAM; CONTRACT YEAR 2023 POLICY AND
TECHNICAL CHANGES TO THE MEDICARE ADVANTAGE AND MEDICARE
PRESCRIPTION DRUG BENEFIT PROGRAMS; POLICY AND REGULATORY
REVISIONS IN RESPONSE TO THE COVID-19 PUBLIC HEALTH EMERGENCY;
ADDITIONAL POLICY AND REGULATORY REVISIONS IN RESPONSE
TO THE COVID-19 PUBLIC HEALTH EMERGENCY”
(RINS: 0938-AU30, 0938-AU31 AND 0938-AU33)

(i) Cost-benefit analysis

The Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) estimated the final rule would lead to net annualized monetized costs in the amount of \$3.1 million at both the seven and three percent discount rates. CMS further estimated the final rule would create transfers from the Medicare Trust Fund to plan enrollees, pharmaceutical manufacturers, states, and providers of duals in the amount of \$4,341,700,000 at the seven percent discount rate and \$4,564,100,000 at the three percent discount rate. Finally, CMS estimated the final rule would create transfers to the U.S. Treasury in the amount of \$26 million at the seven percent discount rate and \$26.5 million at the three percent discount rate.

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

CMS certified the final rule would not have a significant economic impact on a substantial number of small entities.

(iii) Agency actions relevant to sections 202–205 of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. §§ 1532–1535

CMS determined the final rule will not mandate on an unfunded basis any requirements for state, local, or tribal governments, nor would it result in expenditures by the private sector above the UMRA threshold in any one year.

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

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

CMS published a proposed rule on January 12, 2022. 87 Fed. Reg. 1842. CMS received approximately 6,179 timely pieces of correspondence containing one or more comments. Comments were submitted by Medicare Advantage health plans, Medicare Prescription Drug Benefit Plan sponsors, beneficiaries, Medicare Advantage enrollee and beneficiary advocacy groups, trade associations, providers, pharmacies and drug companies, states, telehealth and health technology organizations, policy research organizations, actuarial and law firms, the Medicaid and CHIP Payment and Access Commission, the Medicare Payment Advisory

Commission, Members of Congress, and other vendor and professional associations. CMS addressed the comments in the final rule.

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

CMS determined the final rule contained information collection requirements (ICRs) subject to PRA. CMS identified the associated Office of Management & Budget (OMB) control numbers and summarized the burden for each ICR in the final rule. A description of the ICRs is provided below.

- ICR 42 C.F.R. § 422.107(f), Solicit Committee Members (OMB Control Number 0938-1422)
- ICR 42 C.F.R. § 422.101, Update HRA System (OMB Control Number 0938-1422)
- ICR 42 C.F.R. § 422.107(e), Update Contracts with D SNPS (OMB Control Number 0938-1410)
- ICR 42 C.F.R. § 422.107(e), Update Contracts (OMB Control Number 0938-0935)
- ICR 42 C.F.R. § 422.107(e)(1), Part C Contracts with only D SNPS (OMB Control Number 0938-0935)
- ICR 42 C.F.R. § 422.107(e)(1), Part D Contracts with only D SNPS (OMB Control Number 0938-0936)
- ICR 42 C.F.R. § 422.561, Update Contracts (OMB Control Number 0938-1410)
- ICR 42 C.F.R. § 422.116(f) Update Network Adequacy (OMB Control Number 0938-1346)
- ICR 42 C.F.R. §§ 422.2267(e)(31), 423.2267(e)(33), 1 Pager Multi-Language Insert (OMB Control Number 0938-1421)
- ICR 42 C.F.R. §§ 422.2460, 423.2460, MLR (OMB Control Number 0938-1232)
- ICR 42 C.F.R. §§ 423.100, 423.2305, Part D Pharmacy Price Concessions (ongoing costs of reporting PDEs) (OMB Control Number 0938-0982)
- ICR 42 C.F.R. §§ 423.100, 423.2305, Part D Pharmacy Price Concessions (one-time system change costs) (OMB Control Number 0938-0982)

Statutory authorization for the rule

CMS promulgated the final rule pursuant to sections 1302, 1306, 1395w-101 through 1395w-152, and 1395hh of title 42, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

CMS stated the final rule was economically significant and had been reviewed by OMB.

Executive Order No. 13132 (Federalism)

CMS determined the final rule will not significantly affect the states and that it follows the intent and letter of the law and does not usurp state authority beyond what the Medicare authorizing statute requires.