



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

B-332255

June 17, 2020

The Honorable Chuck Grassley
Chairman
The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate

The Honorable Frank Pallone, Jr.
Chairman
The Honorable Greg Walden
Ranking Member
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 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program*

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 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program” (RIN: 0938-AT97). We received the rule on May 22, 2020. It was published in the *Federal Register* as a final rule on June 2, 2020. 85 Fed. Reg. 33796. The effective date of the rule is August 3, 2020.

According to CMS, the final rule will revise regulations for the Medicare Advantage (Part C) program, Medicare Prescription Drug Benefit (Part D) program, and Medicare Cost Plan program to implement certain sections of the Bipartisan Budget Act of 2018, Pub. L. No. 115–123, 132 Stat. 64 (Feb. 9, 2018), and the 21st Century Cures Act, Pub. L. No. 114–255, 130 Stat. 1033 (Dec. 13, 2016). In addition, CMS states it will enhance the Part C and D programs, codify several existing CMS policies, and implement other technical 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). It was published in the *Federal Register* as a final rule on June 2, 2020. 85 Fed. Reg. 33796. However, as of June 17, 2020, receipt is not reflected by either House of Congress in the *Congressional Record*. According to an HHS official, the Senate confirmed receipt of the rule on June 15, 2020, and the House of Representatives confirmed receipt of the rule on June 16, 2020. See E-mail from Deputy Director, Office of Documents and Regulations Management, Office of the Secretary, Office of the Immediate Secretary, HHS, to Senior Staff Attorney, Appropriations Law Group, Office of General Counsel, GAO (Jun. 16, 2020, 4:00 PM EST). The rule has a stated effective date of August 3, 2020. 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.

A handwritten signature in black ink that reads "Shirley A. Jones". The signature is written in a cursive style with a large, looped initial 'S'.

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 HEALTH AND HUMAN SERVICES,
CENTERS FOR MEDICARE & MEDICAID SERVICES,
ENTITLED
“MEDICARE PROGRAM; CONTRACT YEAR 2021 POLICY AND TECHNICAL
CHANGES TO THE MEDICARE ADVANTAGE PROGRAM,
MEDICARE PRESCRIPTION DRUG BENEFIT PROGRAM, AND
MEDICARE COST PLAN PROGRAM”
(RIN: 0938-AT97)

(i) Cost-benefit analysis

The Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) conducted an economic analysis of this final rule for calendar years 2021 through 2030. According to CMS, the net annualized impact of this rule on the federal government, Medicare Advantage (Part C) organizations, and Medicare Prescription Drug Benefit (Part D) sponsors is a cost of about \$1.9 million per year at both the 7 percent and 3 percent discount rates. CMS estimates that the raw aggregate cost over 10 years is \$18.5 million. CMS also provides estimates of transfers for calendar years 2021 through 2030, noting that transfers between the Department of the Treasury and CMS (Medicare Trust Fund, Plans, and Sponsors) range from \$293.7 million at the 7 percent discount rate and \$334.5 million at the 3 percent discount rate.

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

CMS certified that this final rule does 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 states section 202 of the Act requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require the spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2020, that threshold is approximately \$156 million, according to CMS. Further, CMS noted that this final rule is not anticipated to have an unfunded effect on state, local, or tribal governments, in the aggregate, or on the private sector of \$154 million or more.

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

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

On February 18, 2020, CMS published a proposed rule, entitled “Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program [Part C], Medicare Prescription Drug Benefit Program [Part D], Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly.” 85 Fed. Reg. 9002 (Feb. 18, 2020). According to CMS, it received approximately 490 timely

pieces of correspondence containing multiple comments on the provisions implemented within this final rule from the proposed rule. CMS stated that comments were submitted by Part C health plans, Part D sponsors, Part C and beneficiary advocacy groups, trade associations, providers, pharmacies and drug companies, states, telehealth and health technology organizations, policy research organizations, actuarial and law firms, and other vendor and professional associations. The proposals currently being finalized in this final rule, according to the agency, range from minor clarifications to more significant modifications based on the comments received. CMS reiterated that it intends to address the proposals from the February 2020 proposed rule that are not included in this final rule in subsequent rulemaking. According to CMS, summaries of the public comments received and its responses to those public comments are set forth in the various sections of this final rule under the appropriate headings. CMS also noted that some of the public comments received for the provisions implemented in this final rule were outside of the scope of the proposed rule.

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

CMS determined that this final rule contains information collection requirements (ICRs) under the Act. CMS plans to submit each of the ICRs for review to the Office of Management and Budget (OMB). CMS is creating a new ICR regarding the Medicare Advantage Short Enrollment Form (OMB Control Number 0938–NEW). CMS will be updating an ICR related to the Medicare Advantage Long Enrollment Form (OMB Control Number 0938–0753), Special Supplemental Benefits for the Chronically Ill (OMB Control Number 0938–0763), and two additional forms related to Part C Medical Loss Ratio (OMB Control Number 0938–1252) and the Part D Election Period (OMB Control Number 0938–0964). The agency estimates that the total burden estimate is 332,806 hours and the total estimated annual cost is \$25,462,212.

Statutory authorization for the rule

CMS promulgated this final rule pursuant to sections 300e, 300e–5, 300e–9, 1302, 1306, 1395w–101 through 1395w–152, and 1395hh of title 42, United States Code; and section 9701 of title 31, United States Code.

Executive Order No. 12,866 (Regulatory Planning and Review)

According to the agency, this rule is economically significant under the Order, with over \$100 million in costs, benefits, or transfers annually.

Executive Order No. 13,132 (Federalism)

As stated by the agency, the Order establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. According to the agency, since this final rule does not impose any substantial costs on state or local governments, preempt state law or have federalism implications, the requirements of the Order are not applicable.