



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

B-331085

June 5, 2019

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: Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses*

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 “Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses” (RIN: 0938-AT92). We received the rule on May 23, 2019. It was published in the *Federal Register* as a final rule on May 23, 2019. 84 Fed. Reg. 23832. The effective date of the rule is January 1, 2020.

The final rule amends the Medicare Advantage program regulations and Prescription Drug Benefit program regulations to, according to CMS, support health and drug plans’ negotiation for lower drug prices and reduce out-of-pocket costs for Part C and D enrollees. According to CMS, these amendments will improve the regulatory framework to facilitate development of Part C and Part D products that better meet the individual beneficiary’s health care needs and reduce out-of-pocket spending for enrollees at the pharmacy and other sites of care.

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 Janet Temko-Blinder, Assistant General Counsel, at (202) 512-7104.

signed

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
“MODERNIZING PART D AND MEDICARE ADVANTAGE TO
LOWER DRUG PRICES AND REDUCE OUT-OF-POCKET EXPENSES”
(RIN: 0938-AT92)

(i) Cost-benefit analysis

The Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) summarized the costs and benefits for the major provisions of the final rule. Regarding the provision on E-prescribing and the Part D Prescription Drug Program, CMS found that there will not be significant costs to implement the provision. Additionally, based on the comments CMS received about the savings potential due to reduced drug costs arising from cheaper alternatives, CMS determined that the E-Prescribing provision provides a qualitative savings. For the provision on Explanation of Benefits, which requires the inclusion of negotiated drug pricing information and lower cost alternatives, CMS estimated a cost of \$4.7 million in the first year of implementation and annual estimated costs in all years of \$5.7 million. With respect to the provision on Medicare Advantage and Step Therapy for Part B Drugs, CMS estimated savings to enrollees due to reduced out-of-pocket costs to range from \$5 and \$8 million for 2020-2029 resulting in an aggregate savings of \$62 million over 10 years. CMS also noted that the savings to the Trust Fund are between \$145 and \$240 million for 2020-2029, and that there is a cost to the government and its contractors of \$1 to \$1.3 million in 2020-2029 due to a projected increase in appeals, resulting in an aggregate cost of \$11.2 million over 10 years. Finally, CMS estimated that the total cost of reviewing this final rule is \$816,000.

(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 will not have a significant economic impact on a substantial number of small entities. Additionally, CMS certified that this final rule will not have a substantial 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 not have an effect on state, local, or tribal governments, in the aggregate, or on the private sector of \$150 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 November 30, 2018, CMS issued a proposed rule. 83 Fed. Reg. 62152. In response to the proposed rule, CMS received 7,898 comments. CMS responded to comments in the final rule.

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

CMS stated that in its November 30, 2018, proposed rule, it solicited public comment on the proposed information collection requirements, burden, and assumptions. 82 Fed. Reg. 62152. CMS also stated that because of difficulty with determining the burden of the information collection requests, CMS will be publishing stand-alone 60- and 30-day *Federal Register* notices under the Act.

Statutory authorization for the rule

CMS stated that this final rule was promulgated pursuant to 42 U.S.C. §§ 1302, 1395hh, and 1395w-101 through 1395w-152.

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

CMS stated that, in accordance with the provisions of the Order, this final rule was reviewed by the Office of Management and Budget.

Executive Order No. 13,132 (Federalism)

CMS found that this final rule does not impose any substantial costs on state or local governments.