



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

B-331055

May 24, 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: Medicare and Medicaid Programs; Regulation To Require Drug Pricing Transparency*

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 and Medicaid Services (CMS) entitled “Medicare and Medicaid Programs; Regulation To Require Drug Pricing Transparency” (RIN: 0938-AT87). We received the rule on May 10, 2019. It was published in the *Federal Register* as a final rule on May 10, 2019. 84 Fed. Reg. 20732. The effective date of the rule is July 9, 2019.

The final rule revises the Federal Health Insurance Programs for the Aged and Disabled by amending regulations for Medicare Parts A, B, C, and D programs, as well as the Medicaid program, to require direct-to-consumer television advertisements of prescription drugs and biological products for which payment is available through or under Medicare or Medicaid to include the Wholesale Acquisition Cost of that drug or biological product.

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
“MEDICARE AND MEDICAID PROGRAMS;
REGULATION TO REQUIRE DRUG PRICING TRANSPARENCY”
(RIN: 0938-AT87)

(i) Cost-benefit analysis

The Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) stated that this final rule will affect the operations of prescription drug or biological product manufacturers. CMS estimates that this final rule will require individuals employed by these entities to spend time in order to comply with these regulations. CMS used the hourly wages of individuals affected by the final rule by using the National Occupational Employment and Wage Estimates provided by the U.S. Bureau of Labor Statistics to estimate the costs of this final rule. For initial and ongoing compliance with the rule, CMS estimates costs of \$4.74 million in the first year and \$2.36 million in subsequent years following the publication of this final rule after adjusting for overhead and benefits. Additionally, CMS estimates costs of \$474,884 in the first year following publication of the final rule. These costs are for businesses to review the rule. CMS also estimates \$20,472 for costs per year for direct advertisement review. Finally, CMS considered the opportunity costs, among other costs, but determined that it lacked data to quantify the effects.

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

CMS determined that this final rule will 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 stated that this rule is not anticipated to have an effect on state, local, tribal governments, or the private sector in the aggregate of \$154 million.

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

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

On October 18, 2018, CMS published a proposed rule. CMS received 147 comments and responded to comments in the final rule.

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

CMS determined that section 403.1202 of the final rule requires that advertisements for certain prescription drug or biological products on television contain a statement or statements

indicating the Wholesale Acquisition Cost. CMS estimated that 25 companies will run an estimated 300 distinct pharmaceutical advertisements that appear on television each quarter and will be affected by this final rule. CMS estimated that the costs of verifying the prescribed language will be \$20,472 per year in each year following publication of the final rule after adjusting for overhead and benefits. CMS also stated that it published a 60-day notice announcing the proposed information collection and solicited comments.

Statutory authorization for the rule

CMS stated that this rule was promulgated pursuant to 42 U.S.C. §§ 1302 and 1395hh.

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

CMS stated that the Office of Management and Budget (OMB) determined that this is an economically significant regulatory action under the Order. CMS also stated that this final rule was reviewed by OMB.

Executive Order No. 13,132 (Federalism)

CMS determined that this final rule would not significantly affect the rights, roles, and responsibilities of state or local governments.