U.S. GOVERNMENT ACCOUNTABILITY OFFICE

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

B-332827

January 8, 2021

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, Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements*

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 "Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements" (RIN: 0938-AT82). We received the rule on December 23, 2020. It was published in the *Federal Register* as a final rule on December 31, 2020. 85 Fed. Reg. 87000. The effective date of the rule is March 1, 2021, except for amendatory instructions 7, 10.a, 14, 16, and 17, which are effective on January 1, 2022, and amendatory instructions 9 and 11, which are effective on January 1, 2023.

CMS stated that the rule will advance CMS's efforts to support state flexibility to enter into innovative, value-based purchasing arrangements (VBPs) with manufacturers, and to provide manufacturers with regulatory support to enter into VBPs with payers, including Medicaid. According to CMS, to ensure that the regulatory framework is sufficient to support such arrangements and to promote transparency, flexibility, and innovation in drug pricing without

undue administrative burden, CMS is finalizing new regulatory policies and clarifying certain already established policies to assist manufacturers and states in participating in VBPs in a manner that is consistent with the law and maintains the integrity of the Medicaid Drug Rebate Program (MDRP).

CMS further stated that the rule revises regulations regarding: authorized generic sales when manufacturers calculate average manufacturer price (AMP) for the brand name drug; pharmacy benefit managers accumulator programs and their impact on AMP and best price when manufacturer-sponsored assistance is not passed through to the patient; state and manufacturer reporting requirements to the MDRP; new Medicaid Drug Utilization Review provisions designed to reduce opioid-related fraud, misuse, and abuse; the definitions of CMS-authorized supplemental rebate agreement, line extension, new formulation, oral solid dosage form, single source drug, multiple source drug, innovator multiple source drug for purposes of the MDRP; payments for prescription drugs under the Medicaid program; and coordination of benefits and third party liability rules related to the special treatment of certain types of care and payment in Medicaid and Children's Health Insurance Program.

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

ENCLOSURE

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
"MEDICAID PROGRAM; ESTABLISHING MINIMUM STANDARDS IN MEDICAID STATE DRUG UTILIZATION REVIEW (DUR) AND SUPPORTING VALUE-BASED PURCHASING (VBP) FOR DRUGS COVERED IN MEDICAID, REVISING MEDICAID DRUG REBATE AND THIRD PARTY LIABILITY (TPL) REQUIREMENTS"
(RIN: 0938-AT82)

(i) Cost-benefit analysis

The Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) projected the financial impacts by fiscal year at the federal and state level of the line extension provision, and determination of best price and average manufacturer price and manufacturer reporting requirements.

(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. CMS also certified that the 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 have no consequential effect 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 June 19, 2020, CMS published a proposed rule. 85 Fed. Reg. 37286. CMS responded to comments in this final rule.

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

CMS stated that this final rule impacts information collection requirements (ICRs) previously approved by the Office of Management and Budget (OMB) as follows: (1) for ICRs regarding state plan requirements, findings, and assurances, OMB Control Number 0938-1385, an estimated annual burden of 306 hours at a cost of $36,200 annually; (2) for ICRs regarding requirements for states, OMB Control Number 0938-0582, a one-time system ID/password access burden of 280 hours at a cost of $52,192, and an estimated annual burden of 112 hours at a cost of $20,877; and (3) for ICRs regarding the payment of claims, OMB Control Number

0938-1265, an estimated annual burden of 224 hours at a cost of $8,550 annually. CMS stated that these changes will be submitted to OMB for approval.

Statutory authorization for the rule

CMS promulgated this final rule pursuant to sections 1302 and 1396r-8 of title 42, United States Code.

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

CMS determined that this final rule is economically significant and CMS stated that the rule was reviewed by OMB.

Executive Order No. 13,132 (Federalism)

CMS determined that this final rule does not impose any substantial direct compliance costs on state or local governments, preempt state law, or otherwise have federalism implications.