U.S. GOVERNMENT ACCOUNTABILITY OFFICE
**441 G St. N.W.**
**Washington, DC 20548**

B-330938

April 22, 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 and Medicaid Services: Medicaid Program; Covered Outpatient Drug; Line Extension Definition; and Change to the Rebate Calculation for Line Extension Drugs*

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 "Medicaid Program; Covered Outpatient Drug; Line Extension Definition; and Change to the Rebate Calculation for Line Extension Drugs" (RIN: 0938-AT09). We received the rule on April 5, 2019. It was published in the *Federal Register* as a final rule and interim final rule with comment period on April 1, 2019. 84 Fed. Reg. 12130. The effective date of the rule is April 1, 2019.

According to CMS, the interim final rule revises the regulatory text to reflect the applicable statutory language describing the rebate calculation for the line extension drugs which was revised by the Bipartisan Budget Act of 2018. *See* Bipartisan Budget Act of 2018, Pub. L. No. 115-123, 132 Stat. 64 (2018). Additionally, the final rule responds to comments on the definition and identification of line extension drugs for which CMS requested additional comments in the Covered Outpatient Drugs final rule with comment period published in the February 1, 2016, *Federal Register*.

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 April 1, 2019. 84 Fed. Reg. 12130. It was received by the House of Representatives and the Senate on April 5, 2019. 165 Cong. Rec. H3127, S2384. The rule has a stated effective date of April 1, 2019. Therefore the final rule does not have the required 60-day delay in its effective date.

However, the 60-day delay in effective date can be waived if an agency finds for good cause that delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates the findings and a brief statement thereof in the rule issued. 5 U.S.C. § 808(2). Here, although CMS did not specifically mention the CRA's 60-day delay in effective date requirement, the agency found good cause to waive notice and comment procedures and incorporated a brief statement of reasons. Specifically, CMS found good cause to waive the notice and comment requirements as, according to CMS, it would be unnecessary and impracticable to undergo notice and comment procedures before finalizing, on an interim basis with an opportunity for public comment, the policies described in the final rule because the provisions of section 53104 of the Bipartisan Budget Act of 2018 are otherwise self-implementing as of the effective date required by statute.

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

ENCLOSURE

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 AND MEDICAID SERVICES
ENTITLED
"MEDICAID PROGRAM; COVERED OUTPATIENT DRUG;
LINE EXTENSION DEFINITION; AND
CHANGE TO THE REBATE CALCULATION FOR LINE EXTENSION DRUGS"
(RIN: 0938-AT09)

(i) Cost-benefit analysis

The Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) reported that during the drafting of the Bipartisan Budget Act of 2018, the Congressional Budget Office scored an estimated savings for the revised line extension rebate calculation of $1.877 billion over 5 years and $5.65 billion over 10 years. Additionally, CMS's Office of the Actuary estimated the savings for the revised line extension rebate calculation to be $1.64 billion over 5 years and $3.95 billion over 10 years. CMS stated that the savings will be the result of additional rebates being paid by drug manufacturers to the federal government.

(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 this final 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.*

CMS found good cause to waive the notice and comment requirements under sections 553(b)(B) of the Act as it would be unnecessary and impracticable to undergo notice and comment procedures before finalizing, on an interim basis with an opportunity for public comment, the policies described in the final rule because the provisions of section 53104 of the Bipartisan Budget Act of 2018 are otherwise self-implementing as of the effective date required by statute. According to CMS, the notice and comment procedures would be unnecessary, as CMS is not altering the calculations required in the Bipartisan Budget Act of 2018.

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

CMS determined that the actions in this final rule and interim final rule with comment period do not impose any new or revised information collection, reporting, recordkeeping, or third-party disclosure requirements or burden on manufacturers.

Statutory authorization for the rule

CMS stated that this final rule was promulgated pursuant to 42 U.S.C. §§ 1302 and 1396r−8.

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

CMS found this final rule to be economically significant under the Order. CMS stated that the final rule was reviewed by the Office of Management and Budget.

Executive Order No. 13,132 (Federalism)

CMS determined that the final rule does not impose any costs on state or local governments and that the requirements of the Order are not applicable.