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May 18, 2021

The Honorable Ron Wyden
Chairman
The Honorable Mike Crapo
Ranking Member
Committee on Finance
United States Senate

The Honorable Frank Pallone, Jr.
Chairman
The Honorable Cathy McMorris Rodgers
Ranking Member
Committee on Energy and Commerce
House of Representatives

Subject: *Department of Health and Human Services, Centers for Medicare & Medicaid Services: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2022 and Pharmacy Benefit Manager Standards*

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 "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2022 and Pharmacy Benefit Manager Standards" (RIN: 0938-AU18). We received the rule on May 4, 2021. It was published in the *Federal Register* as a final rule on May 5, 2021. 86 Fed. Reg. 24140. The effective date is July 6, 2021, but some of the provisions became effective on the date of publication.

According to CMS, the final rule sets forth payment parameters and provisions related to the risk adjustment program and cost-sharing parameters. CMS stated it includes changes related to special enrollment periods; direct enrollment entities; the administrative appeals processes with respect to health insurance issuers and non-federal governmental group health plans; the medical loss ratio program; income verification by Exchanges; and other related topics. CMS stated that the final rule also revises the regulation requiring the reporting of certain prescription drug information by qualified health plans or their pharmacy benefit managers.

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 60-day delay in effective date can be waived however if the agency finds for good cause that delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the findings and its reasons in the rule issued. 5 U.S.C. §§ 553(B)(3)(B), 808(2). CMS determined it had good cause to waive the 60-day delay for some of the provisions of the final rule because CMS needed to implement

a decision of the district court in recent litigation, and CMS determined not addressing the decision in the final rule would create confusion for regulated entities.

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: Kathy Applewhite
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 & MEDICAID SERVICES
ENTITLED
"PATIENT PROTECTION AND AFFORDABLE CARE ACT;
HHS NOTICE OF BENEFIT AND PAYMENT PARAMETERS
FOR 2022 AND PHARMACY BENEFIT MANAGER STANDARDS"
(RIN: 0938-AU18)

(i) Cost-benefit analysis

The Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) estimates the final rule will lead to a cost savings of $30.99 million per year for the period from 2021 to 2025, at the 3 percent discount rate, or $31.57 million per year at the 7 percent discount rate for the same period. CMS further estimated the final rule will result in federal transfers of $277.3 million per year at the 3 percent discount rate, or $266.1 million per year at the 7 percent discount rate, for the 2021 to 2025 period. CMS also estimated other transfers of $23 million per year at both the 3 and 7 percent discount rates for the same period. A description of qualitative costs and benefits can be found in the final rule.

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

CMS stated it did not expect the final rule to affect a substantial number small entities and that the Secretary determined it would not have a significant economic impact on 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 stated it did not expect the costs of the final rule on state, local, or tribal governments or the private sector to exceed the Act's statutory threshold.

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

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

On December 4, 2020, CMS published a proposed rule. 85 Fed. Reg. 78572. CMS received 542 comments on the proposed rule from state entities, such as departments of insurance and state exchanges, health insurance issuers, providers and provider groups, consumer groups, industry groups, national interest groups, and other stakeholders. CMS responded to the comments in the final rule.

Several of the provisions of the final rule were not included in the proposed rule. CMS waived notice and comment proceedings for these provisions for good cause. 5 U.S.C. § 553(b)(3)(B). CMS determined it had good cause to waive notice and comment proceedings because CMS

needed to implement a decision of the district court in recent litigation and CMS determined not addressing the decision in the final would create confusion for regulated entities.

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

CMS determined the final rule contained information collection requirements (ICRs) subject to the Act. Each of the ICRs are associated with Office of Management and Budget (OMB) Control Number 0938-NEW. CMS estimated the burdens associated with each ICR in the final rule.

Statutory authorization for the rule

CMS promulgated the final rule pursuant to section of 36B of title 26, and sections 300gg-18, 300gg through 300gg-63, 300gg-91, 300gg-92, 1302, 1320b-23, 18021 through 18024, 18031 through 18033, 18041 through 18042, 18044, 18051, 18054, 18061 through 18063, 18071, and 18081 through 18083 of title 42, United States Code, as well as Public Law 116-136.

Executive Order No. 12866 (Regulatory Planning and Review)

CMS determined the final rule was significant and stated the rule was reviewed by OMB.

Executive Order No. 13132 (Federalism)

CMS stated it has engaged in efforts to consult with and work cooperatively with affected states, including participating in conference calls with and attending conferences of the National Association of Insurance Commissioners, and consulting with state insurance officials on an individual basis. While developing this rule, CMS stated it attempted to balance the states' interests in regulating health insurance issuers with the need to ensure market stability.