U.S. GOVERNMENT ACCOUNTABILITY OFFICE

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

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December 22, 2020

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, Office of Inspector General: Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees*

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, Office of Inspector General (HHS) entitled "Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees" (RIN: 0936-AA08). We received the rule on December 8, 2020. It was published in the *Federal Register* as a final rule on November 30, 2020. 85 Fed. Reg. 76666. The stated effective date of this final rule is January 29, 2021.

According to HHS, discounts for prescription pharmaceutical products are central to this final rule, in which the HHS amends the safe harbor regulation concerning discounts. HHS stated that amending this regulation changes the definition of certain conduct that is protected from liability under the federal anti-kickback statute of the Social Security Act (the Act). *See generally* 42 U.S.C. §§ 1302; 1320a-7b; 1320a-7d. HHS also stated, new regulatory text in the

amendment revises the discount safe harbor. HHS stated further, by excluding from the definition of a discount eligible for safe harbor protection certain reductions in price or other remuneration from a manufacturer of prescription pharmaceutical products to plan sponsors under Medicare Part D or pharmacy benefit managers (PBMs) under contract with them, HHS modifies the existing discount safe harbor in particular contexts. According to HHS, existing safe harbors otherwise remain unchanged. HHS stated that safe harbors are also created for two additional types of arrangements. HHS also stated that the first protects certain point-of-sale reductions in price on prescription pharmaceutical products, and the second protects certain PBM service fees.

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). This final rule was published in the *Federal Register* on November 30, 2020. The Senate received this rule on December 11, 2020. 166 Cong. Rec. S7541 (daily ed. Dec.16, 2020). The House received the rule on December 16, 2020. Cong. Rec. H7276 (daily ed. Dec. 18, 2020). The stated effective date of this final rule is January 29, 2021, except for amendments to 42 C.F.R. 1001.952(h)(5), which are effective on January 1, 2022. Therefore, with exception to the amendments made to 42 C.F.R. 1001.952(h)(5), the final rule does not have the required 60-day delay in its effective date.

Enclosed is our assessment of HHS'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 OF HEALTH AND HUMAN SERVICES,
OFFICE OF INSPECTOR GENERAL
ENTITLED
"FRAUD AND ABUSE; REMOVAL OF SAFE HARBOR PROTECTION
FOR REBATES INVOLVING PRESCRIPTION PHARMACEUTICALS AND
CREATION OF NEW SAFE HARBOR PROTECTION FOR
CERTAIN POINT-OF-SALE REDUCTIONS IN PRICE ON PRESCRIPTION
PHARMACEUTICALS AND CERTAIN PHARMACY
BENEFIT MANAGER SERVICE FEES"
(RIN: 0936-AA08)

(i) Cost-benefit analysis

The Department of Health and Human Services, Office of Inspector General (HHS) prepared an analysis of the cost and benefits of this final rule. According to HHS it is difficult to accurately quantify the benefits of this rule due to the complexity and uncertainty of stakeholder response. HHS stated that it relied on qualitatively describing potential benefits and it anticipates that the amendments to regulations by this rule will help beneficiaries make more actuarially favorable decisions, because the new point-of-sale price reductions negotiated by pharmacy benefit managers would be reflected in the price paid by beneficiaries at the point-of-sale. HHS also stated, with reduced out-of-pocket payments, patient adherence and persistence with prescription drug regimens may improve. HHS stated further that lower out-of-pocket costs may lead to fewer enrollees abandoning prescription drugs, which could result in beneficiaries filling more prescriptions, thus increasing spending, as prescriptions that were once unaffordable are now attainable. HHS asserted that the changes could also lead to lower total costs-of-care, if increased adherence led to improved health outcomes.

HHS presented the quantified cost associated with this final rule in 2016 dollars. HHS estimated the cost over 5 years to be $1,591 million at a 3 percent discount and $1,448 million at a 7 percent discount. HHS also estimated the annualized value over 5 years to be $347 million at 3 percent discount and $353 million at a 7 percent discount.

HHS estimated transfers in the following categories: Medicare beneficiary spending, employee premium and out-of-pocket spending, beneficiary premium and cost-sharing spending, federal spending, state spending, and manufacturer coverage gap discount.

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

HHS determined that the rule would 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

According to HHS this final rule may have effects on states through its effects on the Medicaid Drug Rebate Program. HHS stated, if the rule reduces the average manufactures price, it will also reduce Medicaid prescription drug rebates and the loss of revenue from these rebates can exceed the savings from lower list prices. HHS stated further, if the overall effect of lowering list pricing is achieved and that results in lower prices to commercial customers (and wholesalers) or pricing components of non-federal average manufactures price, it is possible the Department of Veterans Affairs may realize some additional savings.

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

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

On February 6, 2019, HHS published the proposed rule titled, "Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees." 84 Fed. Reg. 2340. HHS stated that it received responsive comments from approximately 26,000 distinct commenters, including, but not limited to, individuals, pharmaceutical manufacturers, pharmacies, pharmacy benefit managers, wholesalers, plan sponsors under Part D, Medicaid, managed care organizations, and trade associations representing various individuals and entities. HHS stated further that it divided the public comment summaries and its responses into discrete sections in the final rule.

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

According to HHS, this rule imposes documentation and disclosure requirements on pharmacy benefit managers for one of the new safe harbors. However, HHS asserted that the documentation requirements necessary to enjoy safe harbor protection do not qualify as an added paperwork burden because the requirements deviate minimally, if at all, from the information pharmacy benefit managers and manufacturers would routinely collect in their normal course of business.

Statutory authorization for the rule

HHS promulgated this final rule pursuant to sections 1302; 1320a-7; 1320a-7b; 1395u; 1395w-104; 1395y; 1395cc; 1395hh; and 1842 of title 42; and section 6101 note of title 31, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

HHS determined this rule is a significant regulatory action as defined by the Order.

Executive Order No. 13132 (Federalism)

HHS determined that this regulation would not impose any direct costs on state or local governments, preempt state law, or otherwise have federalism implications.