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PROPOSED REVISIONS TO THE ANTI-KICKBACK REGULATORY DISCOUNT SAFE HARBOR: WHAT DOES THIS MEAN FOR THE DRUG INDUSTRY AND FOR YOUR DRUG PRICES IN 2020?

by Jennifer Perry and Rachel Freeman
February 7, 2019

Continuing the Trump administration's efforts to lower drug prices and reduce patient out-of-pocket costs, on February 6, 2019, the U.S. Department of Health and Human Services Office of Inspector General ("HHS") released a much-anticipated proposed rule setting forth significant changes to the regulatory discount safe harbor under the federal Anti-Kickback Statute ("AKS"), with the potential to substantially disrupt existing arrangements between drug manufacturers, pharmacy benefit managers[1] ("PBMs") and health plans.

Under the AKS, discounts and certain other reductions in price offered by drug manufacturers are not considered prohibited remuneration if they are structured to comply with either the statutory discount exception[2] or the regulatory discount safe harbor[3]. If adopted, the proposed rule would exclude discounts and rebates paid by drug manufacturers to Medicare Part D plans, Medicaid MCOs and PBMs acting on their behalf from protection under the regulatory discount safe harbor. Notably, the proposed rule is limited to Part D plans and Medicaid MCOs. This means that it does not alter the regulatory safe harbor protection for drug discount arrangement involving other entities, like wholesalers or pharmacies. While the proposed rule is limited in scope, HHS did take the opportunity to reiterate its position that "carve-out" arrangements implicate the AKS, and that this position would extend to pharmaceutical rebate arrangements.

The Proposed Rule

Though the proposed rule removes protection for discounts and rebates paid to Part D Plans, Medicaid MCOs and their PBMs, it also introduces two new safe harbors intended to encourage a move away from the current rebate system, and to incentivize both discounts for patients at the point-of-sale and transparency.

(1) **Point-of-Sale Discounts:** The first proposed safe harbor would protect certain prescription drug discounts that are set in advance with the plan sponsor, do not involve a rebate and are ultimately passed along to the beneficiary at the point of sale.
(2) **PBM Service Fees:** The second proposed safe harbor would protect certain fixed fee arrangements between PBMs and drug manufacturers where the PBM provides bona fide services in exchange for a fixed, fair market value fee. If adopted, the rule would also require that these arrangements be disclosed to the health plans that the PBM contracts with and to the Secretary of HHS upon request.

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[1] Pharmacy benefit managers ("PBMs") are companies that administer prescription drug programs on behalf of health plans, and act as an intermediary between the health plans and drug manufacturers. The PBM negotiates with drug manufacturers to obtain discounts on the price of drugs and decides which drugs are placed on a health plan's formulary (i.e., the list of drugs that are covered by the insurance plan). In other words, PBMs decide which drugs the consumer gets in the pharmacy and how much they will cost. It is undoubtedly in a drug company's interest for a PBM to put their drugs on a formulary, and it has been common practice for a drug company to offer rebates to a PBM in addition to reduction in price.
[2] 42 U.S.C. § 1320a-7b(b)(3)(A).
[3] 42 C.F.R. § 1001.952(h).

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The Impact

It is without question that the proposed rule, if adopted, will disrupt the existing supply chain for prescription drugs and leave stakeholders minimal time to come into compliance. With a proposed effective date of January 1, 2020, affected companies should not delay in reviewing current arrangements for viability under the proposed rule, and begin assessing the business opportunities provided by the two new safe harbors. From a consumer perspective, HHS projects that the adjustment in safe harbor protection will result in lower Medicare Part D beneficiary spending as a whole, as the reduced out-of-pocket costs are expected to outweigh any potential premium increases. It is worth noting that, while the proposed rule does not directly impact commercial insurance drug rebates, an indirect effect may materialize. In the short term, it is anticipated that PBMs and health plans may try to make up for any lost revenues by increasing premiums and patient co-pay obligations. With approximately $150 billion in negotiated rebates and discounts affected by the proposed rule, lobby groups on both sides will be vehemently debating the rules effectiveness and/or necessity.

The proposed rule was published in the *Federal Register*[4] on February 6, 2019, and stakeholder comments must be submitted no later than April 8, 2019. HHS currently proposes an effective date of January 1, 2020, for the new exclusion from the regulatory discount safe harbor. The effective date of the new safe harbors would be 60 days after the rule becomes final.

ABOUT THE AUTHORS

Jennifer Perry, Counsel - Gray Reed - jperry@grayreed.com

Jennifer Perry focuses her practice on healthcare compliance issues, physician practice formation and general corporate matters for a variety of healthcare clients, ranging from hospital systems, physician practices and surgery centers to pharmacies and laboratories. They rely on Jennifer to advise on the numerous health regulations that impact their businesses, including Joint Commission regulations, the anti-kickback statute, Stark Law, non-profit regulations, media and marketing regulations, and HIPAA/HITECH regulations. She also has significant experience handling hospital operational issues related to regulatory compliance and risk management. Before joining Gray Reed, Jennifer served as Associate General Counsel at Memorial Hermann Health System, where she handled a variety of transactional, compliance, operational, and media and marketing issues for the various departments and facilities throughout Texas.

Rachel Freeman, Associate - Gray Reed - rfreeman@grayreed.com

Rachel Freeman focuses her practice on advising healthcare providers on operational, transactional and compliance matters including drafting a variety of healthcare contracts and documents. These providers include hospitals, ambulatory surgery centers, physicians, dentists, practices, assisted living facilities, pharmacies, clinical research entities, laboratories and other ancillary service providers. Through her experience with the Anti-Kickback Statue, the Stark Law, HIPAA, EMTALA, and the Food, Drug and Cosmetic Act, among others, Rachel routinely counsels on best practices for health care providers to maintain compliance with the federal and state regulatory frameworks that affect their day-to-day operations. In addition, she represents clients in entity formation, preparation of corporate documents, transactions and private offerings. Before joining Gray Reed, Rachel served as the compliance and privacy officer of four physician-owned hospitals.

[4] 84 F.R. 2340, available at: https://www.govinfo.gov/content/pkg/FR-2019-02-06/pdf/2019-01026.pdf.