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Drug Pricing and Payment Policy: Sweeping HHS Rebate Reform Proposal and First 2019 Congressional Hearings

HHS proposes to remove rebates from the Anti-Kickback Statute's "discount" safe harbor and add new safe harbor for point-of-sale discounts.

On January 31, 2019, the Department of Health and Human Services (HHS) announced a proposed rule that would remove the safe harbor protection under the Anti-Kickback Statute (AKS) for rebates paid by manufacturers to Medicare Part D plan sponsors, Medicare Advantage plan sponsors that offer prescription drug coverage, Medicaid managed care organizations (MCOs), and the pharmacy benefit managers (PBMs) under contract with them. At the same time, the proposed rule would add two new anti-kickback safe harbors to protect discounts provided to beneficiaries at the point of sale, and protect certain fees that manufacturers pay to PBMs.

The HHS proposal reflects policies first floated in the Trump Administration's *American Patients First* drug pricing blueprint, which noted that it would consider measures to restrict the use of rebates, including "revisiting the safe harbor under the AKS for drug rebates."[1] This proposed rule is a part of a broader Administration effort to reduce out-of-pocket drug costs for consumers, particularly Medicare beneficiaries, by driving price reductions downstream through the dug distribution chain. This proposed rule was announced at the end of the same week that saw Congress hold its first drug pricing hearings, which explored several potential policies aimed at reducing drug prices in Medicare, including Part D plan design, international reference pricing for drugs, and drug importation.

The HHS proposed rebate rule and drug pricing hearings in the US House of Representatives and Senate kicked off what is expected to be an extremely busy year for drug pricing and payment policy. All stakeholders, including providers, manufacturers, distributors, insurers, and patients, will have the opportunity to shape this debate, including through comments to administrative proposals and other targeted advocacy. The proposed rule is scheduled to be published formally on February 6, 2019, with a 60-day public comment period. This *Client Alert* provides an initial summary of the proposal as part of an ongoing series of detailed analysis of the proposed rule.

Overview of Proposed Rebate Rule

The "safe harbor" regulations under the AKS describe various payment and business practices that are not treated as AKS violations, even though they otherwise would potentially implicate the statute. These regulations include a safe harbor for "discounts," meaning reductions in the amount a buyer is charged for an item or service based on an arms-length transaction.[2] The discount safe harbor was created to encourage price competition that benefits the Medicare and Medicaid programs.

The proposed rebate rule from HHS consists of three primary policy changes, each of which changes the scope of the regulatory "discount" safe harbor:

- **Eliminates Safe Harbor Protection for Price Reductions Paid to Medicare Drug Plans, Medicaid MCOs, and PBMs:**
  - HHS proposes to remove from the discount safe harbor price reductions from manufacturers to plan sponsors under Medicare Part D (which includes Medicare Advantage organizations offering a Medicare Advantage prescription drug plan) or Medicaid MCOs, either paid directly or through PBMs, acting under contract with the plan sponsors or MCOs. HHS intends for the discount safe harbor to continue to protect discounts on pharmaceutical products offered to other entities (*e.g.*, wholesalers, hospitals, physicians, and pharmacies), as well as price reductions required by law (*e.g.*, rebates under the Medicaid Drug Rebate Program). This element of the proposed rule, if finalized, would be effective on January 1, 2020.

  - Given that the discount safe harbor applies to items payable under Medicare, Medicaid, and other federal health care programs, HHS is also soliciting comments on whether the change should also include pharmaceutical products payable under other HHS programs (*e.g.*, Medicare Part B).

- **Adds Safe Harbor for Point-of-Sale Discounts**
  - While HHS proposes to eliminate the discount AKS safe harbor for certain rebates, it proposes a new safe harbor intended to protect certain point-of sale discounts provided to the patient for prescription drugs that are payable under Medicare Part D or by Medicaid MCOs that meet certain criteria. To comply with this proposed safe harbor, price reductions must meet three criteria:
    - Price reductions offered to Medicare Part D plan sponsors or Medicaid MCOs would have to be set in advance, meaning with fixed terms and disclosed in writing
    - Price reductions could involve a rebate unless the full value of the reduction in price is provided to the dispensing pharmacy through a chargeback or a series of chargebacks, or the rebate is required by law
    - The price reduction is completely reflected in the price the pharmacy charges to the beneficiary at the point of sale

  - HHS is soliciting comments on many aspects of this proposal, including the extent to which the safe harbor, if finalized, would incentivize manufacturers to provide point-of-sale discounts. This proposed safe harbor would become effective 60 days after publication of the final rule.

- **Adds Safe Harbor for PBM Service Fees**
  - HHS is also proposing a new AKS safe harbor that would protect fixed fees that manufacturers pay to PBMs for services rendered to the manufacturers that meet certain criteria. This proposed safe harbor would provide a pathway, specific to PBMs, to protect

remuneration in the form of flat service fees for services rendered to the manufacturer (and not the health plan) that would be low risk if they meet specified criteria:
    - A written agreement that covers all of the services the PBM provides to the manufacturer, including the services to be provided and the compensation for each service
    - Compensation provided to the PBM is consistent with fair market value, is a fixed (rather than percentage) fee, and is not determined in a manner that considers the volume or value of any referrals or business otherwise generated between the parties
    - PBMs disclose in writing to each health plan with which they contract, at least annually, the services rendered to each pharmaceutical manufacturer and the associated costs for such services

- In contrast to the Group Purchasing Organization (GPO) safe harbor under the AKS, percentage-based fees for PBMs would be disfavored under this proposal because all fees would be *required* to be fixed, rather than paid on a percentage basis in order to qualify for safe harbor protection.

While the safe harbor regulations explicitly govern only government-funded pharmacy benefit plans, HHS notes in a fact sheet that accompanied the proposed rule that rebate arrangements between pharmaceutical manufacturers and commercial insurers may also implicate the AKS. HHS notes that Congress has more power to prohibit rebates in commercial insurance, but the clear implication of this discussion is that rebate arrangements between manufacturers and insurers of all types may be subject to additional scrutiny and disfavored treatment.

Congress Holds First Drug Pricing Hearings of 2019

Two days before HHS announced its proposed rebate rule, Congress held its first hearings of the year on drug pricing. The House Committee on Oversight and Reform and the Senate Finance Committee each held their own hearings to examine drug pricing, with both hearings focused on drug price increases instituted by pharmaceutical manufacturers. Both hearings also featured a number of healthcare policy experts from leading academic medical centers and think tanks discussing the regulatory and business factors that affect pharmaceutical prices.

Throughout the hearings, witnesses and committee members discussed various policy changes that could be implemented with the aim of reducing drug prices, including increased drug supply, price restrictions, and reform of the intellectual property protections and regulatory exclusivities that apply to pharmaceutical products. Examples of the potential policy changes include:

- Part B Payment Reforms (such as converting the 6% add-on fee for Part B drugs to a flat dispensing fee)
- Shortened regulatory exclusivities for new drugs and biologics, with discussion focused on shortening the 12-year exclusivity for new biologics
- Allowing for direct negotiation of drug prices by the Medicare program
- Restricting the ability of manufacturers to use orphan designations, Risk Evaluation and Mitigation Systems (REMS), and other tools to prevent competition
- Investigation by the Federal Trade Commission into possible anticompetitive practices in the pharmaceutical industry, particularly in the market for insulin

Many of these potential reforms are reflected in legislation that was introduced at the start of this legislative term, and represent a continuation of legislative efforts in 2019 focused on drug pricing and reimbursement. We will analyze a number of these legislative proposals in forthcoming *Client Alerts*.

Conclusion

These early 2019 drug pricing developments suggest that many policy discussions on drug pricing and distribution in 2018 will continue this year. Although many manufacturers, insurers, and PBMs have already negotiated (and sometimes executed) contract amendments governing 2020 rebates, the Administration proposes to reconfigure the discount safe harbor effective January 1, 2020. With so many aspects of the proposed rule open for comment, stakeholders may be hard-pressed to formulate changes to their own business arrangements should a final rule be published in 2019. Early and specific input from pharmaceutical manufacturers, PBMs, insurers, and other stakeholders will be critical as HHS and Congress consider more rapid changes to achieve their clearly stated goals of reducing prices of pharmaceutical products and patients' out-of-pocket costs.

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Endnotes

[1] HHS, American Patients First – The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (May 2018).

[2] 42 C.F.R. § 1001.952(h)(5).