HHS ISSUES PROPOSED RULE TO REMOVE SAFE HARBOR FOR DRUG REBATES

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U.S. Health Care Alert

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On January 31, 2019, the U.S. Department of Health & Human Services ("HHS") issued a long-awaited proposed rule (the "Proposed Rule") which, if finalized, would modify the discount safe harbor under the federal Anti-Kickback Statute ("AKS") to eliminate protection for certain drug discounts paid by manufacturers to plan sponsors under Medicare Part D or Medicaid managed care organizations ("MCOs") or the pharmacy benefit managers ("PBMs") working with these organizations. [1] The Proposed Rule would also create two new AKS safe harbors that would extend protection for certain point-of-sale discounts on prescription drugs provided to pharmacies and passed through to patients as well as certain fixed-fee service arrangements between drug manufacturers and PBMs. Stakeholder comments on the Proposed Rule must be submitted by 5:00 p.m. Eastern time on April 8, 2019.

The Proposed Rule is a key part of the Trump administration's plan to address rising drug prices. At a recent Association for Accessible Medicines conference, HHS Secretary Alex Azar stated that rebates paid by manufacturers to PBMs based on a percentage of the drug's wholesale acquisition cost was the primary cause for the over utilization of brand drugs when more affordable generic versions are available. The Trump administration clearly believes that eliminating rebates will result in lower prices for Part D beneficiaries and appears to be determined to implement the Proposed Rule.

BACKGROUND

The AKS prohibits any person from knowingly and willfully offering, paying, soliciting, and/or receiving any remuneration directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward the referral of business reimbursable under a federal health care program, including Medicare or Medicaid. [2]

Under the existing framework, the HHS Office of Inspector General has excluded drug rebates — defined as "any discount the terms of which are fixed at the time of the sale of the good or service and disclosed to the buyer, but which is not received at the time of the sale of the good or service" — from the definition of "remuneration" under the AKS. [3] However, the Proposed Rule describes how this current framework lacks transparency and poses a significant hurdle to the administration's efforts to reduce drug prices. [4] For example, HHS explains that: (a) PBM rebates increase drug costs to beneficiaries in the deductible phase and those with percentage-based cost-sharing obligations; (b) current rebates skew PBM and plan formulary decisions in favor of drugs with the highest rebates, which may be more expensive and less effective than drugs with lesser rebates; and (c) current rebates lack transparency. [5]

AMENDMENT TO EXISTING SAFE HARBOR FOR DRUG REBATES

Citing the "prominence of rebate arrangements in the prescription drug supply chain" [6] as a potential barrier to lowering drug costs, effective January 1, 2020, HHS proposes to eliminate existing protection for rebates paid by manufacturers to plan sponsors under either Medicare Part D or Medicaid managed care — either directly or through PBMs, unless required by law. [7] To accomplish the change, HHS would add an explicit exception to the AKS definition of "discount" to exclude such rebates from the discount safe harbor effective January 1, 2020. [8]

HHS proposes to interpret the term "plan sponsor under Medicare Part D" to include the sponsor of a prescription drug plan as well as a Medicare Advantage organization offering a Medicare Advantage prescription drug plan. [9] However, it is seeking comments on the appropriateness of the definition and whether an even broader definition should be adopted (e.g., one that applies to other federal health care programs, including Medicare fee-for-service). HHS is also seeking feedback from stakeholders on whether the change might impact beneficiary access to prescription drugs either due to cost or formulary placement. [10]

Notwithstanding the change above, HHS also emphasizes that it intends for the discount safe harbor to continue to protect discounts on drugs offered to other entities, including wholesalers, hospitals, physicians, and pharmacies. The change would also not impact the statutory exception protecting certain discounts under the AKS, which HHS asserts does not apply to most rebates paid by drug manufacturers to PBMs or payors. [11]

PROPOSED "POINT-OF-SALE PRICE REDUCTIONS" SAFE HARBOR

he Proposed Rule also contains two new safe harbors, the first of which would protect point-of-sale price reductions offered by drug manufacturers on certain products payable under Medicare Part D or by Medicaid MCOs (or PBMs working on behalf of such entities) if three conditions are satisfied: [12]

1. The reduction in price is set in advance with the plan sponsor under Medicare Part D, the Medicaid MCO, or the PBM.
2. The reduction in price does not involve a rebate unless the full value of the reduction in price is provided to the dispensing pharmacy through a chargeback [13] (or a series of chargebacks) or the rebate is required by law; and
3. The reduction in price is completely reflected in the price the pharmacy charges to the beneficiary at the point of sale. [14]

The proposed effective date for the new safe harbor would be 60 days after publication of the final rule. HHS is asking for feedback on various issues, including how the above conditions could be modified to encourage point-of-sale price reductions without posing any additional risk to federal health care programs or patients.

PROPOSED "PBM SERVICE FEES" SAFE HARBOR

The second proposed safe harbor would protect fixed fees that drug manufacturers pay to PBMs for services the PBMs provide for the benefit of the manufacturer when such services relate to the PBMs' provision of pharmacy

benefit management services to health plans. [15] Under the Proposed Rule, the safe harbor would only protect such payments if the following conditions are met:

4. The PBM and the drug manufacturer have a written agreement that: (a) covers all of the services the PBM provides to the manufacturer in connection with the PBM's arrangements with health plans for the term of the agreement, and (b) specifies each of the services to be provided by the PBM and the corresponding compensation for such services; and
5. Compensation paid to the PBM is: (a) consistent with fair market value in an arm's-length transaction; (b) a fixed payment, not based on a percentage of sales; and (c) not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties, or between the manufacturer and the PBM's health plans, for which payment may be made in whole or in part under Medicare, Medicaid, or other federal health care programs. [16]

The PBM must also disclose annually in writing to each health plan with which it contracts, and to the HHS Secretary upon request, the services it rendered to each manufacturer that are related to the PBM's arrangements with that health plan and the associated costs for such services. [17] The Proposed Rule does not specify an effective date for this new safe harbor provision.

NEXT STEPS

It is unclear whether he Proposed Rule, if finalized, would actually result in the lower drug prices. However, it is clear that the Proposed Rule would significantly alter the contracting relationships between manufacturers, PBMs, and pharmacies. PBMs and manufacturers would need to develop novel approaches to provide discounts that fall within the new safe harbors. Existing Part D and managed care Medicaid rebate agreements will need to reviewed and amended prior to the implementation date. With regard to Part D plan beneficiaries, those who have not yet met their deductibles or have co-insurance based on a percentage of a drug's list price stand to benefit significantly from the corresponding reductions in out-of-pocket expenses. However, Part D beneficiaries may also see rising premiums as plans stop applying drug manufacturer rebates to reduce these payment obligations.

Companies involved in arrangements affected by the Proposed Rule should assess potential business opportunities associated with arrangements structured to fit under the two new safe harbors, as well as legal and compliance risks. The K&L Gates' health care and food, drugs, medical devices and cosmetics (“FDA”) practice regularly advises clients in all facets of the drug distribution chain in compliance, distribution contracting, and operational matters and stands ready to assist in assessing the impact of the changes on their current and future operations, as well as preparing formal comments on the Proposed Rule.

NOTES:

[1] HHS OFF. OF INSPECTOR GEN., 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 (Jan. 31, 2019), https://s3.amazonaws.com/public-inspection.federalregister.gov/2019-01026.pdf. The Proposed Rule is expected

to be published in the Federal Register on February 6, 2019.
[2] *See* 42 U.S.C. § 1320a-7b.
[3] 42 C.F.R. § 1001.952(h). For example, HHS explains that: (a) PBM rebates increase drug costs to beneficiaries in the deductible phase and those with percentage-based cost-sharing obligations; (b) current rebates skew PBM and plan formulary decisions in favor of drugs with the highest rebates, which may be more expensive and less effective than drugs with lesser rebates; and (c) current rebates lack transparency.
[4] Proposed Rule at 7–18.
[5] *Id.*
[6] *Id.* at 6
[7] *Id.* at 38.
[8] *Id.* at 23
[9] *Id.* at 38-39
[10] *Id.* at 41
[11] *Id.* at 33, n. 58. *See also* 42 U.S.C. § 1320a-7b(b)(3)(A).
[12] Proposed Rule at 44–45.
[13] *Id.* at 47. HHS proposes to define "chargebacks" in a way that guarantees that a pharmacy is paid an amount that is at least equal to the price agreed upon in writing by the plan sponsor and the manufacturer.
[14] *Id.* at 46–48.
[15] *Id.* at 49–50.
[16] *Id.* at 52–55.
[17] *Id.* at 54

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