

HHS Proposes Eliminating Anti-Kickback Statute Protections for Rebates and Creating New Safe Harbors Allowing Point-of-Sale Discounts to Consumers and Fixed Service Fee Payments for Pharmacy Benefit Management Companies

Proposed Rule Officially Published in *Federal Register* on February 6, 2019

Comments Due on April 8, 2019

Proposed Implementation Date: January 1, 2020

On January 31, 2019 the Department of Health and Human Services (HHS) proposed sweeping changes to the current system for medication pricing and contracting by pharmacy benefit management (PBM) companies in federal programs--namely Medicare Part D and Medicaid programs. The proposed rule, [*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*](#) would eliminate the safe harbor protections for rebates that exists in the federal Anti-Kickback Statute (AKS) and replace these protections with proposed new safe harbors allowing for point-of-sale discounts to beneficiaries and for manufacturer-paid service fees to PBMs. The Administration states that the goal of these changes is to lower prescription drug prices and patient out-of-pocket costs consistent with its initiative entitled: [*American Patients First: Blueprint to lower Drug Prices and Out-of-Pocket Costs*](#) released in May 2018. According to HHS Secretary Alex Azar and the proposed rule, these provisions may curb list price increases for prescription drugs while reducing financial burdens on beneficiaries and thus could lower federal government expenditures in Medicare Part D and in Medicaid Managed Care Organizations and improve transparency.

Despite the HHS rhetoric, it is unclear how the savings could really add up without further reforms and clarification. HHS' own analyses included in the proposal suggest that net savings or costs to the Medicare Part D program and the Medicaid program at both the federal and state levels are uncertain. According to HHS, implementation of this rule could result in premium increases in Medicare Part D by approximately \$3-\$5/month¹ but the potential for savings is not clearly defined in the proposal and may not benefit all patients consistently, including those who may receive single source expensive products, for example cancer medications. Some patients who take high cost medications with competition may experience some relief, but as a recent article in the *New York Times* notes, patients whose medications cost thousands of dollars may not experience significant relief from skyrocketing costs.² A February 5, 2019 *Fortune* article that quotes AMCP CEO Susan A. Cantrell, notes that the the proposal does not make changes to Medicaid best price provisions which is a key barrier in allowing for price negotiation for prescription drug prices.³ Finally, the proposal does not directly consider rebates offered in

¹ *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*. [Vol. 84] Federal Register [No. 25] February 6, 2019. Table 2.A. Pg. 2357.

² Abelson R, Thomas K. How Trump's latest plan to cut drug prices will affect you. *New York Times*. February 5, 2019. Available at: <https://www.nytimes.com/2019/02/05/health/drug-prices-rebates-sotu.html>. Accessed February 6, 2019.

³ Tully S. The best way to lower drug prices: end the Medicaid program that blocks discounts. *Fortune*. February 5, 2019. Available at: <http://fortune.com/2019/02/05/the-best-way-to-lower-drug-prices-end-the-medicaid-program-that-blocks-discounts/>. Accessed February 6, 2019.

commercial markets. During a recent speech before the Bipartisan Policy Center, HHS Secretary Alex Azar noted that expansion to commercial insurance markets will require Congress to pass a law.⁴ Of further note, the proposal does not change the basic tenets of the AKS to prohibit improper direct or indirect remuneration for purposes of inducing business in federal health care programs.

AMCP is studying the proposed rule in more depth but generally cautions that focusing only on rebates is a diversion from coming up with real solutions to lowering drug costs. The rebate system is the model currently in place, and it is unclear what would replace this important lever that payers now use to lower drug costs for millions of Americans. The HHS proposal suggests that prices would automatically fall in the absence of rebates, but we think this is unrealistic. AMCP supports a competitive marketplace that allows payers to negotiate prices with manufacturers to ensure lower overall costs for consumers. Any new system must include the use of proven managed care pharmacy levers, such as formularies and utilization management tools, to help people get the right medications, at the right time and at the right cost. AMCP's specific summary of the provisions is below. AMCP welcomes feedback on the proposal by Friday, March 22, 2019 and is also planning a session at on this proposal at the Annual Meeting in San Diego, CA. Visit <https://www.amcpmeetings.org/> for more details regarding the meeting and to register.

Proposed Revisions to Discount Safe Harbor

Elimination of Ability of Manufacturers to Provide Rebates to Plan Sponsors

Specifically amends the discount safe harbor in the AKS to exclude price reductions on prescription drugs to plan sponsors from manufactures under either the Medicare Part D program or through Medicaid MCOs that are made directly to plans or through PBMs unless such discounts are required by law. HHS seeks comments in defining the following entities and terms used in the new safe harbors: manufacturer; wholesaler; distributor; PBMs; and prescription pharmaceutical product.

Proposal for New Point-of-Sale Price Reductions to Benefit Patients

The proposed point-of-sale price reductions would be considered protected under a safe harbor so long as all of the following criteria are met:

- Price reduction is set in advance between the Medicare Part D plan, Medicaid MCO, or PBM;
- The full value of the price reduction is paid to the pharmacy through chargebacks (not rebates) or is otherwise required by law. The proposal defines chargeback as "a payment made directly or indirectly by a manufacturer to a dispensing pharmacy so that the total payment to the pharmacy for the prescription pharmaceutical product is at least equal to the price agreed upon in writing between the manufacturer and the Medicare Part D plan, the Medicaid MCO, or PBM."
- The price reduction must be applied completely to the price of the pharmaceutical product charged to the beneficiary at the point of sale.

Proposal New Safe Harbor for Fixed Payment "PBM Services" Provided for Manufacturers

HHS also proposed a new safe harbor protection for services provided by PBMs under certain conditions as described below:

- Written agreement between the PBM and manufacturer that covers all of the services the PBMs provide to the manufacturers with the specifics of each service provided by the PBM and the

⁴ Alonso-Zaldivar R. Trump health chief asks congress to pass drug discount plan. US News & World Report. February 1, 2019. Available at: <https://www.usnews.com/news/politics/articles/2019-02-01/prescription-discounts-channeled-to-patients-in-trump-plan>. Accessed on February 6, 2019.

compensation for each service. The scope of services covered are those provided by the PBM to the manufacturer and not to health plans. The compensation requirements generally align with other areas of the AKS:

- Represent the fair market value of the service provided outlined in an arms length transition;
 - Fixed payments, and not based on percentage of sales; and
 - Not consider volume or value of referrals or other business between the parties or between the manufacturer and health plans that do business with the PBM for which payment may be made in whole or in part under federal health care programs.
- PBMs must provide annual written disclosures to its contracted health plan the services provided to manufacturers related to its contracts and the associated costs and provide this information to HHS upon request.

HHS provides examples of PBM services in the proposal, including network contracts with pharmacies; payment levels for network pharmacies'; developing and managing formularies, preferred drug lists, and prior authorization programs; performing drug utilization review; and operating disease management programs. Interestingly, the proposal also includes negotiating rebate arrangements as a PBM service. Other than examples given, HHS does not specifically define PBM services because it intends that this will expand over time. HHS seeks comment on this approach and the examples of PBM services.

If fully implemented, the proposed rule would take effect beginning on January 1, 2020, but HHS notes that manufacturers may make changes sooner than that date.