**Part D PBM Draft Legislation – Section-by-Section Analysis**

**Section 1 – Title**

The *“*Protecting Patients Against PBM Abuses Act.”

**Section 2 – Delinking, Anti-Spread Pricing, and Anti-Steering**

Amends the Part D statute (at section 1860D-12 of the Social Security Act) to add new contractual requirements on the Part D sponsor with respect to a PBM acting on the sponsor’s behalf (including cases where the Part D sponsor is acting as its own PBM).

Delinking. To ensure PBMs do not have an incentive to steer enrollees toward high-cost drugs, the provision requires the Part D sponsor to ensure that the PBM derives no income for Part D services other than through flat dollar service fees. Such fees cannot be contingent upon drug prices, discounts, rebates, or other remuneration with respect to covered Part D drugs, or any other circumstance prohibited by the Secretary.

Anti-Spread Pricing. The PBM also cannot charge an amount for the covered Part D drug’s ingredient cost or dispensing fee that is different from the amount reimbursed to the pharmacy.

Anti-Steering. To ensure against PBMs steering patients toward their own affiliated pharmacies, the language prohibits the PBM from compensating a network pharmacy less than affiliated pharmacies.

Report of Off-Formulary Therapeutic Equivalents. The PBM must submit a report to the plan of the difference between the negotiated price of an on-formulary drug versus the national average drug acquisition cost of any off-formulary, AB-rated therapeutic equivalent within the same category or class.

Reporting. Each year, the Part D sponsor and PBM would be required to certify compliance with these requirements.

Disgorgement. If a PBM receives fees violating the provision, the fees would need to be disgorged to the Secretary. The Part D sponsor must suspend payments to the PBM for failure to disgorge amounts or for other violations of the provision.

**Section 3 – Conflict of Interest**

This provision would amend already-existing conflict-of-interest provisions applicable to a Part D plan’s pharmacy and therapeutics (P&T) committee. Current law requires that the P&T committee (the committee that designs the formulary) include at least two independent individuals, one a pharmacist and one a physician. However, current law includes only conflicts with a Part D sponsor or plan – but not a PBM. Thus, pharmacists/physicians affiliated with the sponsor’s PBM could serve on the P&T committee and not be viewed as conflicted. OIG previously recommended this change (see OIG, HHS, Gaps in Oversight of Conflicts of Interest in Medicare Prescription Drug Decisions, March 2013, available at <https://oig.hhs.gov/oei/reports/oei-05-10-00450.pdf>.)

**Section 4 – PBM Transparency**

Amends existing PBM transparency requirements, but only with respect to Part D plans (this includes MA-PD plans and stand-alone PDP plans), by:

(a) Requiring reporting of the following data points:

(A) Aggregate dollar amount of all rebates the PBM received from drug manufacturers with respect to drugs furnished under a Part D plan;

(B) Aggregate dollar amount of all administrative fees the PBM received from drug manufacturers with respect to drugs furnished under such Part D plan;

(C) Aggregate dollar amount of all rebates that the PBM received from drug manufacturers that the PBM did not pass through to the plan sponsor;

(D) Aggregated retained rebate percentage from drug manufacturers; and

(E) Highest and lowest aggregate retained rebate percentage with respect to all PDP and MA-PD plans for which the PBM manages prescription drug coverage.

(b) Requiring the Secretary to report the information it receives from PBMs with respect to Part D business on a public website without disclosing the identity of a specific plan, prices charged for specific drugs or classes of drugs, or the amount of any rebates provided for specific drugs or classes of drugs.

**Sections 5-6 – Effective Date and Regulations**

Effective date of January 1, 2024.

Authority for the Secretary to initially implement the provision through interim final regulations.