

Summary Points: The Proposed PBM Compensation Disclosure Regulations

- On Thursday, Jan. 29th, the Department of Labor (DOL) finally released long-awaited proposed regulations clarifying – and confirming – that a Pharmacy Benefit Managers (PBM) and any other service provider that furnishes “pharmacy benefit management services” to a self-insured group health plan are subject to the ERISA’s 408(b)(2)(B) Compensation Disclosure requirements.

“Types” of Compensation That Must Be Disclosed

- The proposed regulations would require the disclosure of at least 8 different “types” of compensation streams a PBM or service provider providing “pharmacy benefit management services” receives from (1) the health plan, AND ALSO, (2) from drug manufacturers and (3) other entities in the drug supply chain.
- Note, these proposed PBM Compensation Disclosure regs go further than what the statutory requirements set forth under ERISA section 408(b)(2)(B) call for with regard to the “types” of compensation that must be disclosed by an entity providing services to an ERISA-covered health plan.
 - For example, the statute calls for the disclosure of “indirect compensation” from other third parties, but the statute does NOT define the “types” of indirect compensation that should be disclosed. These proposed regs, on the other hand, explicitly enumerate and define the “types” of compensation PBMs and service providers providing “pharmacy benefit management services” must disclose, including:
 - **Direct Compensation** paid by (1) the plan OR (2) the plan sponsor.
 - **Payments from Drug Manufacturers**, including rebates, fees, and other compensation, and the Disclosure must specify amounts that will be passed on to (1) the self-insured plan or (2) the plan sponsor, and also, the amounts retained by the PBM or service provider.
 - **Spread Pricing**, which includes (1) the amount the PBM or service provider *received* from the plan and (2) the amount the PBM *paid* to the pharmacy dispensing the prescription drugs.
 - **Co-Pay Clawbacks**, which includes the dollar amount of the difference between a copayment or coinsurance amount paid to the pharmacy by a plan participant and the reimbursement to the pharmacy that the PBM or service provider recouped from the pharmacy.
 - **Price Protection Agreements**, which includes any inflation protection or price protection agreements that the PBM or service provider has entered with any drug manufacturer or other party and the amount that will be passed on to (1) the plan or (2) the plan sponsor (if any).
 - **Formulary Placement Incentives**, which would include the amount of any formulary placement incentives that the PBM or service provider receives from a drug manufacturer and a description of the PBM’s or service provider’s authority to modify the formulary, such as by adding or deleting drugs or changing their tiering, and an explanation of the reasons for retaining such authority.
 - **Termination of Contract Payments**, which would include the amount of compensation (if any) the PBM or service provider would receive if the contract with the plan is terminated, and how any pre-paid amounts (if any) would be calculated and refunded upon termination.
 - **Drug Pricing Methodology**, which would include a description of the net cost to the self-insured plan of each drug on the formulary, and for each dispensing channel, expressed as a dollar amount.

Frequency of the Disclosures

- The “types” of compensation noted above must be disclosed (1) through an “Initial Disclosure” (30 days prior to entering into or renewing a contract with the plan), AND ALSO, (2) through a “Semiannual Disclosure.”
 - If any compensation stream increases by 5% above the amounts disclosed in the Initial Disclosure, the Semiannual Disclosure must identify the amount of the overage and explain the reason for the increase.

Disclosures Only to the Fiduciary of a Self-Insured Group Health Plan

- These “types” of compensation streams must be disclosed to the fiduciary of a self-insured group health plan ONLY. The DOL suggested that they may issue guidance extending the proposed requirements to fully-insured plans some time in the future.

Sharing the Disclosed Compensation Information With Other Third Parties

- Importantly – and significantly – the plan IS PERMITTED to share the disclosed information with third parties (such as consultants, attorneys, and other service providers for the self-insured plan), so long as these third parties agree to keep the disclosed information confidential and agree NOT to share the information with other parties (i.e., these third-parties cannot share the information with fourth parties).

PBMs and Other Service Providers Providing “Pharmacy Benefit Management Services”

- Importantly, it does not matter whether a person, business, or entity performing the following “pharmacy benefit management services” identifies itself as a PBM. What matters is whether the person, business, or entity is *actually performing any* of the following:
 - Acting as negotiator or aggregator of rebates, fees, discounts, and price concessions for prescription drugs.
 - Establishing or maintaining prescription drug formularies.
 - Establishing or maintaining pharmacy networks, including a mail-order, specialty, retail, nursing home, or long-term care pharmacy, and an infusion or other outpatient pharmacy, to provide prescription drugs.
 - Processing and payment of claims for prescription drugs.
 - Performing utilization review and management, including the processing of prior authorization requests, step-therapy protocols, patient compliance analyses, conducting therapeutic intervention, and administering generic substitution programs.
 - Adjudicating appeals or grievances related to the self-insured plan’s prescription drug benefits.
 - Recordkeeping related to the self-insured plan’s prescription drug benefits.
 - In conjunction with any of these other services, performing regulatory compliance with respect to the self-insured plan’s prescription drug benefits under the contract or arrangement.

Audit Rights

- The self-insured plan must be permitted to audit the PBM or service provider at least once per year to ensure that the Compensation Disclosure is accurate, and the PBM/service provider cannot limit the period of the audit, the location of the audit, or the number of records to be provided for the audit.
 - The plan must be able to select their own auditor, and the plan shall bear all expenses related to the auditor, while the PBM or service provider must pay for the cost of providing all information to the auditor.

Other Interesting Aspects of These Proposed Regulations

- The DOL requests comments on whether the Department should extend these Compensation Disclosure requirements to apply to TPAs providing “third-party administrative services.”
- The DOL also requests comments on whether the required Disclosure should also include other items like claims data, payments to providers, and pricing information.
 - In other words, should claims data and pricing information be considered “compensation” under ERISA section 408(b)(2)(B), thus requiring the disclosure of claims data and pricing information to a self-insured plan’s fiduciary?