DOL Regulations Confirm That PBMs Are Subject to ERISA's Compensation Disclosure Requirements

On Thursday, Jan. 29th, the Department of Labor (DOL) finally released long-awaited proposed regulations implementing – and clarifying – important aspects of the 408(b)(2)(B) Compensation Disclosure requirements. In short, these proposed rules clarify – and confirm – that Pharmacy Benefit Managers (PBMs) and any other service provider that furnishes "pharmacy benefit management services" to a self-insured group health plan are subject to the Compensation Disclosure requirements. The proposed rules further confirm that PBMs and these service providers would be required to furnish specified disclosures to the self-insured plan's fiduciary, and also to permit the plan's fiduciary to conduct an audit for accuracy of the Disclosures.

What Led to the Development of These Proposed Regulations?

At the end of 2020, the Consolidated Appropriations Act of 2021 (CAA 2021) was enacted into law. Among other provisions included in the CAA 2021 was a requirement that an entity or individual furnishing specified services to a group health plan must disclose to the plan's fiduciary the "direct" and "indirect" compensation paid to the entity/individual. This new requirement – set forth in ERISA section 408(b)(2)(B) (hence the name 408(b)(2)(B) Compensation Disclosure requirements) – used the terms "Brokage Services" and "Consulting," which led the industry to believe that ERISA's Compensation Disclosure requirements ONLY applied to "Brokers" and "Consultants."

However, on December 14, 2022, Congress sent a letter to the DOL explaining that Congress intended for the Compensation Disclosure requirements to apply to ANY entity/individual furnishing services set forth in an enumerated list of services in the statute, including PBMs and also Third-Party Administrators (TPAs) that, for example, develop a provider network or prescription drug formulary, process claims and maintain records, and negotiate rates for covered medical items and services or prescription drugs.

While the Biden Administration's DOL did not issue guidance in response to Congress's letter, on April 15, 2025, the most recent Trump Administration issued an Executive Order directing the Trump DOL to develop regulations confirming that PBMs are subject to the 408(b)(2)(B) Compensation Disclosure requirements. These proposed regulations are in response to President Trump's directive.

What Do the Proposed Regulations Say?

The following provides you with a detailed summary of the most important aspects of these proposed regulations. Note, public comments are due on March 31st. SIIA will be submitting comments.

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Proposed 408(b)(2)(B) Compensation Disclosure Regulations Applicable to PBMs and Other Service Providers

As part of confirming that PBMs and other service providers are subject to ERISA's Compensation Disclosure requirements, the proposed regulations explain that any person, business, or entity furnishing "pharmacy benefit management services" to a self-insured plan or a providing advice, recommendations, or referrals regarding the provision of "pharmacy benefit management services"

must disclose to the plan's fiduciary (1) the "types" of services provided to the plan and (2) the "types" of compensation received from the plan, from other third parties, and from any other arrangements with any parties in the pharmaceutical supply chain.

Pharmacy Benefit Management Services - Defined

Importantly, the proposed regulations define "pharmacy benefit management services" as services necessary for the management or administration of the self-insured plan's prescription drug benefits, including, for example:

- Acting as a negotiator or aggregator of rebates, fees, discounts and other price concessions for prescription drugs;
- Establishing or maintaining prescription drug formularies;
- Establishing or maintaining pharmacy networks, through contract or otherwise, including a mail-order pharmacy, a specialty pharmacy, a retail pharmacy, a nursing home pharmacy, a 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 for drugs, 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; and
- 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.

The proposed regulations confirm that it does not matter whether the person, business, or entity performing these services identifies itself as a PBM. What matters is whether the person, business, or entity is performing *any* of these services (and if the person, business, or entity ***is*** performing any of these services, then ***they are*** subject to these Compensation Disclosure requirements).

Disclosure of the "Types" of Services

The proposed regulations would require PBMs and other service providers to include in their Compensation Disclosures a description of each "pharmacy benefit management service" or of the advice, recommendations, or referrals regarding the provision of "pharmacy benefit management services" to be provided to the plan pursuant to the contract with the plan.

Disclosure of the "Types" of Compensation Received

"Direct Compensation": The Compensation Disclosure would be required to include a description of "direct compensation" paid to the PBM or service provider directly (1) from the self-insured plan itself (with plan assets) AND/OR (2) from the plan sponsor on behalf of the plan (for example, from the plan sponsor's general assets). This description must include the dollar amount of all "direct compensation" – both in the aggregate and by service – that the PBM or service provider reasonably expects to receive on a quarterly basis from (1) the plan AND/OR (2) the plan sponsor.

Payments from Drug Manufacturers: The proposed regulations would also require the Compensation Disclosure to include the amount of any payments (including rebates, fees, and other compensation)

from drug manufacturers, as well as from rebate aggregators or other entities that negotiate rebates with drug manufacturers. This disclosure must cover the amount of any payment – both in the aggregate and for each drug on the formulary – and it must be expressed as an amount reasonably expected to be paid on a quarterly basis. Importantly, this disclosure must specify the amount that will be retained by the PBM or service provider, and also, the amount that will be passed on to (1) the self-insured plan or (2) the plan sponsor (if applicable).

Spread Pricing: Referred to as "Spread Compensation" in the proposed regulations, the Disclosure would be required to include (1) the amount the PBM or service provider *received* each quarter from the plan and (2) the amount the PBM or service provider *paid* each quarter to the pharmacy dispensing drugs – both in the aggregate and for each drug on the formulary – and for each dispensing channel (i.e., retail, mail-order, and specialty pharmacy).

Drug Pricing Methodology: The Disclosure would be required to include a description of the net cost to the self-insured plan of each drug on the formulary, for each dispensing channel, expressed as a dollar amount. If a dollar amount is not ascertainable, the PBM or service provider must disclose the methodology used to determine the cost the plan will pay for each drug on the formulary, for each dispensing channel, along with an objective means to verify the accuracy.

Co-Pay Clawbacks: The Disclosure would also be required to include a description of the quarterly amount of co-pay clawback compensation (i.e., the dollar amount of the difference between a copayment or coinsurance amount paid to the pharmacy by a plan participant or beneficiary and the reimbursement to the pharmacy) that the PBM or service provider recouped from a pharmacy in connection with prescription drugs dispensed under contract with the plan, also specifying the anticipated total number of transactions resulting in recoupment.

***Price Protection Agreements*:** The Disclosure would include a description of any inflation protection or price protection agreements that the PBM or service provider has entered with any drug manufacturer or other party in connection with prescription drugs dispensed under the contract with the plan, specifying the quarterly amount reasonably expected to be retained by the PBM or service provider in connection with each such inflation protection or price protection contract or arrangement and the amount that will be passed on to (1) the plan and/or (2) the plan sponsor (if applicable).

Formulary Placement Incentives: The Disclosure would be required to include a description of any formulary placement incentives that the PBM or service provider has entered with any drug manufacturer in connection with the contract with the plan, along with an explanation of how the incentives affect services to, and are aligned with, the interests of the plan and/or its participants. If the PBM or service provider has the authority to modify the formulary during the term of the contract with the plan – such as by adding or deleting drugs or changing their tiering – the Disclosure must include an explanation of the reasons for retaining such authority, the expected frequency of such changes, and that the plan fiduciary will be notified reasonably in advance of any modifications that are expected to have a material impact on the reasonableness of compensation paid to the PBM or service provider, as well as the plan's right to terminate the PBM's or service provider's contract on reasonably short notice under the circumstances.

Termination of Contract: The PBM or service provider would be required to disclose the amount of compensation (if any) they will receive if the contract with the plan is terminated, and how any pre-paid amounts (if any) will be calculated and refunded upon termination.

Other Important Stuff In These Proposed Regulations

If a TPA (who is not otherwise a PBM) contracts with a self-insured plan to provide "pharmacy benefit management services" to the plan, that TPA would become subject to these Compensation Disclosure requirements, even if the TPA intends to rely on another service provider to perform those "services." In this case, the TPA would be responsible for making the required Disclosures discussed above, and therefore, must be able to obtain information necessary for furnishing the proper Disclosure from the other service provider performing the "pharmacy benefit management services."

Separately, but also related to TPAs, the DOL explicitly requests comments on whether the Department should extend these Compensation Disclosure requirements to apply to TPAs that are performing "third party administrative services," which is a "service" set forth in the enumerated list of services in the statute.

The DOL also requests comments on whether the proposed required Compensation Disclosure should 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?