Drug Pricing and PBM Compensation: DOL Proposed Rule for Improving Transparency

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On January 30, 2026, the U.S. Department of Labor ("DOL") published a proposed rule entitled, "Improving Transparency into Pharmacy Benefit Manager Fee Disclosure" (the "Proposed Rule").[1] Under the Proposed Rule, pharmacy benefit managers ("PBMs" or, singularly, a "PBM") are generally required to disclose to fiduciaries of self-insured (also referred to as "self-funded") group health plans certain information, including compensation (both direct and indirect), formulary placement incentives, drug prices, price protection agreements and a statement of the plan's audit right.

The Proposed Rule has two main purposes: (1) to allow responsible plan fiduciaries to better fulfill their responsibility of ensuring that PBM service contracts are reasonable under the Employee Retirement Income Security Act of 1974 ("ERISA"), and (2) to enhance market efficiency and improve access to affordable prescription drugs for consumers. The DOL is requesting comments on the Proposed Rule, with the goal of having the final rule apply to ERISA self-insured group health plans for plan years beginning on or after July 1, 2026. Below is a discussion of the background leading to the Proposed Rule, select key concepts regarding the Proposed Rule and recent related developments since the issuance of the Proposed Rule.

Background

Within the prescription drugs supply chain, PBMs (along with applicable related parties, i.e., affiliates, agents and subcontractors)[2] are intermediaries (or "middlemen") among the following key players: plan participants and beneficiaries,[3] plan sponsors (e.g., employers), plan administrators, drug manufacturers, drug wholesalers and retail pharmacies. As intermediaries, PBMs play a vital and powerful role in providing medications to the end users—plan participants and beneficiaries.

PBMs generally negotiate drug prices, establish drug formularies (lists of covered drugs under a plan), create pharmacy networks, process and pay claims, perform utilization review and management and decide appeals of denied claims. A recurring complaint of plan sponsors, plan fiduciaries and government entities is that they

do not know how much compensation PBMs are actually receiving, whether that compensation is reasonable or competitive and to what extent conflicts of interest are present within the PBMs' dealings. Hence, the demands for more transparency.

With the exception of deciding appeals of denied claims (as applicable), PBMs are generally not considered fiduciaries. Each employee benefit plan subject to ERISA must have at least one named fiduciary.[4] Under ERISA, a fiduciary must act with respect to a plan ***solely in the interest of the participants and beneficiaries***, with such actions including payment of no more than reasonable expenses for administering the plan.[5]

ERISA further prohibits a fiduciary from causing a plan to engage in transactions in which there is direct or indirect "furnishing of goods, services or facilities between the plan and a party in interest."[6] PBMs fall within ERISA's definition of a party in interest, which includes "a person providing services" to the plan.[7] Thus, it would appear that plan fiduciaries cannot cause a plan to engage in transactions with PBMs. However, ERISA Section 408(b)(2) provides a statutory exemption from the prohibited transaction rules for a contract or arrangement with a service provider that satisfies the following conditions: (1) the contract or arrangement is reasonable, (2) the service is necessary to the establishment or operation of the plan and (3) no more than reasonable compensation is paid for the service.

The Proposed Rule, based upon the statutory prohibited transaction exemption described above, aims to empower fiduciaries with rights to receive certain information and to audit the validity of the received information. When these rights are honored per applicable law, the contracts or arrangements with the PBMs are deemed reasonable.

The DOL has been down this path before in a somewhat different context. In February 2012, the DOL issued regulations regarding fee disclosures for qualified retirement plans (the "2012 Pension Final Rule").[8]. These regulations are intended to provide plan fiduciaries with, among other things, comprehensive fee information from service providers (record keepers, advisers and brokers) to enable them to assess the reasonableness of their fees.

In explaining the rationale for these pension regulations, the DOL said in July 2010 that the complexity of changes in the industry over the years had "made it more difficult for plan sponsors and fiduciaries to understand what service providers actually are paid for the specific services rendered."[9]. When finalizing the 2012 Pension Final Rule, the DOL thought it best to leave for a future date the "development of specifically tailored disclosure requirements for welfare plans."[10]

In December 2020, Congress passed the Consolidated Appropriations Act, 2021 ("CAA 2021"),[11] which imposes certain disclosure requirements for welfare plans. Under Division BB, Section 202 of CAA 2021, service providers, affiliates and subcontractors are required to disclose in writing all direct and indirect compensation over $1,000 anticipated to be received as a result of performing brokerage services or consulting to ERISA-covered group health plans (whether fully insured or self-insured). CAA 2021 requires such disclosures to the fiduciaries reasonably in advance of the parties entering into, extending or renewing the applicable contract or arrangement.

With respect to PBMs, CAA 2021 appeared to focus on (1) brokerage services regarding the ***selection*** of pharmacy benefit management services and (2) consulting related to ***the development or implementation*** of pharmacy benefit management services. However, CAA 2021 did not define the terms "brokerage services,"

"consulting" and "pharmacy benefit management services." Furthermore, in Field Assistance Bulletin No. 2021.03, the DOL adopted a good faith, reasonable interpretation standard for the disclosures required under Division BB, Section 202 of CAA 2021.

Congress and the DOL are not the only federal entities that have been reviewing PBM compensation arrangements. The U.S. Federal Trade Commission ("FTC"), tasked with protecting the public from deceptive or unfair business practices and from unfair methods of competition, has taken note of PBM influence and methods. Historically, the FTC has in essence taken the position that imposing disclosure requirements on PBMs is not necessary. As will be discussed further below, the FTC's current position is now more in line with the position the DOL has taken in the Proposed Rule.

State governments have also engaged in regulating PBMs. After reviewing each state's publicly available database in November 2021, some state researchers found that all 50 states had enacted regulations specifically directed to PBMs.[12] One recent example involves California, as described in our January 2026 Benefits Report: PBM Fiduciary Provisions of New California Law Challenged by PBM Trade Association as Preempted by ERISA (https://www.truckerhuss.com/newsletter/benefits-report-january-2026/#article2). It is within this environment that the DOL has issued the Proposed Rule.

Select Key Concepts Regarding the Proposed Rule

The Proposed Rule's preamble emphasizes that the pharmaceutical supply chain is highly complex, involving many players and arrangements that can be quite opaque. Hence, the call for transparency. Below are select key concepts regarding the Proposed Rule, along with some background information (as applicable).

Information to be Disclosed

The Proposed Rule requires disclosure of the following information:

(A) Direct *compensation*. A description of direct compensation, both in the aggregate and by service, that the PBM reasonably expects to receive or has received on a quarterly basis from the plan or plan sponsor. An example of such compensation is an administrative fee calculated on a per-participant, per-month basis.

(B) Manufacturer *payments*. A description of manufacture payments, both in the aggregate and by service, that the PBM reasonably expects to receive or has received on a quarterly basis. An example of such compensation is a manufacturer rebate. The Proposed Rule specifies that this disclosure should include both (i) the amount that will be passed on to the plan and/or the plan sponsor and (ii) the amount that will be retained by the PBM.

(C) *Spread compensation*. A description of spread compensation, both in the aggregate and for each drug on the formulary—and for each pharmacy channel (i.e., retail, mail order and specialty pharmacy)—that the PBM reasonably expects to receive or has received on a quarterly basis. Spread compensation means the difference between the negotiated rate reasonably expected to be paid or that was actually paid by the plan to the PBM, and the corresponding negotiated rate to be paid or that was paid by the PBM to the pharmacy for dispensing drugs.

(D) Copay *claw-backs*. A description of the copay claw-backs that the PBM reasonably expects to receive or has received on a quarterly basis. Copay claw-back compensation means the dollar amount of the difference between (i) a copayment or coinsurance amount paid to the pharmacy by a plan participant or beneficiary and

(ii) the reimbursement to the pharmacy. The Proposed Rule provides the following example: if a participant's copayment for a generic drug is $15 dollars, but the PBM has agreed to pay the pharmacy $5, the PBM may "claw-back" the excess $10 from the pharmacy.

(E) Price *protection agreements*. A description regarding any inflation protection or price protection agreements that the PBM has entered with any drug manufacturer or other party in connection with prescription drugs dispensed under the contract or arrangement with the plan. Each description should specify the amount the PBM reasonably expects to retain or has retained on a quarterly basis in connection with each such agreement, and the amount that will be passed on to the plan and/or the plan sponsor.

(F) Other *compensation descriptions*. To the extent not already disclosed, each "other compensation" description should include the following four items: (i) a description of the compensation the PBM reasonably expects to receive or has received on a quarterly basis in connection with the service contract or arrangement; (ii) the identification of the payer of such compensation; (iii) an identification of the services for which such compensation will be received; and (iv) a description of the arrangement between the payer and PBM pursuant to which such compensation is paid.

(G) Description *of services*. 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 covered plan pursuant to the service contract or arrangement. (See further below for the definition of "pharmacy benefit management services.")

(H) Compensation *for termination of service contract or arrangement*. A description of any compensation that the PBM reasonably expects to receive in connection with termination of the service contract or arrangement, and how any prepaid amounts will be calculated and refunded upon such termination.

(I) Description *of formulary placement incentives*. Descriptions or identifications of (i) formulary placement incentives and arrangements between the PBM and any drug manufacturers, along with an explanation of how these incentives and arrangements align with the interests of the plan and/or its participants and beneficiaries; (ii) any reasonably available therapeutically equivalent alternatives and the reason for excluding such alternatives from the formulary for any drug which the PBM reasonably expects to receive compensation from the manufacturer; and (iii) information regarding the PBM's authority, if any, to modify the formulary during the term of the contract or arrangement.

(J) Drug *pricing methodology*. A description of the net cost to the covered plan of each drug on the formulary, for each pharmacy channel, expressed as a monetary amount. If a monetary amount is not ascertainable, the covered service provider must disclose the methodology used by the PBM under the service contract or arrangement to determine the cost the covered plan will pay for each drug on the formulary, for each pharmacy channel, along with an objective means to verify the accuracy.

(K) Statement *of fiduciary status*. If applicable, a statement that the PBM will provide, or reasonably expects to provide, services pursuant to the service contract or arrangement directly to the covered plan as a fiduciary (within the meaning of ERISA Section 3(21)). Along with this statement, the PBM must disclose any activity or policy that may create a conflict of interest.

(L) Statement *of audit right*. A statement of the covered plan's right to an audit, as specified in the Proposed Rule, and the procedures for requesting such an audit. The terms of the Proposed Rule provide, in part, that a plan is entitled to an audit at least annually for the purpose of validating the accuracy of any disclosure made

pursuant to the Proposed Rule. The plan fiduciary has the right to select an auditor, while the plan must bear the responsibility for all reasonable expenses related to the selection and retention of the auditor.

(M) Overage *explanation*. If any category of compensation previously disclosed as a quarterly estimate materially exceeds the actual quarterly amount, in the aggregate, then the amount of the overage (in the aggregate) must be disclosed along with the reason for the overage.

Frequency of Disclosure

- *Initial Disclosure*. Under the Proposed Rule, a covered service provider must disclose items (A) through (L) above by the date that is reasonably in advance of the date on which the service contract or arrangement is entered and extended or renewed. For this disclosure, monetary amounts are generally estimated based on what is reasonably expected to be received.
- *Semiannual Disclosure*. Under the Proposed Rule, a covered service provider must disclose items (A) through (F) and item (M) above on a semiannual basis, and that disclosure must be made no later than 30 calendar days after the end of each six-month period beginning on the date the service contract or arrangement is entered. For this disclosure, monetary amounts are generally actual amounts received.

Covered Plans

The Proposed Rule applies to self-insured group health plans, which are classified into two groups: (1) level-funded self-insured plans that have extensive stop loss policies to emulate features of fully insured arrangements, and (2) other self-insured plans which do not have such policies. The Proposed Rule does not apply to fully insured group health plans. The rationale for excluding fully insured plans is that prescription drug coverage is one component of a comprehensive health insurance policy which a plan sponsor purchases.

In the DOL's view, fiduciaries for fully insured plans will likely focus on different considerations than fiduciaries for self-insured plans when entering into and maintaining contracts or arrangements for services with other parties. Thus, the disclosures mandated by the Proposed Rule may not be helpful to fiduciaries of fully insured plans.

Covered Service Provider

Under the Proposed Rule, a covered service provider is a service provider that enters into a contract or arrangement with the covered plan and reasonably expects to receive $1,000 or more in compensation (direct or indirect) for providing pharmacy benefit management services or for providing advice, recommendations or referrals regarding the provision of pharmacy benefit management services. The services may be performed or the compensation may be received by the covered provider or an affiliate, an agent or a subcontractor of the covered provider.

Under the Proposed Rule, the covered service provider is responsible for disclosing the applicable information to the covered plan. The fact that the covered service provider does not actually perform or receive compensation for all or some of the pharmacy benefit management services is irrelevant. If the covered service provider's affiliate, agent or subcontractor performs the services or receives the compensation instead of the covered service provider, then the latter is responsible for providing the required disclosures. In other words, if a PBM enters into a contract with a plan to provide pharmacy benefit management services but the PBM's affiliate, agent or subcontractor does the work or receives the compensation, the PBM is responsible for providing the required disclosures.

Pharmacy Benefit Management Services

The Proposed Rule broadly defines the term "pharmacy benefit management services" as the "services necessary for the management or administration of a covered plan's prescription drug benefits." The entity or person providing the service need not self-identify as a PBM.

Exemption for Responsible Plan Fiduciary

The Proposed Rule provides that a fiduciary will not be deemed to have engaged in a prohibited transaction under ERISA solely because the covered service provider failed to meet the disclosure requirements set forth in the Proposed Rule, provided the fiduciary take certain steps, including but not limited to (i) timely requesting correction of the failure from the covered service provider, and (ii) timely notifying the DOL Secretary of the covered service provider's failure.

Recent Related Developments

Within days of the DOL publishing the Proposed Rule in the Federal Register, additional federal action contributed to regulation of PBMs in alignment with the Proposed Rule. The Consolidated Appropriations Act, 2026 was signed into law on February 3, 2026 ("CAA 2026"). For more information on CAA 2026, see Mary Powell's article in this issue of the Benefits Report.

The second set of federal actions came from the FTC. By way of background, in September 2024, after further study of the PBM industry, the FTC filed an in-house administrative complaint against the three largest PBMs (i.e., CVS Caremark, Express Scripts, and OptumRx), accusing them of artificially inflating the list price of insulin drugs by using unfair rebating and anticompetitive practices. On February 4, 2026, the FTC announced a settlement with Express Scripts in which Express Scripts agreed, in part, to "Increase transparency for plan sponsors, including … disclosing payments to brokers representing plan sponsors."[13]

Next Steps

For those who want to provide comments to the DOL on the Proposed Rule, the deadline is March 31, 2026.

In this new world, plan sponsors and fiduciaries can expect to receive substantially more information than in the past regarding PBM practices and compensation. Plan sponsors, plan fiduciaries and plan administrators should consider in particular (i) hiring and training the appropriate individuals (whether internal or external to the company) to effectively digest and utilize the enhanced disclosed information, and (ii) conducting audits to validate the accuracy of the disclosed information.

[1] 91 Fed. Reg. 4348 (January 30, 2026). The Proposed Rule implements section 12 of President Trump's Executive Order 14273 of April 15, 2025, *Lowering Drug Prices by Once Again Putting Americans First*. The DOL intends that the Proposed Rule, when finalized, will be codified within the Code of Federal Regulations ("CFR") at 29 CFR § 2550.408b-2 and 29 CFR § 2550.408b-22.

[2] Unless specified otherwise, in this article the term "PBM" means the pharmacy benefit manager and its affiliates, agents and subcontractors, as a whole.

[3] Beneficiaries within the context of group health plans are also known as dependents, which are spouses, domestic partners and children of the plan participants.

[4] ERISA Section 402(a).

[5] ERISA Section 404(a).

[6] ERISA Section 406(a).

[7] ERISA Section 3(14).

[8] These regulations may be found at 29 CFR § 2550.408b-2(c).

[9] 75 Fed. Reg. 41600, 41600 (July 16, 2010).

[10] 91 Fed. Reg. 4348, 4356 (January 30, 2026).

[11] Public Law 116-260 – Dec. 27, 2020.

[12] *State-level policy efforts to regulate pharmacy benefit managers (PBMs),* T. Joseph Mattingly II, Maisie Lewis, Mariana P. Socal and Ge Bai, Research in Social and Administrative Pharmacy 18, 2022, Pages 3995-4002.

[13] U.S Federal Trade Commission, News and Events, News, Press Releases, *FTC Secures Landmark Settlement with Express Scripts to Lower Drug Costs for American Patients: Settlement resolves FTC lawsuit alleging that Express Scripts' conduct resulted in artificially inflated insulin drug prices*, February 4, 2026.

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