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BLOG

New Transparency Requirements for Pharmacy Benefit Managers: What Group Health Plan Sponsors Need to Know

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Recent developments at the federal legislative and regulatory levels signal a significant shift toward greater transparency requirements in the pharmacy benefit management (PBM) industry. While group health plan sponsors (plan sponsors) have been grappling with PBM reform laws at the state level, plan sponsors should now be aware of two key developments at the federal level:

- A new federal law, *Lowering Prescription Drug Costs* (HR 7148), was enacted as part of the Consolidated Appropriations Act, 2026 (CAA 2026). HR 7148 amends the Employee Retirement Income Security Act (ERISA), the Internal Revenue Code, and the Public Health Security Act to establish new statutory requirements for PBM reporting, disclosure and financial practices for both fully-insured and self-funded group health plans HR 7148 also makes changes to the PBM industry impacting Medicare and Medicaid. Most provisions of HR 7148 are effective for plan years beginning on or after 30 months from the date of the CAA 2026's enactment; for calendar plan years, the effective date is January 1, 2029.
- On January 29, 2026, the U.S. Department of Labor (the DOL) issued a proposed rule (the Proposed Rule) that, if finalized, would require providers of PBM services and affiliated brokers and consultants providing advice, recommendations, or referrals regarding the provision of PBM services to disclose information about their compensation to fiduciaries of self-insured group health plans. The Proposed Rule, issued under section 408(b)(2) of ERISA, provides an exemption from ERISA's section 406(a) prohibited transaction rules for certain service contracts and arrangements between ERISA-covered plans (including self-insured group health plans) and PBMs and other service providers that reasonably expect $1,000 or more in compensation. To qualify for this exemption, the following three conditions must be met: (i) the contract or arrangement must be "reasonable"; (ii) the services must be "necessary" for the establishment or operation of the plan; and (iii) no more than "reasonable compensation" may be paid for the services. The proposed applicability date is plan years beginning on or after July 1, 2026. There is a 60-day notice and comment period for the Proposed Rule.

Together, these developments will fundamentally reshape the business and financial practices of PBMs and how plan fiduciaries engage with and monitor their PBMs and other service providers. Both initiatives share a common objective: ensuring that plan sponsors have the information necessary to fulfill their fiduciary duties under ERISA when selecting and monitoring PBMs. While the rules overlap in some respects, there are also differences in scope and effective dates as discussed below.

ENHANCED DISCLOSURE REQUIREMENTS

Initial Disclosures Under the Proposed Rule

The Proposed Rule requires covered service providers to furnish comprehensive written disclosures to responsible plan fiduciaries in advance of entering into, extending, or renewing a PBM contract. These disclosures must include a description of each PBM service to be provided, along with detailed information regarding compensation arrangements.

The Proposed Rule requires disclosure of direct compensation expected to be received, both in the aggregate and broken down by service on a quarterly basis. PBMs and any affiliated brokers and/or consultants must also disclose amounts expected to be received from drug manufacturers or aggregators for each drug on the formulary, specifying what portion will be passed through to the group health plan versus retained by the PBM service provider. Additionally, PBMs must disclose expected spread compensation—the difference between what the group health plan pays the PBM and what the PBM pays the dispensing pharmacy—for each drug and pharmacy channel.

Other required disclosures include copay claw-back amounts, price protection agreement terms, termination compensation, formulary placement incentives, drug pricing methodology, and whether the PBM will act as an ERISA fiduciary. The PBM service provider must also disclose any activity or policy that may create a conflict of interest for the service provider – for example, if the PBM service provider will financially benefit from step therapy protocols that require participants to first try a drug that generates greater manufacturer rebates than other therapeutically equivalent drugs on the formulary.

Ongoing Reporting Obligations

Both HR 7148 and the Proposed Rule establish semiannual reporting requirements. Under HR 7148, PBMs must submit reports to group health plans in plain language and machine-readable format, with quarterly reporting available upon request. These reports must include drug-by-drug data encompassing the total number of paid claims, plan payments, participant cost-sharing, gross and net spending, and rebates and other remuneration received from applicable entities. The Proposed Rule similarly requires semiannual disclosures of actual compensation received, due within 30 days after each six-month period. In addition, if any category of compensation, in the aggregate, materially exceeds the corresponding quarterly estimate provided as part of the initial disclosure by five percent (5%) or more, the PBM service provider must identify and explain the overage.

REBATE PASS-THROUGH REQUIREMENT

One of the most significant provisions in HR 7148 is the requirement that PBMs remit 100% of rebates, fees, alternative discounts, and other remuneration received from applicable entities to the group health plan or health insurance issuer. A PBM arrangement is not considered “reasonable” under ERISA Section 408(b)(2) unless the PBM remits 100% of rebates, fees, alternative discounts, and other remuneration received from applicable entities related to drug utilization or spending to the group health plan. This represents a fundamental change from current industry practice, where PBMs often retain all or a portion of manufacturer rebates and other payments as part of their compensation. In some cases, these amounts offset some of the PBM’s administrative fees.

Under HR 7148, rebate payments must be made within 90 days after the end of each quarter, and must be fully disclosed and enumerated. The legislation clarifies that it does not prohibit reasonable payments to PBMs for bona fide services using a transparent, quantifiable fee structure, effectively encouraging a shift toward fee-based compensation models.

AUDIT RIGHTS

The Proposed Rule establishes detailed audit rights that will strengthen and clarify contractual terms. Under the Proposed Rule, group health plans would have the right to conduct audits at least once per year, with the auditor selected by the group health plan’s fiduciary rather than the PBM service provider. Importantly, PBM service providers may not restrict auditor selection, and must provide access to all records necessary to verify compliance, including contracts with pharmacies and drug manufacturers.

The Proposed Rule further prohibits PBM service providers from imposing restrictions on the location of the audit, the number of records that may be reviewed, or the time period covered by the audit, except that PBMs may limit the audit to the disclosure period. These provisions address longstanding concerns by plan sponsors that contractual audit restrictions have undermined plan sponsors' ability to verify PBM performance and compensation.

Under HR 7148, records of rebates, fees, alternative discounts, and other remuneration remitted to the group health plans must be available for audit at least once per plan year. In addition, rebate contracts with rebate aggregators or drug manufacturers must be available for audit by the group health plan, subject to reasonable confidentiality restrictions.

AFFILIATED PHARMACY DISCLOSURE

Both the Proposed Rule and HR 7148 require enhanced disclosure regarding PBM-affiliated pharmacies, which have been the target of many anti-steerage provisions in state laws. For example, HR 7148 requires PBMs to explain benefit design parameters that encourage use of affiliated pharmacies and to provide detailed pricing comparisons between affiliated and non-affiliated pharmacies. The Proposed Rule also requires disclosure of spread pricing by pharmacy affiliates, which will shed light on preferential pricing arrangements.

PARTICIPANT NOTICE REQUIREMENTS

HR 7148 imposes a new obligation on group health plans to provide annual written notice to participants regarding PBM reporting requirements. This notice must be provided no later than the date on which the annual benefits summary is furnished to participants.

FIDUCIARY PROTECTIONS AND OBLIGATIONS

Both HR 7148 and the Proposed Rule include provisions protecting group health plan fiduciaries who act in good faith based on certain safe harbors. Under HR 7148, responsible group health plan fiduciaries are protected from prohibited transaction liability if they did not know of a PBM's failure to remit required rebate amounts and timely take corrective action upon discovery. However, this exception does not relieve group health plan fiduciaries from their ongoing fiduciary duty to monitor their PBM service providers. The Proposed Rule provides similar relief under ERISA Section 406(a)(1)(C) and (D) for fiduciaries who did not know of PBM non-compliance and take timely corrective action. If a PBM fails to correct deficiencies within 90 days of a written request, fiduciaries must notify the DOL and assess whether to terminate the contract, consistent with their fiduciary duty of prudence.

KEY DIFFERENCES BETWEEN HR 7148 AND THE PROPOSED RULE

While both initiatives advance transparency objectives, they differ in important respects. The following table highlights key distinctions:

Feature	HR 7148	Proposed Rule
100% Rebate Pass-Through	Required- PBMs must remit 100% of rebates to the insurer and self-funded group health plan	Not required- disclosure only
Audit Rights	Not explicitly Provides for annual audit rights relating rebates and other remuneration	Detailed audit framework- annual right, no restrictions on auditor, access to all records

Disclosure Timing	Disclosure not expressly required before contracting; requires ongoing semi-annual disclosures	Required in advance of entering into, extending, or renewing contracts; semi-annual thereafter
Spread Pricing Disclosure	Spread pricing not permitted	Requires detailed spread disclosure- by drug and pharmacy affiliates
Copay Claw-back Disclosure	Not specifically addressed	Disclosure of amounts and transaction counts required
Formulary Placement Incentives	Requires rationale for top 50 drugs	Requires disclosure of all formulary placement incentives and alignment explanation
Price Protection Agreements	Not specifically addressed	Requires disclosure of all price and inflation protection agreements
Fiduciary Status Disclosure	Not addressed	Required if PBM acts as ERISA fiduciary
Enforcement	Civil monetary penalties	Prohibited transaction consequences; DOL enforcement
Effective Date	Generally, 30 months after enactment	Regulatory applicability date to be finalized
Participant Notice	Annual participant notice required	Not required

PREPARING FOR COMPLIANCE

Plan sponsors should take a proactive approach to preparing for these new requirements. The Proposed Rule's effective date will be established following the notice and comment period and publication of a final rule. It is likely that the DOL will try to align the requirements of the Proposed Rule with the new legislation where there is overlap which may delay publication of a final rule. HR 7148's requirements will not take effect for several years, but the law instructs the tri-agencies with enforcement jurisdiction to draft regulations implementing the statutory requirements

within 18 months. Both initiatives are designed to align with existing ERISA reporting and disclosure requirements, including Form 5500 Schedule C and the Prescription Drug Data Collection under section 725 of ERISA.

The increased transparency requirements may ultimately make fully pass-through or fee-based PBM models more attractive to plan sponsors even prior to the effective date of HR 7148, and many PBMs have announced plans to eliminate rebates and spread pricing as part of their compensation.

Given the myriad and overlapping requirements of the Proposed Rule and HR 7148, plan sponsors should begin now to assess the terms and conditions of their current PBM contractual arrangements and identify areas that will require amendment. This will involve bringing together various stakeholders, including benefits, legal, and finance teams, to assess current PBM arrangements against anticipated requirements. Plan sponsors will also need to engage with PBMs and other health plan vendors to understand their readiness to provide required disclosures and consider issuing RFPs that incorporate the new transparency standards.

RECOMMENDED ACTION ITEMS:

- **Rebates/Spread Pricing** - Plan sponsors should review existing PBM contracts to assess current rebate retention practices and begin evaluating whether contract amendments or renegotiations will be necessary. Consider a transition to a fully pass-through or fee-based PBM arrangement now to simplify future compliance.
- **Audit Rights** - Plan sponsors should review and assess audit provisions in current PBM, consulting, and broker agreements. Plan sponsors should ensure future PBM contracts incorporate audit rights consistent with the legislative and regulatory requirements, including auditor selection and full access to underlying pharmacy and manufacturer contracts.
- **Affiliated Entities/Steerage** - Plan sponsors should critically evaluate whether benefit designs that steer participants toward PBM-affiliated pharmacies serve the best interests of plan participants or primarily benefit the PBM. Plan sponsors should request and review comparative pricing data to inform this assessment.
- **Governance Structures** - Plan sponsors should establish and document robust PBM monitoring practices and procedures to preserve fiduciary protections. If plan sponsors have not already done so, they should consider formalizing group health plan governance to document fiduciary decisions and delegations and monitor vendor compliance and fee, pricing, and compensation disclosures.
- **Participant Communications** - Plan sponsors should begin preparing for a participant communication strategy as plan designs change to accommodate the new legal requirements.

The convergence of legislative and regulatory action on PBM transparency represents a watershed moment for plan sponsors. These developments will provide fiduciaries with new visibility into PBM compensation structures and practices, giving them the ability to better negotiate and monitor drug and PBM pricing. However, this increased information flow to plan sponsors will necessitate enhanced monitoring and oversight obligations, reporting and disclosure obligations, and new standards of fiduciary care. With additional transparency and audit tools available to plan sponsors, failure to monitor and audit PBMs, avoid conflicts of interests, and determine reasonableness of compensation paid to PBMs will come with heightened risk of DOL audits and participant class action lawsuits under ERISA. Plan sponsors who begin preparing now will be better positioned to meet their fiduciary obligations under these new rules.

Please contact a member of the Winston & Strawn Employee Benefits and Executive Compensation Practice or your Winston relationship attorney for further information.

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Amy Gordon

Susan Nash

Joanna Kerpen

Erin Haldorson Weber

Jamie Weyeneth

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