ML STRATEGIES

From Proposal to Final Rule: DOL's Long-Awaited Final PBM Fee Disclosure Rule Includes Significant Changes and Clarifications

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VIEWPOINT TOPICS

- Health Care

On October 29, 2026, the Department of Labor (DOL) announced the **pharmacy benefit manager fee disclosure final rule** (the Final Rule), which establishes compensation disclosure and audit requirements for pharmacy benefit managers (PBMs) and affiliate brokers and consultants. DOL promulgated the Final Rule transparency requirements in response to the April 15, 2025 **Executive Order 14273**, *Lowering Drug Prices by Once Again Putting Americans First*, which calls on DOL to impose requirements to increase employer health plan transparency into the direct and indirect compensation received by PBMs. DOL **expects** the Final Rule to lower prescription drug costs for health plans and participants by as much as $22 billion over the next 10 years.

Among other things, the Final Rule implements the statutory disclosure framework set forth in the Consolidated Appropriations Act of 2026 (CAA 2026) amendments to ERISA section 408(b)(2)(B), under which PBM arrangements must satisfy specified disclosure requirements in order to qualify for ERISA's prohibited transaction exemption.

Given that many stakeholders have already begun preparing for implementation based on the proposed rule (the Proposed Rule), this blog post first summarizes the most significant differences between the Proposed Rule and the Final Rule, before further discussing the requirements imposed by the Final Rule and the anticipated impact on PBMs, self-insured group health plans, and other industry stakeholders.

Narrowed Applicability, Expanded Demands

The Final Rule preserves much of the Proposed Rule's basic structure but also introduces several significant changes that will impact compliance obligations. As some critical examples, the Final Rule:

- Narrows the scope of covered plans. Covered plans subject to the Final Rule include only (i) self-insured group health plans offered by "specified large employers" and (ii) self-insured group health plans that are "specified large plans" (i.e., employers or self-insured group health plans that have an average of at least 100 employees or participants, respectively, during the prior calendar year).
  - Smaller self-insured group health plans, fully insured group health plans, and self-insured group health plans that are sponsored by an entity that is, or is affiliated with an entity, in the drug supply chain are excluded from the Final Rule.
- Revises the default reporting standard for data from a quarterly basis to a semiannual basis. In the Proposed Rule, both initial disclosures and semiannual disclosures required data to be broken out on a quarterly basis (e.g., the Proposed Rule required a covered service provider to disclose in its initial disclosure the direct compensation it reasonably expected to receive on a quarterly basis). The Final Rule, however, defaults to allowing covered service providers to disclose data on a semiannual basis.
- Provides covered plans with the option to receive quarterly reporting rather than semiannual reporting. The Final Rule gives covered plans the option to request quarterly reporting rather than the default semiannual reporting. Similar to semiannual reports, any quarterly reporting must be provided within 30 calendar days of the applicable reporting period.
- Establishes a list of core and ancillary PBM services to clarify what qualifies an entity as providing PBM services. Commenters identified the PBM services definition from the Proposed Rule as being so broad that it could inadvertently pick up entities that should not be considered to be providing PBM services. In response, DOL has created a bifurcated list of PBM services consisting of core services (rebate negotiation, formulary management, pharmacy networks, utilization management) and ancillary services (claims processing, appeals, recordkeeping, compliance) paired with a core service.
- Introduces and clarifies the scope of indirect compensation. To better align with ERISA section 408(b)(2)(B), the Final Rule introduces the concept of indirect compensation and specifically defines the types of compensation that must be disclosed thereunder to include: (i) manufacturer payments; (ii) spread compensation; (iii) pharmacy recoupment; and (iv) price protection agreements.
- Clarifies disclosable categories of "other compensation." While DOL notes the inclusion of "other compensation" resulted in debate between commenters, DOL indicates in the preamble of the Final Rule that this has been left in to capture any additional compensation streams that may impact the

reasonableness of the arrangement, including compensation related to copay maximizer, copay accumulator, and alternative funding programs, as well as compensation tied to technology fees, shared-savings payments, float, and data fees. DOL declined to enumerate categories for fear of overcomplicating the regulatory text.

- Removes disclosure of compensation made to "officers, directors, employees, and partners" of a covered service provider, affiliate, subcontractor, or agent. DOL clarifies through the Final Rule that disclosure of compensation paid to individuals who are officers, directors, employees, or partners of a covered service provider, or its affiliates, subcontractors, or agents is not required.
- Contemplates a forthcoming standardized template. DOL notes in its preamble to the Final Rule that it is considering developing a standardized template of the Final Rule's disclosure requirements. We will continue to monitor any updates relating to a standardized template.

Effective Date

The Final Rule takes effect 60 days after publication and applies to plan years beginning on or after July 1, 2027. For plans that follow the calendar year, the requirements will apply to plan years beginning January 1, 2028.

Noncompliance with the Final Rule can render the arrangement a prohibited transaction under ERISA, exposing service providers and fiduciaries to DOL enforcement and civil penalties.

With respect to the covered service provider disclosure requirements under ERISA section 408(b)(2)(B), as amended by the CAA 2026, DOL noted that it interprets those disclosure requirements as having already taken effect beginning February 3, 2026. Nonetheless, DOL has announced a temporary enforcement policy under the Final Rule, pursuant to which covered service providers and responsible plan fiduciaries will not face enforcement action and an arrangement will not be deemed a prohibited transaction through July 1, 2027, provided that the entities make good faith efforts to comply with the statute.

Reporting Requirements

The Final Rule requires covered service providers to furnish both initial and semiannual (or quarterly upon a covered plan's request) disclosures. Initial disclosures must be provided in connection with the execution, renewal, or extension of a contract or arrangement, while semiannual disclosures must be provided throughout the term of the arrangement. Disclosures must be clear, concise, and sufficiently detailed to allow plan fiduciaries to evaluate the reasonableness of a PBM arrangement and may not rely on undefined industry jargon or generic terminology.

A covered service provider includes: (i) entities that directly contract with self-insured group health plans to provide PBM services (i.e., typically the PBM), and (ii) PBM-affiliated brokers and consultants who provide advice, recommendations, or referrals regarding PBM services.

Initial Disclosures

A covered service provider must furnish initial disclosures to the responsible plan fiduciary in writing "reasonably in advance" of entering into, extending, or renewing a contract for services. The Final Rule clarifies that for contract renewals or extensions, 90 calendar days in advance is deemed reasonably in advance, which is a shift from the Proposed Rule which considered 30 days sufficient. The Final Rule's required compensation disclosures include: direct compensation received from the covered plan or sponsor, indirect compensation (i.e., manufacturer payments, spread compensation, pharmacy recoupment, and price protection agreements), termination compensation, remuneration derived from formulary placement incentives or drug pricing methodologies, and any other compensation not otherwise disclosed. The Final Rule also requires the covered service provider to make two affirmative disclosures: (i) a statement of fiduciary status, which outlines whether the covered service provider expects to provide services to the plan as an ERISA fiduciary; and (ii) a statement of audit rights, which outlines the plan's audit rights and the procedures for requesting and conducting an audit under the Final Rule.

Semiannual (or Quarterly upon request), Ongoing Disclosures

In addition to the initial disclosures, the Final Rule requires covered service providers to furnish ongoing compensation disclosures to covered plans on a semiannual basis, although a covered plan may request quarterly disclosures. Unlike the initial disclosures, which are based on projected compensation, the semiannual disclosures report the actual compensation received under the arrangement and generally cover the same compensation categories included in the initial disclosures. Ongoing disclosures aim to allow for comparison against the estimates outlined in the initial disclosure estimates but also require covered service providers to report and explain the reason for any material overage for specified compensation categories. An overage is material if it exceeds the previously disclosed estimate by 5% or

more.

Audit Rights

The Final Rule also grants large, self-insured group health plans the right to audit their covered service providers on an annual basis. The responsible plan fiduciary has sole authority to select the auditor, and the covered service provider may not impose restrictions on the auditor's selection or otherwise limit the plan's audit rights. Upon a covered plan's written request, a covered service provider must provide access to records, claims data, transaction-level data, and other information reasonably necessary to validate its disclosures. This audit requirement includes information maintained by affiliates, agents, and subcontractors.

Covered service providers must acknowledge audit requests within 10 business days and generally must provide the requested information within 60 calendar days. The covered plan is responsible for the auditor's fees, while the covered service provider must bear the cost of producing the requested information.

Implications for PBMs and Self-Insured Group Health Plans

The Final Rule establishes a comprehensive framework for PBM compensation disclosures and audit rights intended to assist large, self-insured group health plan fiduciaries in evaluating the reasonableness of PBM arrangements under ERISA section 408(b)(2). Because compliance with the Final Rule's disclosure and audit requirements is linked to the availability of the prohibited transaction exemption under ERISA section 408(b)(2), the Final Rule provides a more detailed roadmap for PBMs, plans, and other stakeholders in structuring and administering covered arrangements. The Final Rule will require updates to existing PBM and plan compliance, contracting, and operational processes.

As an additional nod to the interrelatedness of the Final Rule with the CAA 2026, DOL indicated in its preamble to the Final Rule that it is considering future rulemaking and guidance relating to the CAA 2026 100% rebate passthrough requirements, which go into effect on August 3, 2028. In the meantime, we will also continue to monitor for any standardized template DOL may release in connection with the Final Rule.

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