Proposed PBM Transparency Regulations Issued

By Kerri Willis and Ben Lupin | Compliance & Policy Consulting (CPC)

February 2026

Key Takeaways

- On January 30, 2026, the Department of Labor (DOL) issued proposed regulations requiring "covered service providers" including pharmacy benefit managers (PBMs) to disclose comprehensive information related to compensation they receive to fiduciaries of self-insured health plans to ensure that the contracts with and compensation to those service providers are reasonable under ERISA.
- Disclosures are required in advance of the date the contract with the covered service provider is entered into, semi-annually, and upon request of the plan sponsor and are subject to audit rights by plan fiduciaries.
- If finalized, the regulations would become effective 60 days after they are issued, with an applicability date for plan years beginning on or after July 1, 2026 (i.e., January 1, 2027, for calendar year plans).
- Many of the provisions in the proposed regulation are similar to the provisions in the legislation passed by Congress earlier this year (Consolidated Appropriations Act (CAA), 2026) but differ in various respects. The final regulations will likely look to harmonize those varying provisions.

The Details

The DOL recently issued proposed regulations requiring comprehensive disclosure of information regarding compensation to self-insured group health plan fiduciaries. The intent is to increase transparency into the direct and indirect compensation provided to certain service providers (including PBMs) and provide plan fiduciaries with information to determine whether the contracts with and the compensation provided to those service providers is "reasonable" as required under ERISA. The proposed regulations include detailed disclosure requirements by "covered service providers" and allow group health plan fiduciaries to audit these service providers.

Note: the proposed regulations do not include fully insured plans (for now) nor governmental or church plans not subject to ERISA.

Who Must Disclose

"Covered service providers" are required to make the disclosures outlined below and are subject to audits by the plan. Entities that are covered service providers are (1) providers of "pharmacy benefit management services" (see description below) and (2) providers of advice, recommendations, or referrals for pharmacy benefit management services who are themselves providers of pharmacy benefit management services or their affiliates.

"Pharmacy benefit management services" include:

- 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 (including mail-order, specialty, or retail);
- Processing and paying prescription drug claims;
- Performing utilization review and management;
- Conducting appeals and grievances of prescription drug benefits;
- Recordkeeping related to the plan and prescription drug benefit; and
- Performing regulatory compliance activities in connection with any of the services above.

Whether an entity identifies as a PBM is irrelevant to the requirement to make the required disclosures. A covered service provider will be an entity that provides any of the services listed above, not necessarily all of them. The DOL is requesting comments on the proposed definition of "pharmacy benefit management services."

When Information Must Be Disclosed

The disclosures must be made by the covered service provider to the plan fiduciary at three separate times:

1. An initial disclosure is required "reasonably in advance of the date in which the contract is entered, extended, or renewed" (which is 30 calendar days in advance for extensions or renewals);

2. Semi-annual disclosures are required 30 days after the end of each six-month period; and

3. Disclosures must be made upon request by the plan sponsor to meet its reporting obligations (e.g., 5500 reporting, etc.).

All disclosures must reference amounts paid in monetary amounts (not formulas or percentages), unless specifically permitted under the regulations. Information must be disclosed in a machine-readable format upon request by the plan fiduciary.

What Information Must Be Disclosed

The regulations set out the specific information that must be included in the initial disclosure:

- *Description of services:* description of each PBM service, or instance of advice, recommendations, or referrals regarding PBM services, to be provided under the contract.

- *Direct compensation:* all direct compensation, both in aggregate and by service, that the covered service provider (including affiliates, agents, subcontractors) reasonably expects to receive on a quarterly basis.
- *Compensation from drug manufacturers:* payments (rebates, fees, discounts, price concessions, etc.) reasonably expected to be received from drug manufacturers or rebate aggregators on a quarterly basis, both in aggregate and per formulary drug.
- *Spread compensation:* for each drug on the formulary and for each pharmacy channel (retail, mail-order, specialty) the dollar amount of expected spread compensation to be received per quarter.
- *Copay clawback compensation:* the list amounts (both expected dollar amount and total number of transactions) reasonably expected to be recouped from pharmacies through copay clawbacks per quarter.
- *Price protection agreements:* any inflation protection or price protection agreements that the covered service provider has entered into with a drug manufacturer in connection with the drugs dispensed under the service contract or arrangement.
- *Termination fees:* compensation the covered service provider reasonably expects to receive upon termination of the arrangement, along with information on how prepaid amounts will be calculated and refunded.
- *Other compensation:* a catch-all provision for compensation not captured with the other disclosures listed above that a covered service provider reasonably expects to receive on a quarterly basis in connection with the agreement.
- *Formulary placement incentives:* formulary placement incentives and arrangements with drug manufacturers, including an explanation of how these incentives affect services to align with the interests of the plan and plan participants. If the covered service provider receives payments from a manufacturer or rebate aggregator for any drug on the formulary that is not passed through to the plan, it must identify reasonably available therapeutically equivalent alternatives and explain why those alternatives were omitted.
- *Drug pricing methodology:* the net cost to the plan of each drug on the formulary for each pharmacy channel, expressed as a monetary amount.
- *Statement of fiduciary status:* if applicable, a statement that the covered service provider will provide services as an ERISA fiduciary, along with any activities or policies that may create conflicts of interest.
- *Statement of audit rights:* a statement that the plan has the right to audit and the procedures for doing so (see more on audit rights below).

The semi-annual reporting requirements include much of the same information. Additionally, upon request of the plan fiduciary, the covered service provider must provide any other information related

to the contract or arrangement that is required by the plan to comply with its reporting and disclosure requirements under ERISA.

Audit Rights

Self-insured plans will have the right to audit covered service providers once a year to verify the accuracy of the disclosures. Comments are requested as to whether the scope of the audit should be broader (i.e., to ensure compliance with the contract, arrangement, law, etc.). Plans will have the sole right to select the auditor, and parties will split the audit costs—with the group health plan paying for the auditor, and the covered service provider paying for the cost of providing the information, data, and other materials needed to perform the audit.

Penalties

Plan fiduciaries may be subject to prohibited transaction claims under ERISA if these disclosures are not made. However, there is an exemption for plan fiduciaries if the plan fiduciary did not know of the covered service provider's failure to provide this information and reasonably believed the requirements had been satisfied. In such case and upon discovery, the fiduciary must request in writing that the covered service provider correct the failure. The plan fiduciary must also notify the DOL if the covered service provider fails to comply within 90 days. The plan fiduciary must also determine whether to terminate the contract with a service provider that does not meet these obligations, taking into account its fiduciary duties under ERISA.

Effective Date

If finalized, these regulations will take effect 60 days after the date of enactment and will be applicable for plan years on or after July 1, 2026. Many of the provisions of the proposed regulations are similar, but not identical, to the PBM disclosure provisions passed by Congress in CAA, 2026. Since these proposed regulations were issued prior to the passage of that legislation, it is expected that those differing provisions may be harmonized when these final regulations are issued.

Comments on these proposed regulations are due by March 31, 2026.

About Aon:

Aon exists to shape decisions for the better — to protect and enrich the lives of people around the world. Through actionable analytic insight, globally integrated Risk Capital and Human Capital expertise, and locally relevant solutions, our colleagues provide clients in over 120 countries with the clarity and confidence to make better risk and people decisions that help protect and grow their businesses.

Follow Aon on LinkedIn, X, Facebook and Instagram. Stay up-to-date by visiting Aon's newsroom and sign up for news alerts here.