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April 15, 2026

The Honorable Lori Chavez-DeRemer
Secretary
U.S. Department of Labor
Office of Regulations and Interpretations
Employee Benefits Security Administration
Room N–5655
200 Constitution Ave, N.W.
Washington, D.C. 20210

Dear Secretary Chavez-DeRemer:

BIO appreciates the opportunity to comment on the Department of Labor's (DoL or the Department's) proposed rule, "Improving Transparency into Pharmacy Benefit Manager Fee Disclosure" (RIN 1210–AB37). As noted by the Department, the proposed rule is designed to end long-running confusion about how ERISA disclosure obligations apply to PBMs under the Consolidated Appropriations Act, 2021, and give fiduciaries of ERISA self-insured group health plans significantly expanded visibility into PBM services and compensation.

The Biotechnology Innovation Organization (BIO) is the premier biotechnology advocacy organization representing biotech companies, industry leaders, and state biotech associations in the United States and more than 35 countries around the globe. BIO members range from biotech start-ups to some of the world's largest biopharmaceutical companies—all united by the same goal—to develop medical and scientific breakthroughs that prevent and fight disease, restore health, and improve patients' lives. BIO also organizes the BIO International Convention and a series of annual conferences that drive partnerships, investment, and progress within the sector.

Scope and Applicability

Applicable to Self-Insured Group Health Plans[1] Only, p. 4383. The Proposed Rule ***would apply only to ERISA-covered self-insured group health plans***. Fully insured group health plans[2] would be excluded from the Proposed Rule, but DoL states it has

[1] Self-Insured (Self-Funded) Plans: In a self-insured plan, the employer assumes the financial risk for providing health benefits to employees, rather than paying a fixed premium to an insurance carrier. Additionally, the employer pays for claims as they are incurred. While this can save on premiums and administrative costs, it exposes the employer to volatility, thus employers often buy "stop-loss" coverage to protect against high-cost, catastrophic claims. Under self funding, employers have more control over the plan design, allowing them to customize coverage to employee needs. Here, benefits are typically managed by a Third-Party Administrator (TPA), and the plan is subject to federal ERISA regulations but exempt from many state-mandated benefits. The self-insured option may be preferable for larger, stable companies.

[2] Fully Insured Plans: By contrast, in a fully insured plan, the employer pays a fixed monthly premium to an insurance carrier that assumes all risk for paying claims. Premiums are generally fixed for a year, providing high budget predictability. Under this model, employers have more limited design flexibility, since plans are standardized by the insurance carrier. For fully insured plans, the insurer manages all claims processing, network management, and regulatory compliance and must adhere to both federal and state-mandated insurance and coverage regulations. The fully insured model may appeal more to smaller, risk-averse firms.

reserved future rulemaking to address fully insured plan arrangements. A brief discussion of plan models follows for background.

As for reserving disclosure obligations for fully insured plans for future action, DoL explains, "the Department questions whether responsible plan fiduciaries responsible for procuring fully insured health insurance policy would find the specific disclosures proposed in the regulation sufficiently useful when they are negotiating more comprehensive health insurance coverage as to justify the costs associated with the disclosures…." Thus, DoL for now seems to be excluding fully insured plans from the disclosure requirements set forth for self-insured plans since it questions the usefulness of such disclosures to the plan fiduciary, especially when compared to the cost to the PBM of producing the information.

> **BIO Comment:** We recognize, as the Department states, that fully insured health plans are subject to state laws, which do not govern self-insure plans. Nevertheless, BIO believes that to the extent possible, PBM disclosure regulations should be harmonized not only across self-funded and fully insured health plans, but also across Medicare, Medicaid, the Exchanges, and all other payers.
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> In the case of fully insured ERISA plans, the Department should extend PBM compensation disclosure requirements because the same opacity, conflicts of interest, and cost drivers are present regardless of funding mechanisms for group health plans. A self-insured-only rule risks continued opacity for insurer-PBM arrangements, leaving these employers without the transparency that this proposal is designed to provide. Moreover, vertical integration with PBMs and health insurers can obscure internal payment streams and affiliated revenue streams, making transparency essential for plan sponsors to identify conflicts of interest and PBM-related costs. This extension would also align the rule with broader federal transparency framework requiring prescription drug spending and utilization reporting across both the insured and self-insured markets. To that end, we look forward to future proposals from the Department to extend PBM disclosure regulations to fully insured plans, as the Proposed Rule states or a commitment to parallel rulemaking for fully insured plans..

Scope of "Covered Service Providers," p. 4358

The Proposed Rule identifies two categories of covered service providers, i.e., PBMs, to include:

- Entities that directly contract with self-insured group health plans to provide PBM services (i.e., typically the PBM), and
- PBM-affiliated brokers and consultants who provide advice, recommendations, or referrals regarding PBM services.

In each case, to be a covered service provider, the entity must reasonably expect to receive $1,000 or more in compensation. Non-affiliated brokers and consultants remain subject to the disclosures required under the Consolidated Appropriations Act, 2021.

The Department notes that:

"…pharmacy benefit management encompasses a number of services related to developing drug formularies, negotiating with drug manufacturers for rebates and other discounts, negotiating with pharmacies, and processing claims and other functions for self-insured group health plans. The examples provided in the proposed definition are intended to describe the services expansively to ensure comprehensive disclosures are made. Consequently, the proposed definition specifies whether the person providing the services identifies itself (sic) as a PBM is not dispositive of the requirement to disclose. Additionally, a person will be a covered service provider by virtue of performing any of the services identified in the definition; covered service provider status does not depend on comprehensively providing all the services set forth in the proposed definition."

BIO appreciates that the DoL seems to be setting forth a wide net when it comes to defining "covered service providers" by relying on the types and ranges of functions PBMs perform. DOL specifically notes that the term "agent" is intended to capture, for example, rebate aggregators or GPOs outside of the laws of the U.S. The Proposed Rule details the similarities and differences among "affiliates," "subcontractors," "agents," "brokers," and "consultants."

BIO Comment: BIO agrees with and appreciates the Department's approach. For years, PBMs have maximized profits by channeling rebates and fees from drug manufacturers through affiliated entities called pharmacy "group purchasing organizations" (GPOs) or rebate aggregators, which have often been incorporated in foreign countries to evade US tax and business regulations. These so-called "PBM GPOs" negotiate rebates with manufacturers, consolidate market power, and collect fees, blurring the line between procurement and benefit management.

Many of these structures allow PBMs to obscure revenue flows to themselves, evade transparency, and shift funds away from plan sponsors and participants, increasing overall costs to plan sponsors and members. The GPOs (e.g., CVS's Zinc, Express Scripts' Ascent, OptumRx's Emisar) act as an added layer of middlemen to collect rebates and fees from drug manufacturers, which are often <u>not</u> passed on to clients but instead retained as profit. By basing these GPOs in offshore locations, PBMs create regulatory and oversight distance, making it difficult for regulators and employers to trace the exact, high-margin revenue extracted by these entities at the expense of the U.S. health care system.

BIO believes the redefining of "covered service provider" to essentially include any entity that provides pharmacy benefit management services should capture the entities PBMs have set up specifically to evade regulation and reporting obligations and make outsized middleman profits.

To the specific language in this Proposed Rule, we believe the terms "pharmacy benefit management," "affiliate," "agent," and "subcontractor" should be defined as broadly as possible. We therefore recommend the Department extend the definition of "affiliate" to include contractual control as well as ownership control. PBMs may have contractual relationships with entities that effectively make those entities affiliates despite not owning them (e.g., MSO contractual arrangements). Those relationships should be captured in the disclosure and reporting proposals set forth in this Proposed Rule.

Definition of PBM Services, p. 4360

Under the Proposed Rule, PBM services are broadly defined to include services necessary to manage or administer a plan's prescription drug benefit (including drugs covered under the medical benefit), such as rebate aggregation, claims processing, and utilization management (e.g., prior authorization and step therapy).

DoL requests comments on its proposed definition of pharmacy benefit management services, including whether the description of any of the services should be altered and whether any services should be expressly added as examples.

The Proposed Rule defines PBM services as services necessary for the management or administration of a self-insured group health plan's prescription drug benefits (including the self-insured group health plan's provision of prescription drugs through the plan's medical benefit), regardless of whether the person, business, or entity performing the service identifies itself as a 'pharmacy benefit manager.'

According to DoL, the listed examples provided in the proposed definition are intended to describe the services expansively to ensure comprehensive disclosures are made. The Department requests comments on its proposed definition of pharmacy benefit management services, including whether the description of any of the services should be altered and whether any services should be expressly added as examples.

> **BIO Comment:** BIO strongly agrees with the Department's approach and the detailed list of services in the proposed rule on page 4360. Additionally, we recommend that the Department actively monitor the evolution of the PBM business model to update this definition to ensure PBM practices are not changed to thwart regulatory scrutiny. Also, DoL can promulgate regulatory language that allows the proposals herein to capture any such attempt. For example, the Department should aim for the widest possible approach to including specific services in this proposed rule, perhaps by changing the term "necessary for" to "associated with" to describe PBM services. Further, we recommend adding the term "instituting" to prior authorization language, so it reads, "…including the instituting or processing of prior authorization requests for drugs…."

The Proposed Rule Is Inapplicable to Some Medical Claims, p. 4359

TPAs, health insurers, and other entities involved in the administration of a self-insured group health plan's *medical* claims are excluded from the Proposed Rule, though DOL has requested comment on whether the disclosures of the Proposed Rule should be extended to such entities.

Specifically, DoL states the Proposed Rule's focus on providers of pharmacy benefit management services is consistent with President Trump's Executive Order 14273, Lowering Drug Prices by Once Again Putting Americans First, which instructs the Department to propose regulations to improve employer health plan transparency into the direct and indirect compensation received by PBMs.

However, the Department says it recognizes that self-funded group health plans have other service providers that are not covered by this proposal and that may not be considered providers of ''brokerage services'' or ''consulting'' for purposes of ERISA section 408(b)(2)(B). These service providers include TPAs, health insurers, and others involved in the administration of self-insured group health plans' medical claims, such as for hospital stays, surgeries, and chronic treatment. According to DoL, stakeholders have indicated that group health plan fiduciaries may not have access to all claims data, payments to providers, fee and pricing data that could enable negotiation for cost savings to group health plans and participants.

The Department says it seeks comments on whether, and the extent to which, it could and should expand the disclosures in this proposal to cover additional service providers and if so, which service providers should be covered. Additionally, the Department seeks comments on whether the disclosures proposed would be sufficient to bring transparency into arrangements with those additional service providers or whether additional disclosures would be needed, such as claims data, payments to providers, and other fee and pricing data.

> **BIO Comment:** While our understanding is that the Proposed Rule would to apply to PBMs regardless of whether they're engaged in management of prescription drugs under the outpatient prescription drug benefit or medical benefit, BIO believes that the Department is missing a significant opportunity in declining to include Medical TPAs, health insurers, and other entities involved in the administration of a self-insured group health plan's medical claims from the Proposed Rule.
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> PBMs—the subject of this Proposed Rule—are most often part of larger, integrated healthcare systems that include both pharmacy and medical benefits. Focusing only on the pharmaceutical claim "side" misses the opportunity to improve transparency in the medical sector, where similar egregious "middleman" practices can occur.
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> A current strategy for large conglomerates and deep-pocketed private equity firms is to consolidate fragmented medical markets, often by buying up multiple health care practices in a geographic region over time to reduce competition.[3] This "serial" acquisition or "roll up" of small entities allows consolidation to avoid the attention of regulators.[4]
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> Vertical integration has been growing steadily in the market for healthcare and several studies have explored the resultant increase in prices and the effect it has had on patients and providers. In that time, the market for physicians has transitioned from small, physician-owned practices to larger practices owned by corporations such as hospitals, private equity firms, and health insurers. Moreover, studies find health system vertical relationships were associated with increased total medical spending per patient-year.

[3] Richard M Scheffler, Laura M. Alexander, and James R. Godwin, "Soaring Private Equity Investment in the Healthcare Sector: Consolidation Accelerated, Competition Undermined, and Patients at Risk," American Antitrust Institute, June 4, 2021.
[4] Ibid.

One such recent Health Affairs study looked at United Healthcare and its subsidiary Optum.[5] UnitedHealthcare's payments were 17 percent higher to Optum providers than the relative price of its competitors. Further, in markets where UnitedHealthcare had 25 percent or more market share, this percentage increased to 61 percent. The study reveals that intercompany transactions within health care conglomerates—the majority of which are for medical expenses, not pharmacy[6]--exploit market power to raise costs and warrant scrutiny.

Thus, as insurance conglomerates acquire physician practices and grow their business footprints, particularly in markets with little insurance competition, it is important to monitor how intercompany transactions may mask rent-seeking profits because that would interfere with market signals for entry and hinder regulatory enforcement of the medical loss ratio. In short, there is a wealth of actionable information to be extracted on the medical side of health insurance from applying the same types of transparency provisions the Department would apply to PBMs. Patients, employers, and other stakeholders deserve no less than to eliminate the same profit-seeking abuses of middlemen in the medical sphere as the PBM sphere. At the very least, as a plain reading of the proposed rule conveys, we believe the Department should confirm and state explicitly that prescription drugs provided in the outpatient and physician office setting covered under the medical benefit are "pharmacy benefit management services" subject to the provisions in this Proposed Rule.

As a first step, we recommend the Department require that any compensation that accrues to medical benefit entities should be recorded and reported. For example, any steering of health plan enrollees to affiliated medical groups (who in turn might prescribe in such a way to influence pharmacy benefit compensation) or intercompany eliminations between medical benefit and pharmacy benefit affiliates.

Disclosure Requirements, p. 4363

DoL states that the proposed disclosures below are intended to make clear to plan fiduciaries (i) the PBM services that will be provided to the plan, and (ii) all compensation expected to be received by the covered service provider (or any affiliate, agent, or subcontractor) in connection with the arrangement. Disclosures are required prior to the self-insured group health plan entering into a contract or arrangement with a covered service provider and on a semi-annual basis thereafter. Semi-annual disclosures are due within 30 days after each six-month period of the contract term and must detail actual compensation received by category, explain material overages of 5% or more versus initial estimates, and restate audit rights.

DoL explains that the required disclosures in some instances would require disclosure of amounts reasonably expected to be paid to the covered service provider or an affiliate, agent, or subcontractor. The amounts could be estimated to the extent that the actual amount is not reasonably ascertainable, but they must contain sufficient information and

[5] Daniel R. Arnold and Brent D. Fulton "UnitedHealthcare Pays Optum Providers More Than Non-Optum Providers," Health Affairs, November 2025.
[6] Ibid.

specificity to permit evaluation of the reasonableness of the compensation to be received by the covered service provider, an affiliate, agent, or subcontractor.

In making these proposals, the Department intends that disclosures of a monetary amount (even if estimated) in this context would further the transparency goals of this rulemaking which are intended to make possible a responsible plan fiduciary's assessment of reasonableness of compensation and potential for or existence of conflicts of interest. According to DoL, this would also foster a fairer prescription drug market that lowers costs.

> **BIO Comment:** BIO strongly supports the Department's proposal to require PBMs to provide detailed, written disclosures of compensation, fees, and contractual terms to self-insured group health plan fiduciaries. We agree with the inclusion of every item in the proposed list of disclosure requirements, including manufacturer rebates, spread pricing, copay clawbacks before entering, renewing, or extending contracts, including ongoing semiannual updates to ensure fiduciary oversight and cost transparency.
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> However, we believe the requirements as proposed should be more inclusive to protect patients and plan sponsors from the PBM industry's evolving of definitions and re-organization of business practices to thwart regulatory scrutiny. The Department should also require reporting of the following in regard to pharmacy business:
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> 1. Compensation (or savings) derived from steering patients to affiliates, agents, subcontractors, etc. in the chain of vertical integration and from self-preferencing transactions with PBM affiliates.
>   - Examples of compensation derived from self-preferencing transactions include that associated with: health plans paying affiliated pharmacies higher reimbursement rates than unaffiliated pharmacies; incentivizing use of affiliates pharmacies; specialty generic drug mark-ups where PBMs reimburse affiliated pharmacies substantially more than pharmacy acquisition cost as measured by NADAC; paying or reimbursing affiliated providers at higher rates; medical loss ratio manipulation where vertically-integrated insurers meet medical loss ratio requirements through expenditures to affiliated pharmacies and providers and thereby evade payments to CMS or policyholders; and white-bagging or brown-bagging arrangements whereby PBMs generate revenue by requiring provider-administered medicines to be filled at affiliated specialty pharmacies and shipped to provider's office (white bagging) or shipped to the patient to bring to their appointment (brown bagging).
> 2. Compensation from programs that enable diversion of manufacturer patient assistance to the detriment of patients, including accumulators, maximizers, alternative funding/specialty exclusion.
> 3. Any interest rate float from holding plan funds.
> 4. Pharmacy and prescribing data should be reported by pharmacy ownership status i.e., owned/unaffiliated, chain/independent.

5. Pharmacy channel, e.g., retail/mail/specialty.

For manufacturer payments, the Department should clarify that all fees should be reported, including but not limited to data, portal, and enterprise fees that PBMs may articulate as not being directly related to services provided to plans. Further, data reported on drug transactions should be at the aggregate level and should not contravene long-standing data confidentiality conventions and information protected under the Uniform Trade Secrets Act. Additionally, the Department should aim for a wide interpretation for this proposed regulation, as it claims to do in using the phrase "compensation made *in connection with services* provided to the plan." We suggest the Department aim for an even wider interpretation here and suggest wording to the effect of, "compensation made in connection with, as a result of, or in any way connected with, services provided to the plan."

Further, the Department should require PBMs to report compensation from manufacturers (e.g., fees, retained rebates) that are based on the list price or utilization of drugs. Additionally, PBMs should report an explanation for omitting therapeutic alternatives from a formulary—patients may need to take a specific drug and such information will help plan sponsors enlighten their employees.

Finally, we believe that the Department should also collect the data covered service providers would report under this Proposed Rule. As drafted, the Department does not receive the data. We believe the Department should receive and use these data to monitor PBM business practices and intermediary extraction of value that is harming employers, plans, and patients. Specifically, the Department should receive aggregate compensation data and fiduciary status/conflict of interest statement summaries (possibly leveraging the Form 5500 which the Department already receives from plan sponsors for other data). BIO fears many plan sponsors, at least initially, will not have the tools or skills to derive meaningful information from the compensation data, so the Department should also receive it in order to monitor covered service provider activities.

Additionally, we believe the Department should promulgate what it expects plan sponsors to do with the data they receive. Namely, that the data should be used to demonstrate that list-price based fees, PBM steering to affiliates, etc. is unreasonable under ERISA and should be prohibited. Finally, we believe Department of Labor should require PBMs to affirmatively disclose to the plan fiduciary that the plan for which information is being provided is an ERISA regulated plan that is regulated exclusively by the federal government.

Audit Rights, p. 4370

The Proposed Rule establishes annual audit rights for self-insured group health plans to audit their covered service providers to, at minimum, verify the accuracy of the covered service provider's disclosures (though the scope of the audit may be expanded upon the parties' mutual agreement). To minimize barriers to audits, the Proposed Rule also (i) requires that audit costs be shared between the parties, (ii) gives the plan sole authority to select the auditor without limitations or interference by a covered service provider, and (iii)

broadly prohibits covered service providers from imposing restrictive conditions on the auditor, such as traveling to the covered service provider's office to conduct the audit or limiting the number of records that will be provided.

> **BIO Comment:** BIO stands in favor of the paragraph (j) rules adding express audit rights for self-insured group health plans. The aim, rightly, is for annual audits to assess the completeness and accuracy of required disclosures and prohibit the PBM from placing limitations on the plan's choice of auditor. Additionally, we support that the PBM may not impose restrictions such as limiting the period of audit, limiting the number of records to be provided, or similar limits on the audit's scope. This is important because PBMs frequently impose these types of limitations on marketplace participants, including manufacturers.
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> We believe the terms are reasonable in the proposal, that within 10 business days of receiving an audit request, the covered service provider must confirm receipt and begin providing necessary information within a commercially reasonable period, and the cost of the audit must be split between the plan and the covered service provider, with each party bearing 50% of the expense.
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> Nevertheless, as a matter to enhance compliance, BIO believes the Department should clarify that, when applicable, plan-level data must be provided to auditors. The Department should also clarify that confidentiality agreements between PBMs and their affiliates/agents/contractors cannot prevent auditor access to data.

Enforcement and Penalties, p. 4372

Non-compliance can render the arrangement a prohibited transaction under ERISA, exposing service providers and fiduciaries to DoL enforcement and civil penalties. Fiduciaries must report non-compliance to the DoL and may be required to terminate contracts if failures are not remedied within 90 days.

The Department is also proposing an exemption for "responsible plan fiduciaries" in the event covered service providers fail to comply with the regulation, consistent with the relief available in the Department's service provider regulation for pension plans.

> **BIO Comment:** BIO believes DoL should look to the experience of states in enforcing PBM disclosure requirements, where the experience has been mixed at best. States have also targeted PBM practices such as spread pricing, price transparency, pharmacy steering, limitations on retroactive post point-of-sale fees, and protections for patient choice. States have enacted laws requiring PBMs to disclose reimbursement methodologies, respond to pricing appeals, and avoid practices that unfairly discriminate against independent pharmacies.
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> However, despite the breadth of these state laws, PBMs frequently operate as if compliance is optional.[7] For example, some PBMs file incomplete documentation or fail to update regulators when their corporate structures change. Others attempt to

[7] https://www.bipc.com/state-pbm-oversight-has-been-growing-but-enforcement-still-falls-short-why-pharmacies-must-step-up

claim exemptions that do not apply to them. In states with spread-pricing bans, PBMs have sometimes shifted spreads into affiliated entities such as rebate aggregators or passed them through under different names, with the result that the underlying practice persists despite the statutory language.

With some noted exceptions, the experience of many states with PBM regulation has shown that the largest barrier to meaningful reform is not the lack of laws; rather, it is the lack of enforcement. Unfortunately, PBMs often will not comply with state law unless a regulator forces them to do so. Many State Departments of Insurance, Departments of Health, and Boards of Pharmacy are dealing with subpar resources to oversee PBMs effectively. PBMs, backed by large corporate parents, bring enormous legal and political power to bear when challenged. As a result, state agencies often hesitate or do not have resources before initiating investigations or imposing sanctions.

Some regulators simply do not fully understand the complexity of PBM practices or the practical effects those practices have on pharmacies and patients. Others may feel constrained by political pressure, particularly when the state's largest insurers or employers contract with or are controlled by PBMs. The result is a familiar pattern: state laws exist, but PBMs continue business as usual because the risk of consequences is low.

For this reason, we strongly urge the Department to set up the needed infrastructure—including effective regulations, adequate staffing, and necessary resources to properly administer the measures it is planning to take in this proposed regulation. In particular, we believe it is important that the Department oversee PBMs as covered service providers, similar to the way it has extended oversight of nonfiduciary providers in the financial sector, such as record keepers.[8]

Statement of Fiduciary Status, p. 4368

ERISA provides that a person is generally a fiduciary with respect to a self-insured group health plan to the extent he or she exercises any discretionary authority or discretionary control respecting management of such plan or exercises any authority or control respecting management or disposition of its assets, or do so, or has any discretionary authority or discretionary responsibility in the administration of such plan.

According to the Proposed Rule, "an initial disclosure must include, if applicable, a statement that the covered service provider, an affiliate, an agent, or a subcontractor will provide, or reasonably expects to provide, services pursuant to the contract or arrangement directly to the self-insured group health plan as an ERISA fiduciary. Along with this statement, such entity must disclose any activity or policy that may create a conflict of interest, including, for example, if such entity will benefit financially from drug substitution, from incentivizing use of affiliated pharmacies when other network pharmacies offer lower costs, or from step therapy or ''fail first'' protocols that require participants and beneficiaries

[8] https://www.groom.com/wp-content/uploads/2022/11/Law360-A-Primer-On-DOL-Probes-For-ERISA-Plan-Service-Providers.pdf

to use drugs that generate greater manufacturer rebates than other therapeutically equivalent drugs on the formulary."

Thus, although DoL does not deem PBMs fiduciaries in the Proposed Rule per se, it notes that any entity exercising discretionary authority or control over plan management, administration, or assets may act as a fiduciary and is therefore subject to the disclosure requirements described in this Proposed Rule.

The Department states that in complying with these proposals, therefore, the covered service provider would carefully consider whether it, or an affiliate, agent, or subcontractor, will meet this definition in its services to the self-insured group health plan. The Department has previously explained in this respect that a person who performs "purely ministerial functions . . . within a framework of policies, interpretations, rules, practices, and procedures made by other persons" is not a fiduciary under this test.

Thus, to avoid fiduciary status, a PBM or other covered service provider would have to ensure that its services to the self-insured group health plan, and the services of its affiliates, agents, and subcontractors, are not discretionary, but instead operate within policies and procedures disclosed to and approved by the responsible plan fiduciary.

> **BIO Comment:** BIO supports the requirement in the Proposed Rule that covered service providers disclose whether they or their affiliates will act as ERISA fiduciaries and clearly identify any conflicts of interest associated with that status. Awareness of such fiduciary roles is necessary for plan sponsors and fiduciaries to understand whether PBMs or their affiliates have legal obligations to act in the best interest of the plan as required under ERISA. To that end, we believe the Department should adopt more prescriptive disclosure requirements to achieve meaningful transparency.
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> In aid of adopting more prescriptive requirements, BIO encourages the Department to make a thorough examination of the roles PBMs and other covered service providers currently play in exercising discretion in carrying out plan management activities as it impacts plan sponsors and their members. In particular, we believe that PBMs today do indeed exercise judgement and discretion when carrying out the following services and thereby should be subject to disclosure rules discussed in this proposed rule:
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> - Claims adjudication and benefit determinations, including development and application of prior authorization, step therapy, or other utilization management techniques, as well as appeals, grievances or medical necessity overrides following adverse benefit determinations;
> - Allocation of plan funds via retained spread pricing methodologies;
> - Negotiation of manufacturer rebates including payments related to price protection, inflation penalties, or formulary access;
> - Administrative fees tied to utilization of drugs;
> - Pharmacy network design, especially steering beneficiaries toward PBM-owned or affiliated pharmacies;

- Design and application of any direct or indirect programs that manipulate benefit designs or formularies, such as AAPs, copay accumulator and maximizer programs that reallocate cost sharing assistance;
- Design and application of specialty drug dispensing mechanisms (sometimes known as white- or brown-bagging); and
- Communication to plan beneficiaries about coverage.

We believe it is critical to recognize where and how PBMs exercise discretion over plan decisions and thereby act as plan fiduciaries to make this Proposed Rule effective. The Department states that, when the terms of the responsible plan fiduciary class exemption are not satisfied, "plan fiduciaries entering into service arrangements with parties in interest to self-insured group health plans, and the parties in interest themselves, may be subject to enforcement action by the Department and imposition of a civil penalty." The Department further notes that "enforcement will be aided by the requirement in the proposed administrative class exemption that plan fiduciaries report to the Department a service provider's non-compliance with the disclosure or audit provisions." As a result, the effectiveness of the Proposed Rule depends heavily on plan fiduciaries' ability to identify, assess and affirmatively report PBM non-compliance.

Thus, we support the Department's proposed disclosure rules for covered service providers acting in a fiduciary capacity, but we also believe the Department should make a more thorough examination of the breadth and depth with which PBMs and other covered service providers exercise judgement across their book of services and hold them duly accountable.

However, beyond fiduciary disclosure measures as discussed in this Proposed Rule, BIO believes it is time for regulators and other policymakers to critically examine and change as necessary the overall deleterious role PBMs play in our health system. PBMs increasingly leverage formulary restrictions to manage utilization of medicines. Patients attempting to initiate treatment encounter prior authorization requirements, step therapy protocols, or other administrative rejections. These barriers have become increasingly common in recent years and can delay treatment initiation or prevent patients from accessing the medicines their providers prescribe altogether. One recent study finds nearly half of insured adults say they have experienced their health insurance company denying care, delaying care, or requiring them to try alternatives.[9] Such research confirms that access barriers caused by utilization management are pervasive across a wide range of medicines, potentially affecting millions of patients annually, going so far as to confound the very nature and function of health insurance, on which enrollees rely to maintain their physical and financial health. We therefore encourage the Department to look further into the role of PBMs and rein in their abuses.

[9] https://www.kff.org/public-opinion/kff-health-tracking-poll-prior-authorizations-rank-as-publics-biggest-burden-when-getting-health-care/

The Proposed Rule in Light of the Consolidated Appropriations Act of 2026 (CAA 2026) and Other Policy Initiatives

In advance of the passage of CAA 2026, the Department published the Proposed Rule to implement comprehensive federal disclosure requirements for providers of PBM services and their affiliates to disclose all forms of direct and indirect compensation, pricing methodologies, and formulary related incentives to fiduciaries of ERISA covered self-funded group health plans. If finalized, these changes would become effective, for plan years on or after July 1, 2026 (or Jan. 1, 2027, for calendar year plans). Plan sponsors currently do not need to take any action regarding these proposed rules.

CAA 2026 and the Proposed Rule have some similarities and overlap (like the audit provisions and data elements that must be reported/disclosed), but there are also some distinct differences. Notably, the two have differing effective dates as the Proposed Rule features a much earlier effective date than the CAA 2026. Additional distinctions include but are not limited to:

- The proposed regulations include a requirement for compensation disclosures to plan sponsors every six months, while the CAA 2026 follows existing compensation disclosure timing requirements. The CAA 2026 does require drug-level reporting to plan sponsors on at least a six-month basis (and some information required is similar to the information required under the proposed regulations) with employers having the option to receive reporting quarterly.
- CAA 2026 includes significant statutory civil monetary penalties, and the proposed rules rely on ERISA's prohibited transaction penalties.
- CAA 2026 requires an annual notice to participants regarding PBM reporting obligations (there is no such notice in proposed regulations).
- The reporting requirements, summary information for participants, and notice requirements in CAA 2026 are incorporated into ERISA, the Public Health Service Act, and the Internal Revenue Code. The proposed regulations only apply to self-insured ERISA plans.

BIO believes that DoL's proposed rule and the 2026 CAA are additive to one another, not in conflict. In fact, the reporting requirements in the DoL rule will help PBMs and plan sponsors prepare for the full implementation of the CAA in future years. Without plan sponsors having the information necessary to monitor PBM behaviors, it will be more difficult for the CAA to be successfully implemented.

Additionally, in February 2026, the Federal Trade Commission secured a settlement with one PBM—Express Scripts (ESI)—with a goal of lowering U.S. prescription drug costs. The consent agreement requires ESI to restructure certain pharmacy benefits, enhance transparency, and adopt a "Standard Offering" that reduces inappropriate incentives for PBMs to favor high-list-price products. For example, under a "Standard Offering," ESI must enable plan members to receive the benefit of rebates at the point of sale, which is designed to lower patient costs at the pharmacy counter. The Standard Offering must ensure that plan members receive the benefit of discounted drug pricing through the administration's TrumpRx platform and allow plan member payments made through the platform to count toward patient deductibles and maximum out-of-pocket cost, subject to regulatory changes.

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The Federal Trade Commission has also reportedly reached a similar proposed settlement with CVS Caremark, requiring a comprehensive overhaul of rebate pricing practice. The full details have not been released yet, however. Nevertheless, we believe that DoL's implementation timeline need not change despite the 2026 CAA and FTC Consent Agreement with Express Scripts and its affiliates.

Conclusion

BIO thanks the Department for the chance to contribute to this rulemaking process and appreciates its consideration of these comments… We look forward to continuing to work with the Department to ensure patients can access care in an efficient and timely manner. Should you have any questions, please contact us at 202-962-9200.

Sincerely,

/s/
Crystal Kuntz
Senior Vice President
Healthcare Policy & Research
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/s/
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Senior Director
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