April 15, 2026

VIA ELECTRONIC FILING

The Honorable Lori Chavez-DeRemer
Secretary
U.S. Department of Labor
200 Constitution Ave NW
Washington, DC 20210

The Honorable Dan Aronowitz
Assistant Secretary
Employee Benefits Security Administration
U.S. Department of Labor
200 Constitution Avenue NW
Washington, DC 20210

Re: Improving Transparency into Pharmacy Benefit Manager Fee Disclosure Proposed Rule (RIN 1210-AB37)

Dear Madam Secretary and Assistant Secretary Aronowitz:

We, the undersigned patient advocacy organizations, whose missions are described in Attachment A, appreciate the opportunity to comment on the Department of Labor's (DOL) proposed rule, *Improving Transparency Into Pharmacy Benefit Manager Fee Disclosure*.[1] We commend DOL for taking a significant and important step toward addressing pharmacy benefit manager (PBM) practices that harm plan sponsors and participants—the patients we serve—in the self-insured group health plan market. As patient advocates, those patient harms are a core concern for our organizations and the patients that we represent.

We strongly support DOL's objectives and urge prompt finalization of this rule. We believe that this rule can set the stage for necessary regulation of PBMs in the commercial market under DOL's existing authorities under ERISA sections 408(b)(2), 404, and 406. Ultimately, we believe that greater transparency into the PBMs' compensation and business model is imperative and will help demonstrate

[1] 91 Fed. Reg. 4348 (January 30, 2026).

the following to plan sponsors and DOL, with obvious, positive impacts for the patients that we represent:

1. Many forms of PBM compensation and business practices–including list price-based fees and using benefit designs to steer business to affiliates–are facially unreasonable, deceive participants into thinking that they are responsible for a lesser share of costs than they actually are bearing, and should, given their inherently deceptive nature, be recognized as prohibited under ERISA.
2. PBMs regularly act as plan fiduciaries, but fail to act in the best interests of patients and lack accountability or oversight from employers.

We believe greater awareness of these PBM-created harms faced by plan participants—including the patients whom we represent—and plan sponsors require DOL to:

1) prohibit various PBM compensation arrangements as unreasonable; and
2) define which PBM functions constitute fiduciary acts, using a practical standard that is not easily evaded.

These reforms will create the necessary conditions for lower participant and plan sponsor costs, bringing greater plan value to both patients and employers.

To accomplish these essential goals, however, we ask that the proposed rule be strengthened to close various gaps that PBMs, adept at evading reforms, will (without doubt) otherwise exploit to defeat the very transparency that the proposed rule seeks to realize. Sadly, the long history of efforts to address PBMs' unlawful, conflict-ridden, and harmful practices shows their determination to evade disclosure and other obligations, whenever possible.

- As you know, the Federal Trade Commission (FTC) has investigated the "big-three" PBMs (Caremark, Express Scripts, OptumRx), among others, for using their consolidated and vertically integrated model to extract and obscure excessive profits (often in connection with "phantom" or redundant "services") to the detriment of patients and sponsors.[2]

[2] Federal Trade Commission, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* (Washington, DC: Federal Trade Commission, July 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

- Congressional investigations into PBM business practices have also identified PBMs' sharp practices designed to maximize and hide profits at the expense of patients, employers, and the health system as a whole.[3]
- Multiple state audits and legal proceedings have demonstrated how PBMs fail to disclose sources of compensation (e.g., profit from spread pricing) to plan clients, including state agencies.[4]

Without DOL addressing existing gaps, PBMs will, unfortunately, claim that they are complying with the rule while continuing to hide significant sources of compensation and other vital information from their plan clients—to the detriment of patients. That obfuscation will thereby inevitably undermine DOL's intent and purpose as reflected in this important rulemaking. As such, ***we respectfully urge DOL to consider and adopt the following improvements to the rule prior to finalization (Part I). In this regard, we encourage DOL, in the strongest terms possible, to expeditiously finalize the rule notwithstanding the passage of the 2026 Consolidated Appropriations Act (CAA) (Part II).*** That Congressional action, though important and welcome, is also clearly limited in effect and scope. It does not in any way diminish the critical nature of DOL moving forward with its rulemaking.

I. Recommended Improvements to the Proposed Rule

A. Strengthen the proposed PBM fiduciary status statement to ensure that PBMs are required to acknowledge when they are, in fact, acting as fiduciaries

1. The proposed rule's fiduciary status statement requirement is not sufficient in its current form.

We commend DOL for its important focus on fiduciary duties. As proposed, paragraph (e)(11) requires covered service providers to disclose whether they will

[3] *See, e.g.*, U.S. House of Representatives, Committee on Oversight and Accountability, *The Role of Pharmacy Benefit Managers in Prescription Drug Markets*, 118th Cong. (Washington, DC, July 23, 2024), https://oversight.house.gov/wp-content/uploads/2024/07/PBM-Report-FINAL-with-Redactions.pdf.

[4] *See, e.g.*, State of Illinois, Office of the Governor, "Illinois Recovers $45 Million Settlement from CVS Caremark," press release, May 2025, https://www.illinois.gov/news/press-release.31292.html; Texas Office of Inspector General, "PBM Audits Reveal Unallowable Pricing Models," https://oig.hhs.texas.gov/about-us/news/pbm-audits-reveal-unallowable-pricing-models.

provide services as a fiduciary within the meaning of section 3(21) of ERISA. This is an excellent step towards an important reform.

While the intent of this statement serves a critical function – helping plan sponsors and, by extension, participants, understand when PBMs are acting with discretion on a sponsor's behalf – we fear that the current approach is insufficient. As currently formulated, the proposed rule would allow PBMs, rather than DOL, effectively to self-define when they are acting as fiduciaries. Without added clarity on the standard to be applied and what types of functions must be reported in the statement, PBMs will inevitably claim they are not fiduciaries, frustrating DOL's core purpose in establishing the disclosure requirement. The rule should be revised to state that the failure to acknowledge that the PBM is acting as a fiduciary is, itself, a breach of its fiduciary duty.

Central to this issue is the PBMs' oft-repeated argument that they do not make benefit design decisions but only offer "options" and "suggestions". DOL should address this issue head-on. DOL should take the position that, unless a PBM presents a number of differentiated options to a plan sponsor in a neutral fashion, disclosing the different sums that it and its affiliates, agents, and subcontractors are likely to make under each option, the PBM will be deemed, as a functional matter, to have made the benefit decision. Similarly, it should take the position that when a plan sponsor, through lack of expertise or otherwise, effectively defers to the PBM in assessing and selecting among the options presented, it is the PBM that has designed the benefit. DOL should state that the test that it will apply is a totality of the circumstances test and that the fact that a plan sponsor "formally selects" an option shall not necessarily control, where the PBM has, for instance, by failing to act transparently, inaccurately framing the alternatives, failing to disclose required information, or otherwise, improperly influenced the selection of the benefit design. That "influence" standard should, we believe, be specifically required.

Despite the very positive elements of the proposed rule, we believe that it should include specific examples of activities that may constitute a fiduciary act to ensure that PBMs accurately and meaningfully report their fiduciary activities to plan clients. Without this, not only will plan sponsors (and by extension patients) be left in the dark, but PBMs will be able to shift more ERISA litigation risk to employers. This, in turn, will put patients in a difficult position, effectively forcing them to consider litigation against their employers for conduct for which the PBMs, their affiliates, agents, or subcontractors are responsible.

2. *Recommended examples of fiduciary activities for DOL to include in the final rule*

In applying a totality of the circumstances approach, we ask DOL to clarify in the final rule that fiduciary status is affected by whether a PBM advanced or set the criteria under which a given decision was made.

The Department has long recognized that a service provider that performs "purely ministerial functions . . . within a framework of policies, interpretations, rules, practices and procedures made by other persons" is not a fiduciary. The ministerial exception thus applies where the plan sponsor genuinely and substantively makes the decision.

In many cases, however, plan sponsors do not make relevant decisions in a practical, functional, or meaningful manner given the options presented by PBMs, the lack of transparency in presenting those options, the asymmetry in the information available to sponsors vs. the PBM, and the barriers they establish to selecting any other approach.

As a practical and functional matter, as demonstrated by the totality of the circumstances, PBMs often design formularies, develop prior authorization criteria, exclude drugs, or adjudicate claims and present no other option as a reasonable alternative to their "standard offer". These decisions, made by PBMs, result in terrible patient harms, from denying access to life-saving medications to delaying access so long that chronic and rare disease worsen to the point that cannot be treated adequately.

As an essential matter of participant protection, DOL should make clear that in these cases—where the PBM is as a functional and practical matter exercising discretion—it is acting as a plan fiduciary, regardless of whether the plan sponsor, as a formal matter, makes a "selection". **Form cannot override substance** or PBMs will continue to exercise discretion—and be protected from the duties they owe in light of that exercise of that discretion.

To ensure accurate reporting by PBMs, we ask DOL to include the following examples of activities that may constitute fiduciary acts in the final rule:

- Formulary design and management: benefit design, including designing cost-sharing structures, formulary tiers, utilization management criteria, specialty drug programs, and mid-year formulary changes.

- Access determinations: development or administration of utilization management criteria, including prior authorization and step therapy requirements; coverage determinations; and applying clinical criteria or making medical necessity determinations.
- Pharmacy design and management: designing pharmacy networks, including setting reimbursement rates, and determining specialty pharmaceutical dispensing models (including, but not limited to, white bagging and brown bagging).
- Plan management: claims adjudication and the interpretation of plan terms, without regard to whether the plan fiduciary retains some level of purported "oversight".

We recommend that paragraph (e)(11) be revised to include an enumerated list of activities that illustrate when a PBM may be acting in a fiduciary capacity. We believe that the existing examples are thoughtful and helpful, but we believe that certain additions would complement the existing list of PBM conflicts of interest examples that DOL currently provides.

We encourage DOL to also clarify that PBM services provided to multiple plans simultaneously does **not** in any way foreclose the conclusion that those activities constitute fiduciary acts with respect to each individual plan. This is another example where PBMs adopt a form over substance approach to evade ERISA's requirements. We ask DOL to reject that position specifically.

3. Additional statement of compensation reasonableness

In addition to the very positive fiduciary status and conflict of interest disclosures included in (e)(11), which we commend DOL for proposing, we urge DOL to require PBMs to provide a statement affirming, with a justification and supporting evidence, that all compensation retained by the PBM, its affiliates, agents, and subcontractors is reasonable within the meaning of ERISA section 408(b)(2)(A). In addition, that PBM statement should be required to include a description of any circumstance when retained compensation does not reflect fair-market value.

Because legal consequences would flow from such a statement that contains false or misleading statements, this requirement would provide a meaningful measure of protection for plan sponsors and, by extension, participants, including the patients that we represent. In order to encourage PBM compliance, the rule should explicitly advise PBMs that if the statement, justification, or supporting

evidence of a PBM is false, misleading, inaccurate, or incomplete, that will subject the PBM to potential liability.

B. We encourage DOL to close certain gaps in compensation reporting reflected in the proposed rule.

Unfortunately, as noted above, PBMs have a long, well-documented, and checkered history of exploiting reporting gaps and (purported) definitional ambiguities to obscure their compensation and the nature of their arrangements. Without addressing the following issues, we are concerned that the proposed rule's transparency objectives will be undermined.

*1. Prevent gaps in compensation reporting by clarifying that **all** compensation must be reported to plan sponsors*

As written, the proposed rule requires PBMs to report compensation paid "in connection with" services that fit within the term "pharmacy benefit management services". Those services appear, based on our reading, to be limited to those necessary for the "management or administration" of a plan's "prescription drug" benefits. Though those terms are fairly broadly worded, they do not appear to cover many activities and payments that PBMs leverage to profit from plan sponsors and thereby limit the coverage provided to participants, including the patients that we represent.

Examples of activities for which disclosure does not appear to be required, for instance, are PBMs' or their affiliates', agents', or contractors' compensation through the never ending parade of new and expanded "fees"; joint ventures in "private label" drugs; the ownership or operation of physician clinics, ambulatory surgery centers, and other non-prescription drug vertically integrated providers; and claims processing for non-drug items or services, where PBMs control upwards of 80% of all such claims.

Unless **all** PBM, affiliate, agent, and contractor compensation is captured, PBMs will take the entirely fungible payments extracted from plan sponsors and simply reclassify them to achieve the same level of profiteering (or worse). That "game" of PBM "whack-a-mole" operates to the ultimate detriment of participants, including the patients that we represent. The reasonableness of compensation cannot be determined without understanding the whole of the sums generated by PBMs, their affiliates, agents, and subcontractors. In the absence of that kind of 360 degree transparency, transparency fails.

The "in connection with" language, though helpful, is not broad enough in our view, and contributes to the potential issues here. While the preamble indicates that DOL intends this phrase to be construed broadly, PBMs will nevertheless read the phrase narrowly. ***We, thus, urge DOL to augment that "in connection with" language throughout the regulatory text with the additional phrases ", as a result of, or related to, directly or indirectly" to ensure comprehensive disclosure of all compensation.***

2. Require more granular payment reporting.

Proposed paragraph (e)(3) requires disclosure of manufacturer payments in the aggregate and by drug. We commend DOL for taking this important step in the proposed rule.

But, in order to realize DOL's purpose here, we urge the Department to go further and require that PBMs report payments, including retained manufacturer payments, by type. In the case of manufacturer payments, this would include rebate, fee, discount, and other payment "buckets".[5] Without understanding what the underlying "buckets" are, plan sponsors will be unable to assess their reasonableness. Aggregate payment amounts, though helpful, do not provide the transparency necessary to evaluate payments—leaving plan sponsors and patients terribly vulnerable.

Importantly, this issue is not limited to manufacturer payments. We appreciate DOL's request for what disclosure requirements should apply to maximizer, accumulator, and, by extension, alternative funding programs. These programs in our view are often deceptively presented, not included in plan documentation or misleadingly described there, and work terrible harm to patients—interrupting their care, delaying treatment, and, in some cases, exposing them to adulterated and misbranded foreign product imported into the United States in violation of U.S. law.

And these terrible patient harms do not result in cost savings to plan sponsors in part because PBMs, their affiliates, agents, and contractors—as well as the program "vendors"—siphon off large sums in connection with these "programs".

[5] We do not mean to suggest that these should be the "buckets" themselves. These would be too broad. For instance, for "fees", there would be separate reporting of so-called GPO, data, "clinical", contract administration, rebate administration, vendor, membership or participation, access, network, and program.

It is important that PBM, affiliate, agent, and contractor compensation attributable to these programs be disclosed in discrete "buckets" (maximizers vs. accumulators vs. alternative funding programs) to plan sponsors so that they can see that these entities are the ones financially benefiting from these programs—as patients suffer.

With respect to all of the "buckets", PBMs should be required to provide their definitions of the categories employed so that plan sponsors can understand what has actually has been disclosed to them. This requirement is critical, in our view, because, as we have stated above, PBMs have demonstrated a pattern of recategorizing revenue streams to evade disclosure or the passing through of funds to plan sponsors.[6] In addition, without regard to what "buckets" DOL establishes, the PBM should be required to report in a PBM-designated bucket any payment, not a part of a designated bucket, if that type of payment is likely to be material by the sponsor.

Without disaggregated reporting by payment type, plan sponsors will be unable to adequately detect or prevent evasion. Using the definitions provided, plan sponsors will be able to compare disclosure "buckets" from report to report to see how PBMs are manipulating their payments and their disclosures. Participants, like the patients we represent, cannot be protected if plan sponsors do not receive sufficiently specific and defined disclosures.

Additionally, because the relative amount of retained compensation is itself an important factor in assessing its reasonableness, ***PBMs should be required to disclose the percentage of payments in the aggregate and by category.*** In the case of payments related to the price or utilization of a drug, this data element is critical for plan sponsors to understand to what extent PBM revenue is tied to list prices and how such incentives are likely to influence benefit design decisions (e.g., formulary development and utilization management requirements). PBMs should be obligated to provide report to report changes, in aggregate and by category, both in absolute and percentage terms, to facilitate sponsor review.

3. *Expand indirect compensation categories to fully account for PBM compensation*

[6] Buchanan Ingersoll & Rooney PC, "When Pass-Through Isn't Pass-Through: PBM GPOs and the Reengineering of Rebates," January 8, 2026, https://www.bipc.com/when-pass-through-isn%E2%80%99t-pass-through-pbm-gpos-and-the-reengineering-of-rebates.

Proposed paragraph (e)(8) provides a catch-all for "other compensation" not disclosed under the enumerated categories. The fact that this breadth is contemplated in the proposal is commendable and much appreciated. However, rather than deploy this wide a "bucket", DOL should instead require that PBMs provide separate, named reporting categories for the various indirect compensation streams, which will otherwise be hidden within a disaggregated "other" bucket under the materiality test we articulate above. We address multiple issues above that relate to this element of the proposal.

In addition to the payment types we discuss above, DOL should address additional examples of what such PBM compensation streams may include, such as:

- Compensation from float: Any compensation from receiving interest on funds held or transferred on behalf of the plan.
- Compensation from affiliates: Any compensation directly or indirectly received from an affiliate, agent, or subcontractor, including revenue collected by PBM-owned or PBM-affiliated specialty, retail, and mail order pharmacies, physician clinics, ambulatory surgery centers, and others. Reporting should be in aggregate and by affiliate. This "affiliate" reporting should not limit separate "type" reporting. Thus, a data fee paid to an affiliate should be listed in both the "data fee" and "affiliate" buckets.
- Compensation from intercompany eliminations: Any compensation received through intercompany transfers or eliminations resulting from providing services to the plan or participants. Reporting should be in aggregate and by company. The same observation regarding separate type reporting should apply here.

Breaking these streams out of the catch-all "other" category will make the disclosures more useful to plan sponsors—and offer meaningful protection to vulnerable patients. It will also help mitigate PBM attempts at shifting compensation toward categories that are not explicitly included by DOL in paragraph (e).

4. Require reporting by pharmacy ownership to help plan sponsors identify compensation flows to PBM affiliates

One of the most problematic aspects of PBMs' conflict-ridden compensation arrangements are the payments they make to their own affiliated mail, specialty, and retail pharmacies. Plan sponsors need visibility into the flow of plan funds

related to pharmacy payments and dispensing patterns to see where PBMs are steering profitable claims or marking up payments to their affiliated pharmacies. The FTC's finding that the three largest PBMs reimbursed their affiliated pharmacies at significantly higher rates than unaffiliated pharmacies on nearly every specialty generic drug examined underscores the critical importance of this disclosure.[7] Patients cannot be protected from the real harms—both clinical and financial[8]--that flow from these disturbing practices without arming plan sponsors with the information they need to address these issues.

We urge DOL to require that spread pricing, copay clawbacks, and net drug cost data be reported by pharmacy ownership status ((e)(4), (e)(5), and (e)(10) respectively), specifically distinguishing between owned or affiliated pharmacies, on the one hand, and unaffiliated pharmacies, on the other. These "buckets" are needed to allow plan sponsors to see how PBMs serve their own interests to the detriment of plans and participants, like the patients we serve.

As part of this reporting, PBMs should be required to report at the aggregate level, at the pharmacy affiliate level, and at the drug level. Excessive payments to PBM pharmacy affiliates is a scourge, and DOL should require the transparency that will enable sponsors to stop it.

5. *Require service descriptions by affiliate to give plan sponsors a clearer picture of compensation flows and the purported "services" provided*

Descriptions of services in paragraph (e)(1) should be broken out by the specific PBM, affiliate, agent, or subcontractor providing those services, as well as by the total compensation that they receive, by service. This level of granularity is essential for plan sponsors to understand who is providing services purportedly on their behalf and the cost of those services.

As part of this reporting, PBMs should also be required to describe the nature of their business relationship or ownership structure with their affiliates, agents, and subcontractors to help plan sponsors better understand the structure of their PBM's service delivery model and better assess conflicts-of-interest.

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[7] Federal Trade Commission, *Specialty Generic Drugs: A Growing Profit Center for Vertically Integrated Pharmacy Benefit Managers* (Washington, DC: Federal Trade Commission, January 2025), https://www.ftc.gov/system/files/ftc_gov/pdf/PBM-6b-Second-Interim-Staff-Report.pdf.

[8] These higher costs directly lead to higher out-of-pocket costs for patients. This is inexcusable.

Plan participants—the patients we serve—are all too often the ultimate victims where this level of transparency is not provided. Again, plan sponsors should be armed with the information necessary for them to address these highly problematic practices.

6. Require that PBMs provide a total compensation figure

As part of the required reporting, we ask DOL to require that PBMs provide a single inclusive number for all direct and indirect compensation collected across itself, affiliates, agents, and subcontractors. This total figure would serve as a denominator against which other compensation data can be evaluated and would give plan sponsors a clear, central, comparable metric for assessing the overall cost of PBM services, as well as shifts in compensation from period to period. Again, report by report comparisons both in aggregate numbers and the percentage change should be required.

7. Enhance formulary placement incentive reporting to fully capture the impact of incentives on access

Proposed paragraph (e)(9) requires disclosure of formulary placement incentives, including how those incentives align with plan and participant interests. DOL should go further and require PBMs to disclose which drugs were adversely tiered or excluded from the formulary as a function of formulary placement incentives, and whether and how participant access to those drugs is affected. This additional disclosure would help plan fiduciaries identify situations where formulary decisions are driven, at the very least as both a practical and functional matter, by PBM revenue, rather than clinical value or cost-effectiveness--and the impact those incentives have on patient access or affordability.

B. Strengthen the definition of "affiliate" to prevent exclusion of entities from reporting

The proposed definition of "affiliate" in paragraph (m)(1) focuses on control through ownership or common control. However, this definition does not adequately capture PBM relationships, which not infrequently occur through contractual terms, rather than ownership stakes. PBMs increasingly exercise control, secure benefits, and otherwise establish "affiliations" over purportedly independent entities through management services agreements (MSAs), exclusive contracting arrangements, non-completes, nominees, and multiple other mechanisms.

DOL should amend the affiliation definition in several ways. First, with respect to the "control" test, DOL should explicitly state that "control" is to be viewed at a practical and functional level, under a totality of the circumstances analysis, and encompasses ownership or contractual terms and any other mechanisms, regardless of form. Second, and more broadly, we do not believe that "control" can be the exclusive test. PBMs will argue that entities that they functionally and as a practical matter have power over are not "controlled" by them because, at some formalistic level, they purport to make "decisions". Accordingly, we think the test should be whether a PBM, in practice and as a functional matter, under a totality of the circumstances standard, has the ability to influence the affiliate operations in any material manner and to benefit from that influence, directly or indirectly, whether that benefit is realized by the PBM, the affiliate, or another entity with which the PBM or the affiliate has a relationship.

C. Strengthen audit rights to ensure complete audits of PBMs

1. Ensure that PBMs provide plan-level and claim-level data.

We commend DOL for focusing on the importance of audits. Audits are a critically important means of ensuring that plan sponsors secure real transparency which will protect not just those sponsors, but their participants, like the patients that we serve.

In this regard, we ask that DOL clarify, in paragraph (j)(3), that the covered service provider must make plan-level data available when providing information for audits. The current text requires disclosure of "all records, data, and other information reasonably necessary to confirm the accuracy of any disclosure," but explicit reference to plan-level data would prevent PBMs from providing only aggregated data that obscures plan-specific information.

Beyond that, we stress the critical importance of the disclosure of claims level data. A single claim may involve hundreds of thousands of dollars going to a PBM affiliate, but without claims level data being provided, that highly suspect transaction can be utterly and improperly hidden.

PBMs also try to hide behind limiting audits to "samples". This can also be a high-handed effort to obscure highly improper transactions at high dollar values. Audit data should explicitly require the production of all relevant data, not a "sample".

PBMs also try to limit the use of audit data by, for instance, saying that it and the results cannot be used for litigation purposes without redoing a second audit for that purpose. This is an obvious and indefensible increase to sponsor costs that necessarily limits the funds available to support the health care of participants—the patients we serve. There should be no limitation on a sponsor's uses of audit data.[9]

2. *Prevent intercompany and affiliate confidentiality agreements from sheltering data from audits.*

PBMs and their affiliates, agents, and contractors have systematically used "confidentiality" agreements to prevent plan sponsors from gaining access to data necessary to show how they—and their participants, like the patients we serve—are adversely affected by their practices. We urge DOL, in keeping with the important focus its proposed rule brings to this issue, to state in paragraph (j)(7) that confidential agreements made between or among PBMs, affiliates, agents, and subcontractors cannot prevent data from being included in audits or otherwise used by sponsors.

The proposed rule stipulates that covered service providers are responsible for providing audit information held by affiliates, agents, or subcontractors, but PBMs will try to invoke intercompany confidentiality agreements as a basis for withholding information. No such mechanism should be permitted to undermine the audit rights of sponsors.

D. Expand reporting frequency to capture material changes to PBM compensation and services provided

We commend DOL for proposing semiannual disclosure of actual compensation, which reflects an important observation that PBMs, affiliates, agents, and contractors could manipulate and undermine required disclosures by making material alterations in compensation during a plan year.

However, to fully realize DOL's policy, we urge DOL to obligate PBMs to update their statements whenever there is a material change to PBMs' fiduciary status or conflicts of interest or compensation, at either the aggregate or the "bucket" level, with materiality defined explicitly in relation to the affected plan sponsor.

[9] Relatedly, PBMs try to prevent the use of audit and other data in attempting to replace an incumbent PBM. This, too, should be explicitly prohibited.

We also recommend that the fiduciary status statement required under paragraph (e)(11) be changed to require semiannual and material event restatements. Annual or even semiannual updates are insufficient given the dynamic nature of PBM operations, vertical integration, and the frequency with which formulary and network changes can alter fiduciary analysis. A mid-year change affecting just one drug can have a devastating impact on a sponsor—and the patients that we serve.

E. Proactively enforce the proposed rule and ERISA violations, and commit to regulatory nimbleness

The proposed rule's administrative class exemption for responsible plan fiduciaries, which requires notification to DOL when PBMs fail to comply with disclosure obligations, provides DOL with a valuable enforcement tool that can provide important protections to both plan sponsors and, indirectly, plan participants.

We ask that DOL commit to using these notifications, along with the data it receives through investigations, to bring enforcement actions against PBMs that engage in noncompliance, evasion, or unreasonable compensation practices. We believe that a strong, proactive enforcement message is essential to create the needed general and specific deterrence, given the sharpness of PBM practices and their disturbing embrace of manipulative responses to other reforms.

Similarly, we urge DOL to coordinate with the FTC, the Department of Health and Human Services, and state regulators to share information and align enforcement strategies. The FTC's investigation of the big-three PBMs and their rebate aggregators, ongoing state audits and litigation, and Congressional oversight all provide complementary evidence that can inform DOL enforcement priorities. Further, these parties should all be on the lookout for PBMs shifting revenue generation into different books of business to evade scrutiny generated by enhanced transparency in the self-funded market.

Finally, DOL should commit to regulatory nimbleness and closely monitor the market evolution in reaction to this rule. Evidence shows that PBMs rapidly shift into different compensation sources to evade transparency or oversight.[10] DOL

[10] Eric Percher, *Trends in Profitability and Compensation of PBMs and PBM Contracting Entities* (New York: Nephron Research, September 2023), https://nephronresearch.com/trends-in-profitability-and-compensation-of-pbms-and-pbm-contracting-entities/.

should be ready to amend these regulations or to issue additional guidance in response to evidence of evasion or patterns of noncompliance by PBMs.

II. The Department should finalize the rule as soon as possible, notwithstanding the 2026 Consolidated Appropriations Act (CAA)

We urge DOL to finalize this rule without delay, notwithstanding the passage of PBM provisions in the 2026 Consolidated Appropriations Act (CAA).[11] Delaying finalization would be inconsistent with DOL's statutory mandate under ERISA to protect plan participants and beneficiaries, and would leave plan fiduciaries without the tools they need to fulfill their own statutory obligations. The proposed rule provides much needed, and long awaited, transparency into PBM compensation structures—transparency that is essential to ensuring plan fiduciaries can properly evaluate whether PBM compensation is reasonable and whether conflicts of interest are being adequately managed. Although the CAA contains important provisions with potential to help protect plan sponsors and, by extension, patients, the CAA in no way obviates the need for DOL to move forward as soon as possible with this proposed rule, with the additions that we propose.

Separate and apart from the CAA, ERISA plan fiduciaries have an affirmative, ongoing duty to monitor PBM compensation arrangements. Under ERISA sections 404 and 408(b)(2), plan fiduciaries must act prudently in selecting and overseeing service providers, ensure that the plan pays only reasonable expenses necessary for plan administration, and act solely in the interest of plan participants and beneficiaries. The proposed rule is of critical importance in assisting fiduciaries in their efforts to comply with these statutory obligations. The proposed rule and the PBM disclosures it will require regarding their compensation are essential in realizing ERISA's obligations.

As recent ERISA class action litigation against major employers demonstrates, plan participants and courts expect plan sponsors to actively monitor PBM compensation. Without the disclosures required by the proposed rule, plan fiduciaries remain exposed to significant litigation risk, and participants continue to bear the cost of obscure and shadowy PBM compensation models. DOL has recognized this problem for over a decade: the ERISA Advisory Council recommended action in 2014, and the case for transparency has only grown

[11] Consolidated Appropriations Act, 2026, Pub. L. No. 119-75 (2026).

stronger since then.[12] Evidence of PBM profiteering and evasion amassed by the Federal Trade Commission, state attorneys general, Congressional committees, and independent researchers makes DOL's intervention not merely appropriate, but urgent.

The CAA's PBM transparency provisions do not preclude DOL from finalizing this rule. Section 6701 of the CAA contains no preemptive language: it does not rescind, disapprove, or prohibit DOL rulemaking under ERISA § 408(b)(2), nor does it state that its PBM transparency provisions are exclusive or that other disclosure regimes are barred.[13]

Lastly, finalizing this proposed rule advances DOL's core mandate to protect plan participants and beneficiaries, and will provide valuable implementation experience in advance of the CAA's effective date. As the preamble to the proposed rule explains, PBM compensation structures are often complex, opaque, and difficult for plan fiduciaries to evaluate because compensation flows through multiple channels—including drug manufacturer rebates, spread pricing, pharmacy clawbacks, and affiliate arrangements—in ways that are not fully disclosed. By requiring comprehensive advance disclosure, semiannual reporting of actual compensation received, and audit rights, the proposed rule gives plan fiduciaries the information they need to determine whether PBM contracts qualify for an exemption from ERISA's prohibited transaction rules because they involve only "reasonable" compensation. Prompt implementation will also give DOL, plan sponsors, and covered service providers valuable operational experience with fee disclosure and audit requirements before the CAA's broader reforms take effect—which is absolutely necessary to protect patients. To the extent there are overlapping requirements in the proposed rule and the CAA, DOL can harmonize those requirements in the final rule without creating delay.

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[12] Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure* (Washington, DC: U.S. Department of Labor, November 2014), https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/about-us/erisa-advisory-council/2014-pbm-compensation-and-fee-disclosure.pdf.

[13] As the Supreme Court held in *Massachusetts v. EPA*, 549 U.S. 497 (2007), Congress does not silently retract authority it has already conferred, and parallel legislative efforts are not superseding. ERISA § 408(b)(2) is a longstanding statutory exemption whose operation necessarily authorizes DOL to promulgate rules requiring disclosures that enable fiduciaries to assess reasonableness. Moreover, DOL's authority under ERISA § 505 to "prescribe such regulations as [it] finds necessary or appropriate" and to "define accounting, technical and trade terms" provides an express delegation of rulemaking power that remains fully operative notwithstanding Section 6701.

We commend DOL for its proposed rule, as it is a meaningful step toward addressing the harmful opacity, conflicts of interest, and profiteering that have characterized PBM relationships with self-insured group health plan sponsors to the detriment of participants, including the patients that we serve. We urge DOL to strengthen the rule in the ways described in Part I as soon as possible.

We also urge DOL not to view this rule as the end of its work on PBM regulation. The transparency framework established by this rule should serve as the foundation for future enforcement action against unreasonable PBM compensation, conflicted arrangements, and the need for clear fiduciary standards. Plan participants and sponsors deserve not only the ability to see what PBMs are doing, but a regulatory framework that ensures PBMs are doing it in the interest of those they (are supposed to) serve.

We appreciate DOL's consideration of these comments and stand ready to provide additional information or technical assistance as DOL moves towards finalization. Thank you for your service and your commitment to protecting plan participants and sponsors.

Respectfully submitted,

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ATTACHMENT A

ADAP Advocacy Association

The mission of the ADAP Advocacy Association (ADAP Advocacy) is to promote and enhance the AIDS Drug Assistance Programs (ADAPs) and improve access to care for persons living with HIV/AIDS. ADAP Advocacy works with advocates, community members, health care providers, government officials, patients, pharmaceutical companies, and other stakeholders to raise awareness, offer patient education programs, and foster greater community collaboration.

Accessia Health

Accessia Health, a nonprofit patient assistance organization, supports individuals living with rare or chronic health conditions. Through our disease programs we offer case management, financial assistance, education, and other related services. Our holistic, inclusive, and outcomes-focused approach addresses unmet needs and improves access to health care.

Advocates for Compassionate Therapy Now

Advocates for Compassionate Therapy Now works with the medically complex community to provide connection to resources, education, and networking for families and patients.

The AIDS Institute

The AIDS Institute is a national, non-partisan, 501(c)(3) nonprofit organization dedicated to ensuring that people living with or at risk of HIV, hepatitis, and other chronic illness have access to the full range of high-quality health care and support services that they need. Starting as a grassroots advocacy organization in Florida during the height of the AIDS epidemic, The AIDS Institute later incorporated as a 501(c)(3) in 1992. Its stated mission is to promote action for social change through public policy, research, advocacy, and education. The mission of The AIDS Institute continues to center people living with HIV; however, our work applies broadly to all people living with rare, serious, and complex chronic conditions.

Arthritis Foundation

The Arthritis Foundation is boldly pursuing a cure for America's #1 cause of disability while championing the fight to conquer arthritis with life-changing science, resources, advocacy and community connections.

Autoimmune Association

The Autoimmune Association is the world's leading nonprofit organization dedicated to autoimmune awareness, advocacy, education, and research.

Cancer*Care*

For over 80 years, Cancer*Care* has empowered millions of people affected by cancer through free counseling, resource navigation, support groups, educational resources, advocacy, and direct financial assistance. Our oncology social workers improve the lives of people diagnosed with cancer, caregivers, survivors and the bereaved, by addressing their emotional, practical, and financial challenges.

Coalition of State Rheumatology Organizations

Coalition of State Rheumatology Organizations (CSRO) is comprised of over 40 state and regional professional rheumatology societies nationwide, whose mission is to advocate for excellence in the field of rheumatology, ensuring access to the highest quality care for the management of rheumatologic and musculoskeletal disease.

To aid rheumatologists in protecting their patients and their livelihood, CSRO actively advocates on the state and national level, focusing on educating legislators, government officials and the corporate community on the impact that policy and procedural changes may have to the patient's quality of care and disease management options. CSRO also collaborates with patient organizations and other national societies to elevate awareness and provide a forum for an exchange of ideas, fostering a collaborative environment.

CSRO is dedicated to empowering rheumatologists and their practices with resources to proactively increase patient access to rheumatologic care and medication; supporting the formation of new state societies and encouraging active societies to incorporate advocacy into their normal activities; and providing a network for state societies to exchange information.

Colorado Rare Disease Coalition

Colorado Rare Disease Coalition works with the rare disease community to host a collaborative rare disease fair with researchers, industry, and community stakeholders to identify and address gaps in care, access to therapy, and community connection.

The Connecticut Oncology Association

The Connecticut Oncology Association (CtOA) is the sole professional support organization for Connecticut practicing oncologists and their practices, including practice administration and clinical teams. CtOA was instrumental in state legislative discussions regarding Medicaid formularies, several pieces of state legislation affecting oncology patients, co-pay accumulators, national and state guidelines and pathways initiatives, national and state pharmacy regulation issues and changes, and Medicare national and local policies.

Cystic Fibrosis United

Cystic Fibrosis United is a grassroots advocacy organization made up of cystic fibrosis patients and caregivers working hard to ensure continued, affordable access to cystic fibrosis medicine in Colorado and nationwide.

National Bleeding Disorders Foundation

The National Bleeding Disorders Foundation (formerly the National Hemophilia Foundation) is dedicated to finding cures for inheritable blood and bleeding disorders and to addressing and preventing the complications of these disorders through research, education and advocacy enabling people and families to thrive.

National Oncology State Network (NOSN)

NOSN is a nonprofit action organization established by state leaders collaborating on emerging state issues in order to strengthen cancer care and policy across the country.

The Rare Access Action Project (RAAP)

RAAP is a non-profit (501(c)(4)) organization whose membership consists of patient advocates, emerging life science companies, and other rare disease stakeholders advocating for innovative solutions to reduce or eliminate barriers to rare therapies.