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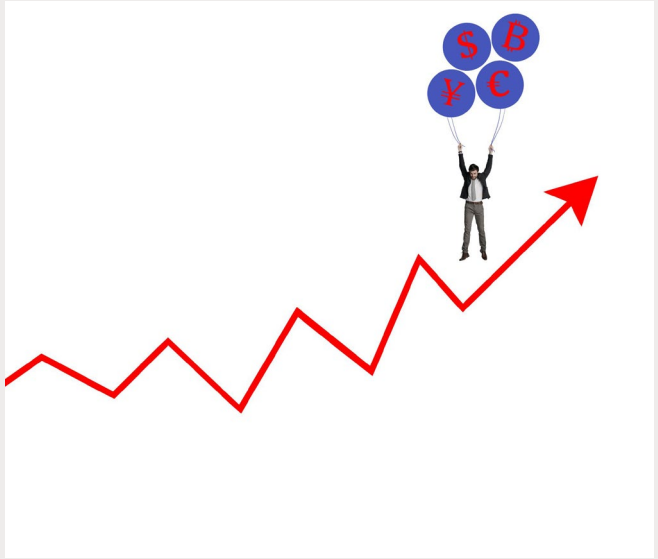
Pharmacy, Fiduciary Risk, and the New Compliance Reality

Navigating regulatory challenges in healthcare administration

PBM Oversight, ERISA Fiduciary Exposure, and Employer Decision-Making

Why This Matters Now



Rising Healthcare Costs

Healthcare costs are increasing faster than inflation and wages, exerting pressure on employer-sponsored benefit plans.

Increased Regulatory Enforcement

Regulators and courts are taking aggressive enforcement actions, especially where employer oversight was limited.

Complex Pharmacy Benefit Risks

Pharmacy benefits involve complex structures creating cost, compliance, and governance risks for employers.

Need for Active Oversight

Employers must actively manage pharmacy benefits to avoid fiduciary risks amid new laws and litigation.

Pharmacy as a Fiduciary Pressure Point

Rising Pharmacy Costs

Pharmacy spending now drives significant health plan cost growth, especially due to specialty drugs and biologics.

Complex PBM Compensation

Pharmacy Benefit Manager revenue involves rebates, fees, and pricing structures lacking transparency, increasing fiduciary complexity.

Fiduciary Accountability and Litigation

Employers face legal risks tied to pharmacy oversight and must ensure governance and documentation to meet fiduciary duties.

Policy Headwinds Are No Longer Theoretical

Regulatory Shift in Pharmacy Benefits

Recent regulations have transformed pharmacy benefits management with stricter federal requirements for employers.

Enhanced Transparency and Reporting

New transparency and disclosure rules provide employers with previously proprietary information to improve oversight.

Expanded Compliance Obligations

Employers must actively comply with evolving regulations, adjusting governance to meet fiduciary standards under ERISA.

PBMs Under the Consolidated Appropriations Act & Proposed Regs: Dual Federal Action

Enhanced Transparency Requirements

The CAA mandates detailed reporting of drug costs, rebates, fees, and net spending to improve system transparency.

Employer Oversight Responsibility

Employers are expected to actively oversee PBM contracts, with restrictions on disclosure delays and penalties for noncompliance.

Fiduciary Implications Under ERISA

PBM oversight under ERISA makes employers liable for prudent management of pharmacy benefit governance.

PBMs Under the Consolidated Appropriations Act & Proposed Regs: Dual Federal Action

Topic	DOL proposed PBM fee disclosure rule	CAA 2026 PBM reform (enacted law)
Legal status	Proposed regulation (not final)	Federal law (signed Feb 3, 2026)
Primary purpose	Transparency so fiduciaries can evaluate reasonableness of PBM compensation	Structural reform: mandatory reporting, rebate pass-through, penalties
Who is regulated	PBMs and PBM-affiliated brokers/consultants- additional notice to employers	PBMs and upstream “applicable entities” (manufacturers, rebate aggregators, affiliates)
Conflicts	Requires disclosure of retained rebates. Annual audit rights required.	Requires 100% rebate pass through. Annual rebate audit rights for ERISA plans only.
Plans affected	Self-insured ERISA group health plans only of all sizes	Self-insured and fully insured group plans – differences in data for 100+ employers
Effective timing	If finalized: plan years on/after 7/1/2026	Plan years 30 months after enactment (1/1/2029 for calendar-year plans)
Enforcement framework	ERISA prohibited transaction / reasonableness	Statutory penalties plus ERISA contract reasonableness

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Proposed Regulation

- On January 29, 2026, the DOL released *proposed* regulations governing Pharmacy Benefit Managers (PBMs) which would require PBMs and certain PBM-affiliated brokers and consultants who enter into contracts with self-funded, ERISA-covered group health plans to provide PBM services where they expect to receive $1,000 or more in direct or indirect compensation, to make to provide initial and semi-annual disclosures to plan fiduciaries
  - Fully insured plans are exempt from these requirements
  - If finalized, will apply to plan years beginning on or after 7/1/26
- Similar to the Broker Compensation Disclosure requirements under the CAA, 2021, these proposed rules are aimed at ensuring compensation for PBMs are reasonable for purposes of ERISA's prohibited transaction rules

- Initial disclosure must include a description of the PBM services that will be provided, any direct compensation reasonably expected to be received from the self-funded group health plan, and any compensation reasonably expected to be received by the PBM, including:
  - Payments from drug manufacturers, including the amounts retained by PBM and any that the PBM will pass on to the plan;
  - Spread compensation;
  - Copay claw-backs;
  - Price protection arrangements, including the amount retained and the amount passed on to the plan;
  - Description of other compensation;
  - Termination compensation;
  - Formulary placement incentives, including (a) an explanation of how the incentives are aligned with the interests of the plan/plan participants (e.g., incentive or arrangements are to control prescription drug costs, provide clinically superior drugs, or both), (b) an identification of any reasonably available therapeutically equivalent alternatives, and the reason for omitting the alternatives from the formulary, for any prescription drug that the PBM will receive payment that is not passed through to the plan; and (c) where the service contract/arrangement allows the PBM to add, delete, change tiers, etc. for any prescription drugs during the term of the contract/arrangement, the disclosure must explain the reasons for retaining such authority, the expected frequency of any changes, and that the plan fiduciary will be notified reasonably in advance of such changes that are reasonably expected to have a material impact on the reasonableness of compensation under the contract

Proposed Regulations on PBM Fee Disclosure

Initial disclosure must also include:

- A description of the drug pricing methodology (i.e., net costs to the covered plan of each drug on the formulary, for each pharmacy channel, expressed in a dollar amount);
- A statement of fiduciary status (if applicable), including a disclosure of any activity that may create a conflict of interest, including, for example, if the PBM 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 to use drugs that generate greater manufacturer rebates than other therapeutically equivalent drugs on the formulary;
- A statement of audit right

Proposed Regulations on PBM Fee Disclosure

Semiannual disclosures must include:

- Direct compensation;
- Manufacturer payments;
- Spread compensation;
- Copay claw-backs;
- Price protection agreements;
- Other compensation
- The semiannual disclosure must also include a description and amount of any overage it received and a statement of audit right

Proposed Regulations on PBM Fee Disclosure

All disclosures made must be clear, concise, free of misrepresentations, and contact sufficient specificity

The descriptions of compensation must be in actual dollar amounts and can be estimated to the extent that the actual amount is not reasonably ascertainable

If a plan fiduciary of the covered plan requests the information in a machine-readable format, the covered service provider must provide the information in such format within a reasonable period of time

PBMs cannot impose restrictions on the plan's use of these disclosures, except that the contract may require the responsible plan fiduciary to require third parties to whom it rediscloses such information to execute reasonable confidentiality agreements preventing rediscloure by such parties

Proposed Regulations on PBM Fee Disclosure

Plan fiduciaries are responsible for ensuring these requirements are met; however, there is an exemption for any plan fiduciary that was not aware of the failure and requests in writing that the PBM correct the failure

If the PBM fails to comply within 90 days of the request, the plan fiduciary must notify the DOL of the failure by providing certain plan information, including a description of the PBM's failure and the date on which the corrective action was requested in writing from the PBM

If the PBM fails to comply with the written request within 90 days, the responsible plan fiduciary also must determine whether to terminate or continue the service contract consistent with its ERISA duty of prudence

The DOL will likely revise these proposed regulations to be consistent with the new PBM reforms contained in the CAA, 2026 which is effective starting in 2029 for calendar year plans

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Consolidated Appropriation Act, 2026

Reforms effective 30 months after enactment – 1/1/29 for CY plans

- Section 6701 — Pharmacy Benefit Manager Oversight
  - Establishes federal reporting and transparency requirements for PBMs
    - PBMs must report drug-level costs, rebates, fees, and net spending to group health plans every 6 months (or quarterly)
    - Requires disclosure of formulary design, dispensing channel data, spread pricing, and participant out-of-pocket costs
    - HHS must create standard formats and regulations for reporting within 18 months
    - Prohibits PBMs from restricting or delaying disclosure of required information.
      - Imposes civil penalties: $10,000/day for not reporting
      - Up to $100,000 per item for knowingly false information
    - Requires plans to provide annual notices to participants about PBM reporting obligations
    - All disclosures must comply with HIPAA and HITECH privacy rules
    - Parallel provisions added to PHSA, ERISA, and the Internal Revenue Code for consistent application

Consolidated Appropriation Act, 2026

- Section 6702 — Full Rebate Pass-Through
  - PBM contracts are not “reasonable” under ERISA unless 100% of rebates, fees, and price concessions are passed through to plans or insurers
  - Requires rebates to be remitted quarterly, fully disclosed, and subject to annual plan audits
  - Rebate aggregators must remit funds to PBMs within 45 days after each quarter
  - Provides a safe harbor for fiduciaries who did not know of PBM non-compliance and take corrective action
  - Clarifies that PBM arrangements qualify as indirect compensation subject to ERISA disclosure rules

PBM Contracts Are Fiduciary Documents

Fiduciary Role of PBM Contracts

PBM contracts regulate plan assets and participant benefits, making them fiduciary documents under ERISA.

Impact of Contract Terms

Pricing guarantees can be diluted by exclusions, rebate retention, and narrow definitions affecting costs and participants.

Need for Rigorous Review

Thorough contract review, documentation, and monitoring are essential to avoid fiduciary failures and ensure proper governance.

PBM Contract Review as a Core Fiduciary Step

PBM contracts should be treated as fiduciary documents.

Employer & broker action:

- Conduct a formal review of contract terms, definitions, and guarantees
- Identify provisions that impact pricing, rebates, fees, and formulary control
- Evaluate whether contract language aligns with ERISA fiduciary standards, not just "market norms"
- Purpose:
- Ensure the plan understands how pharmacy dollars flow
- Reduce reliance on optics or guarantees without substance
- Establish a documented fiduciary review process

ERISA Success: PBM Audit & Monitoring

Ongoing Monitoring Through PBM Audits

Review alone is not sufficient—monitoring is required.

Employer & broker action:

- Validate that PBM contractual promises are actually being met
- Confirm rebate pass-throughs, pricing guarantees, and fee arrangements
- Identify leakage, retained revenue, or misaligned incentives

Why this matters:

- PBM arrangements involve plan assets and plan design decisions
- Failure to monitor service providers is a common theme in ERISA litigation
- Documentation of review and follow-up is as important as the outcome

Broad Fiduciary Considerations

PBM Oversight Is One Part of a Broader Fiduciary Framework

PBM contract review and audit should sit alongside other core fiduciary practices:

- Regular review of TPA and carrier agreements
- Use of RFPs and market checks when appropriate
- Clear documentation of decisions and rationale
- Ongoing compliance audits and recordkeeping
- Ensure pharmacy is in the ERISA plan docs; carved out pharmacy necessitates a 2nd SPD or amended custom wrap

Key takeaway:

- Pharmacy is no longer a carve-out from fiduciary governance
- PBM oversight must be intentional, repeatable, and defensible

Rebates, Fees, and Formularies

Fiduciary Oversight of Rebates and Fees

Rebates and certain fees are plan assets requiring fiduciary duties of loyalty and prudence under ERISA regulations.

Impact of Formulary Design

Formulary decisions affect drug access, out-of-pocket costs, and clinical outcomes, requiring careful cost and clinical value balance.

Employer Responsibility and Compliance

Employers must oversee plan design elements, ensuring documentation, review, and alignment with fiduciary responsibilities.

Inaction Is Also a Decision

Risks of Inaction in Fiduciary Duty

Failing to act on known issues can be as risky as making poor decisions under ERISA guidelines.

Regulatory Scrutiny on Inaction

Courts increasingly scrutinize fiduciaries who ignore data or delay engagement despite red flags.

Importance of Proactive Governance

Proactive engagement, documentation, and reassessment are critical to justify decisions, even if maintaining status quo.

What Questions Must Now Be Asked

Evolving Fiduciary Questions

Fiduciaries must move beyond discounts, understanding PBM compensation and incentive impacts on plan outcomes.

Critical Transparency Issues

Verify net costs independently, ensure full rebate disclosure, and confirm contracts support audit rights.

Governance and Oversight

Document decision-making processes and maintain governance structures to support ongoing fiduciary oversight.

Ongoing Fiduciary Dialogue

Consistent questioning aligns pharmacy strategy with fiduciary duties, reducing compliance and litigation risk.

Implications for Brokers and Consultants

Role in Managing Fiduciary Risk

Brokers and consultants guide employers in understanding and managing pharmacy-related fiduciary risks amid rising regulatory expectations.

Ensuring Transparency and Compliance

Advisors facilitate transparency by explaining complex arrangements and supporting thorough documentation and review processes.

Maintaining Trust and Ethical Standards

Clear communication, disclosure of conflicts of interest, and client education help maintain trust and uphold ethical advisory standards.

Key Takeaways

Pharmacy Benefits and Risk

Pharmacy benefits are a growing source of fiduciary risk requiring careful oversight and compliance.

Transparency and Compliance

Transparency is mandatory for compliance, beyond cost control, impacting contracts and plan outcomes.

Proactive Governance

Inaction is a fiduciary decision; proactive governance and documentation are essential to manage risks.

Advisors' Role

Advisors support employers in aligning compliance and cost strategies to navigate complex fiduciary landscapes.

GLP-1 Coverage

- Rising interest and high costs for GLP-1 medications have employers seeking ways to balance employee desire with the cost of the drugs. This focus is on GLP-1s for weight loss, not for sleep apnea or diabetes.
- If you've seen one GLP-1 point solutions, you've only seen one GLP-1 point solution. Weight loss programs, carve-outs + direct to consumer programs, and more. Each one has to be evaluated.
- If an employer is giving employees money to purchase GLP-1s, it is almost certainly a health reimbursement arrangement and a group health plan- *REGARDLESS OF WHAT A VENDOR CALLS IT*.
    - Plan docs
    - PCORI fees
    - Non-discrimination testing
    - Integration into a group health plan
    - Impact on HSA eligibility (the reimbursement needs to be post-deductible)
        - Some vendors try to say these programs are "excepted benefits" to get around this HSA issue, but prescription drugs are considered significant benefits → the excepted benefit argument doesn't work
        - Some vendors try to say these programs are preventive care when paired w/ weight loss programs to get around this HSA issue based on a 2004 IRS notice. This is unsettled with regulators and is a risky approach. Alera Group should not decide for clients that this is low risk and advocate for these programs or demo them with clients without a robust and documented discussion about the risk.

Self-Funded Plan Considerations

Employers working with a PBM often have contracts with exclusivity provisions, i.e. an employer can only offer employees prescription drugs through the PBM

If an employer with an exclusivity provision carves out GLP-1s for weight loss + implements a point solution or direct-buy program, the PBM could renege on the price guarantees or renegotiate all of the employer's drug pricing provisions.