Attorneys: Concerns Related to PBM Contracts

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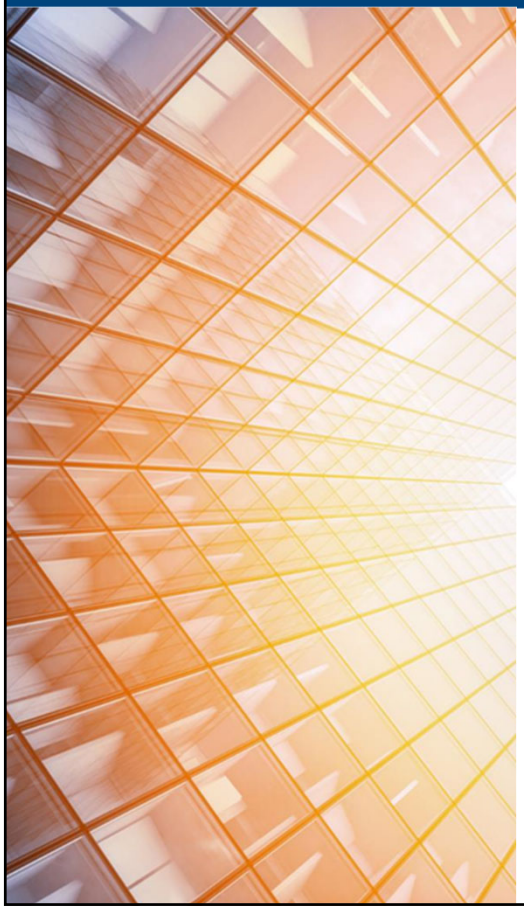
PBM-Related Legislation



- Healthcare price transparency
- Drug pricing and PBM reform

Healthcare Price Transparency

- The Lower Costs, More Transparency Act (H.R. 5378)
  - ***Hospitals, insurance companies***, labs, imaging providers, and ambulatory surgical centers would be required to **publicly list the prices they charge** patients.
  - ***PBMs*** would be required to **provide plan sponsors with detailed information on rebates, drug spending, total out-of-pocket spending and formulary placement** rationale
  - ***PBMs and third-party administrators (TPAs)*** would be required to disclose information about their direct and indirect compensation to plan fiduciaries, including new **price transparency for services like diagnostic lab tests, imaging, and ambulatory surgical centers owned by hospitals**.

https://www.congress.gov/118/bills/hr5378/BILLS-118hr5378ih.pdf

Healthcare Price Transparency

- Bipartisan majority in House of Representatives
- But no action in 2024

Drug Pricing and PBM Reform—Legislative

- Big focus on PBMs as the source of high drug costs
- The broad reach of PBMs within the healthcare system means that at least six congressional committees have jurisdiction over some aspect of PBMs
  - House Committees
    - Energy and Commerce
    - Ways and Means Committee
    - Education and the Workforce
  - Senate Committees
    - Finance
    - HELP
    - Commerce, Science, and Transportation Committee
- Legislation could be considered on the House and Senate floors

Drug Pricing and PBM Reform—Legislative

- Enhanced PBM to plan disclosure requirements
  - Annual reports with detailed data on prescription drug spending
  - Rebates, fees, alternative discounts, other remuneration received by PBMs, out-of-pocket spending, formulary placement rationale
- Prohibition on "spread pricing" where PBM charges plan sponsors more for a drug than the PBM pays the pharmacy based on the discounts it negotiates
- Limitations on PBM rebate retention—Mandating pass-throughs of rebates and discounts
- Regulating retail/specialist/mail pharmacy networks
- Significant limitations on use of step therapy for prescription drugs

Drug Pricing and PBM Reform—Regulatory

- Inflation Reduction Act allows the Federal Government, for the first time, to negotiate drug prices for which Medicare pays.
  - Centers for Medicare and Medicaid Services ("CMS") negotiated prices for 10 drugs, set to take effect January 1, 2026.
- **Estimated Medicare Net savings in 2023:**
  - Compared to 2023 Medicare spending . . . if the prices agreed to between CMS and participating drug companies . . . had been in effect during 2023, ***the negotiated prices would have saved an estimated $6 billion in net covered prescription drug costs, which would have represented 22% lower net spending in aggregate***.
- **Projected savings for people with Medicare Part D coverage:**
  - When the negotiated prices go into effect in 2026, people enrolled in Medicare prescription drug coverage would save . . . an estimated $1.5 billion.

Drug Pricing and PBM Reform—Regulatory

Drug Name	Participating Drug Company	Commonly Treated Conditions	Agreed to Negotiated Price for 30-day Supply for CY 2026	List Price for 30-day Supply, CY 2023	Discount of Negotiated Price from 2023 List Price	Total Part D Gross Covered Prescription Drug Costs, CY 2023	Number of Medicare Part D Enrollees Who Used the Drug, CY 2023
Januvia	Merck Sharp Dohme	Diabetes	$113.00	$527.00	79%	$4,091,399,000	843,000
Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill	Novo Nordisk Inc	Diabetes	$119.00	$495.00	76%	$2,612,719,000	785,000
Farxiga	AstraZeneca AB	Diabetes; Heart failure; Chronic kidney disease	$178.50	$556.00	68%	$4,342,594,000	994,000
Enbrel	Immunex Corporation	Rheumatoid arthritis; Psoriasis; Psoriatic arthritis	$2,355.00	$7,106.00	67%	$2,951,778,000	48,000
Jardiance	Boehringer Ingelheim	Diabetes; Heart failure; Chronic kidney disease	$197.00	$573.00	66%	$8,840,947,000	1,883,000
Stelara	Janssen Biotech, Inc.	Psoriasis; Psoriatic arthritis; Crohn's disease; Ulcerative colitis	$4,695.00	$13,836.00	66%	$2,988,560,000	23,000
Xarelto	Janssen Pharms	Prevention and treatment of blood clots; Reduction of risk for patients with coronary or peripheral artery disease	$197.00	$517.00	62%	$6,309,766,000	1,324,000
Eliquis	Bristol Myers Squibb	Prevention and treatment of blood clots	$231.00	$521.00	56%	$18,275,108,000	3,928,000
Entresto	Novartis Pharms Corp	Heart failure	$295.00	$628.00	53%	$3,430,753,000	664,000
Imbruvica	Pharmacyclics LLC	Blood cancers	$9,319.00	$14,934.00	38%	$2,371,858,000	17,000

Note: Numbers other than prices are rounded to the nearest thousands. List prices are rounded to the nearest dollar and represent the Wholesale Acquisition Costs (WACs) for the selected drugs based on 30-day supply using CY 2022 prescription fills. Drug companies' participation in the Negotiation Program is voluntary; the figures above represent estimates based on continued drug company participation in the Medicare program.

Drug Pricing and PBM Reform—Enforcement

- Federal Trade Commission ("FTC") action
  - Lawsuit filed*
  - Counter-lawsuit by PBM against FTC

* www.ftc.gov/terms/pharmacy-benefits-managers-pbm

What Is a Pharmacy Benefit Manager?

- We generally think of PBMS as:
  - Entities that administer the prescription drug portion of a health plan
  - Middlemen between health plans/consumers and drug companies
  - The entity that negotiates drug prices and creates drug formularies.
- PBMs negotiate with pharmaceutical companies for rebates but the PBMs also negotiate with pharmacies for fees and discounts
- Employers may not have insight as to the amount of direct/indirect compensation paid to the PBMs

The Main Players

- Group Health Plan
  - The employer (or plan) contracts with a PBM for it to manage and administer the prescription drug portion of the plan
- PBM
  - Receives fees for providing services such as creating a network of pharmacies and administering claims and appeals
- Pharmacies
  - PBM enters into contracts with pharmacies that dispense the drugs, and those contracts address the amount the pharmacies will be paid for the drugs dispensed to the GHP participants
- Drug manufacturers
  - Have agreements with PBMs as to rebates manufactures pay to PBMs

Where the Money Is Made

- There are numerous ways PBMs receive compensation. Some examples include:
  - Spread compensation
  - Formulary fees
  - Market share fees
  - MAC lists
  - Rebates

PBM ERISA Litigation

- Several ERISA lawsuits pending relating to plans/participants paying "excessive" amounts for prescription drugs.
- Allege wrongdoing by PBMs
- But PBMs are not defendants
- Plan fiduciaries are the defendants

Litigation Background—Rising Costs of Healthcare

- Over half of the nonelderly U.S. population receives their health insurance through an employer
- Among people with employer insurance, spending per person increased 21.8% between 2015 and 2019
  - Healthcare services and prescription drug prices were the biggest drivers
- Premiums and deductibles account for 11.6% of median household income—Nearly 10% increase from 10 years ago
  - Outpacing wage growth
- Healthcare system notoriously lacks transparency

https://www.commonwealthfund.org/sites/default/files/2021-10/Collins_Senate_Finance_Comm_Testimony_10-20-2021_final.pdf
https://www.americanprogress.org/article/health-insurance-costs-are-squeezing-workers-and-employers/

Impacts of ERISA 401(k) Litigation

- Plaintiffs' counsel is applying 401(k) fee litigation theories to health care space.
  - Fees continue to decline—Down an average of 0.03% in 2022
- Defendants' response: 401(k) plans and healthcare plans are **not** the same.

Sources:
- George S. Mellman and Geoffrey T. Sanzenbacher, 401(k) Lawsuits: What Are the Causes and Consequences?, Center for Retirement Research at Boston College, Issue in Brief No. 18-8 at 5 (May 2018).
- Ashlea Ebeling, 401(k) Fees Continue To Drop, FORBES (Aug. 20, 2015).
- American Society of Pension Professionals & Actuaries, 401(k) Plan Fees Decline (Again) (Feb. 24, 2023).

Consolidated Appropriations Act (CAA)

- CAA amended ERISA section 408(b)(2) to require certain GHP service providers to disclose to plan fiduciaries direct or indirect compensation they expect to receive in connection with services provided to the GHP
  - Applies to those who provide "brokerage services" or "consulting" services to GHPs and expect to receive over $1,000 in compensation
  - **Includes PBM services**, recordkeeping, benefits administration, etc.
  - Applies to contracts and agreements entered into, extended, or renewed after December 27, 2021
- Interest in extending 401(k) excessive fees litigation theories to GHPs following the CAA

Recent Caselaw

- *Knudsen v. MetLife*, No. 2:23-CV-00426 (D.N.J. July 18, 2023)
  - Alleged that the employer plan sponsor wrongfully retained rebates instead of defraying costs to plan participants
    - Plan document states the employer would retain rebates, but did not specify how they should be used
  - Dismissed on standing grounds
    - Court found that even if the rebates should have been returned to the plan, participants were not entitled to the general pool of plan assets
    - Claims that copays or coinsurance could have been reduced were "speculative and conclusory"

Recent Caselaw

- *Knudsen v. MetLife*, — F.4th —, 2024 WL 4282967 (3d Cir. Sept. 25, 2024)
  - Affirmed dismissal for lack of Article III standing
  - Plaintiffs:
    - Failed to establish injury because they failed to allege "which out-of-pocket costs increased, in what years, or by how much."
    - Failed to allege employer's retention of prescription drug rebates, was the but-for-cause of their alleged injury, i.e., increased out-of-pocket costs.
    - That employer "may have" used rebates to reduce participant contribution or "may have" distributed rebates to participants was speculative.

Recent Caselaw

- *Knudsen* (continued)
  - Important discussion of Supreme Court's *Thole* decision
    - "[W]e decline to hold that *Thole* and *Perelman* require dismissal, under Article III, *whenever* a participant in a self-funded healthcare plan brings an ERISA suit alleging that mismanagement of plan assets increased his/her out-of-pocket expenses."

Knudsen, 2024 WL 4282967, at *6, https://1.next.westlaw.com/Document/I2d96d1607b7a11ef861f9b5d0624970e/View/FullText.html?transitionType=Default&contextData=(oc.Default)&documentSection=co_pp_sp_999_6

Recent Caselaw

- *Lewandowski v. Johnson & Johnson et al.*, No. 1:24-cv-00671 (D.N.J. February 5, 2024)
  - Complaint alleges that GHP fiduciaries are liable for excessive payments to PBMs for specialty generic drugs
    - For example, alleges that the plan paid its PBM over $10,000 for a drug available for $40-80 over the counter
  - Additionally contends that the fiduciaries allowed the PBM to encourage participants to use its own mail-order pharmacy at an inflated price
  - Alleges breach of fiduciary duties, not violation of ERISA §408(b)(2)

Recent Caselaw

- *Lewandowski v. Johnson & Johnson* (continued)
  - Amended Complaint filed June 2024
  - Motion to Dismiss briefing completed
  - Both sides argue that *Knudsen* decision supports their respective claims

GHP Litigation Challenges

- Article III Standing
  - *Thole v. U.S. Bank*, N.A., 140 S. Ct. 1615 (2020)
    - Participants in defined benefit plans are entitled to the same benefit regardless of how the fiduciaries manage the plan
    - Employer bears the risk—Thus no individual injury for mismanagement if employee continues to receive their benefit
  - Some courts analogize GHPs to defined benefit plans; premiums and benefits are fixed and do not fluctuate based on fees the plan pays
  - **Example:** *Winsor v. Sequoia Benefits & Ins. Servs., LLC*, 62 F.4th 517 (9th Cir. 2023).
    - But see *Knudsen*.

GHP Litigation Challenges

- Standing (continued)
  - *Johnson & Johnson* asserts injury to participants via higher drug payments, deductibles, coinsurance, copays, and lower wages
  - *Acosta v. Bd. of Trustees of Unite Here Health*, No. 22 C 1458, (N.D. Ill. Mar. 31, 2023)
    - Court determined that plaintiffs sufficiently alleged individual injury by pointing to plan terms to support their allegations that their wages were decreased when they made plan contributions
    - More recent ruling finding that Plaintiffs had alleged sufficient details as to "comparator" plans. 2024 WL 3888862 (Aug. 21, 2024)

GHP Litigation Challenges

- Were the defendants acting as fiduciaries?
- Were plan assets involved?
- No clear benchmarks for determining what constitutes "excessive" fees in the GHP space
  - Explains why PBM contracts will be the likely first target—AWP/MAC give starting point for drug price comparisons
- Possible fiduciary breach arguments
  - Need for RFPs
  - Consider pass-through PBMs
  - "Carve out" specialty drug programs

Let's Be Realistic

- **Be realistic about your plan's leverage with the PBM**
  - If your plan is small (e.g., 100–5000 lives):
    - Your leverage is limited
    - You will want to seek a company whose "off-the-shelf" product best meets your needs at the best price
  - If your plan is part of a several million-life coalition:
    - The coalition leverage will be considerable
    - The coalition will be able to insist on a custom agreement and specified services

Let's Be Realistic

- **The "Bigs"**
  - The Big Three
    - **Caremark** business of CVS Health
    - **Express Scripts** business of Cigna
    - **Optum Rx** business of UnitedHealth Group
  - Processed nearly 80% of all prescription claims

Let's Be Realistic

- **Don't ignore the midsize PBMs**
  - Most have customers in the collectively bargained and non-bargained spaces
  - They may be able to provide:
    - Comparable pricing
    - Superior customer service
    - Flexibility in contract terms
    - More "hands on" care for participants.

Key Terms

- **Rebates:** Rebates are refunds from drug manufacturers and pharmacies paid to the PBM on a lagging basis. The PBM passes on a portion of the rebates to the plan.
  - Regardless of how the contract defines "rebate," it is essential to negotiate ***the highest possible guaranteed rebate***, because PBMs consider the actual rebates they receive for each drug proprietary information.

Key Terms

- **Manufacturer Rebates:** It's essential that the contract spell out the manufacturer rebates applicable to each category of drug
  - Rebates may vary by pharmacy channel, day supply, and specialty versus non-specialty brand drugs (rebates are not usually provided for generic drugs).
    - Specialty drugs usually have separate, higher rebate guarantees.

Key Terms

- **Pharmacy Rebates:** Preferred pharmacies may negotiate rebates with PBMs
  - Pharmacy rebates can apply to generic drugs in addition to brand and specialty drugs. These rebate amounts are on a flat dollar basis and may vary based on pharmacy.

Key Terms

- **Performance Guarantees: Key standards**
  - Retail claim financial and processing accuracy
  - Mail order claim financial and processing accuracy
  - Rebate amounts (across all channels) and remittance timeliness
  - Customer service responsiveness
    - Average time to answer
    - Abandonment rate
    - Resolution rate of questions
    - Member satisfaction

Key Terms

- **Performance Guarantees:** Performance guarantees should be meaningful, measurable and auditable
  - Make sure the contract provides for the reporting necessary to track and measure guarantees in a timely way
  - State the PBMs at-risk amounts clearly, and to what performance guarantees they apply
  - Describe in detail what performance guarantee failures will trigger a payout

Key Terms

- **Audit Provisions:** PBM audit provisions are generally highly restrictive, and PBMs oppose any changes to the scope of the audit or the identity of the auditor
  - Ideally, the audit language should provide that a plan can select its independent auditor; can audit for the period of the entire contract term; and has access, with appropriate safeguards, to the PBM's contracts with manufacturers

Key Terms

- **Audit Provisions:** The plan should be able to determine from an audit whether the PBM is accurate with respect to:
  - Your plan's benefit design
  - Financial guarantees
  - Rebates
  - Distribution channel
  - Utilization management programs
  - Participant cost-share.

Key Terms

- **Termination Clauses:** Remember that 29 CFR § 2550.408b-2(c)(3) applies to PBM contracts
  - **Termination of contract or arrangement.** No contract or arrangement is reasonable within the meaning of section 408(b)(2) … if it does not permit termination by the plan without penalty to the plan on reasonably short notice under the circumstances to prevent the plan from becoming locked into an arrangement that has become disadvantageous.

Key Terms

- **Termination Provisions:** A general rule of thumb is that "reasonably short notice" is 90 or 120 days.
  - The parties can reasonably agree to no termination within the first year, given the costs of establishing a new relationship with a plan
  - Review any termination "fee" to ensure that it is not a penalty, e.g., a refusal to pay rebates for a period prior to the termination
  - May be reasonable to agree to a multi-year arrangement if the contract includes price guarantees for both prescriptions and fees

Key Terms

- **Market Checks:** The pharmacy marketplace changes quickly, so ensure that your contract includes an annual "market check," which should include, at a minimum:
  - Review of a significant number and types of plans;
  - Review of all pricing terms across channels; all administrative and dispensing fees; and all rebates and financial guarantees.

Key Takeaways

- What should plan fiduciaries be doing?
  - RFPs
  - Consultant analyses/market checks
  - Meeting minutes

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