



Decoding ERISA Fiduciary Rules in the Prescription Landscape

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Seyfarth Shaw LLP

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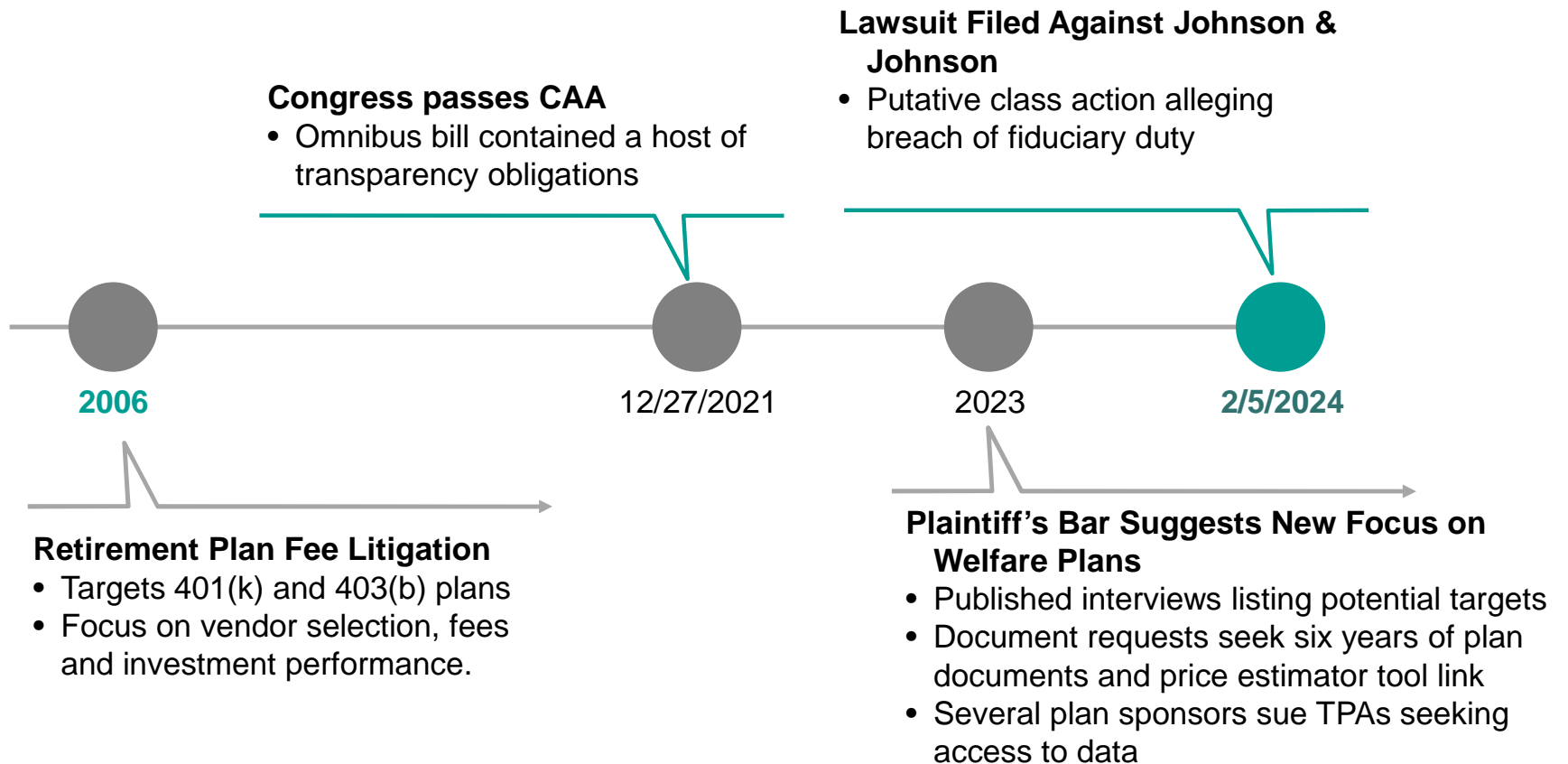
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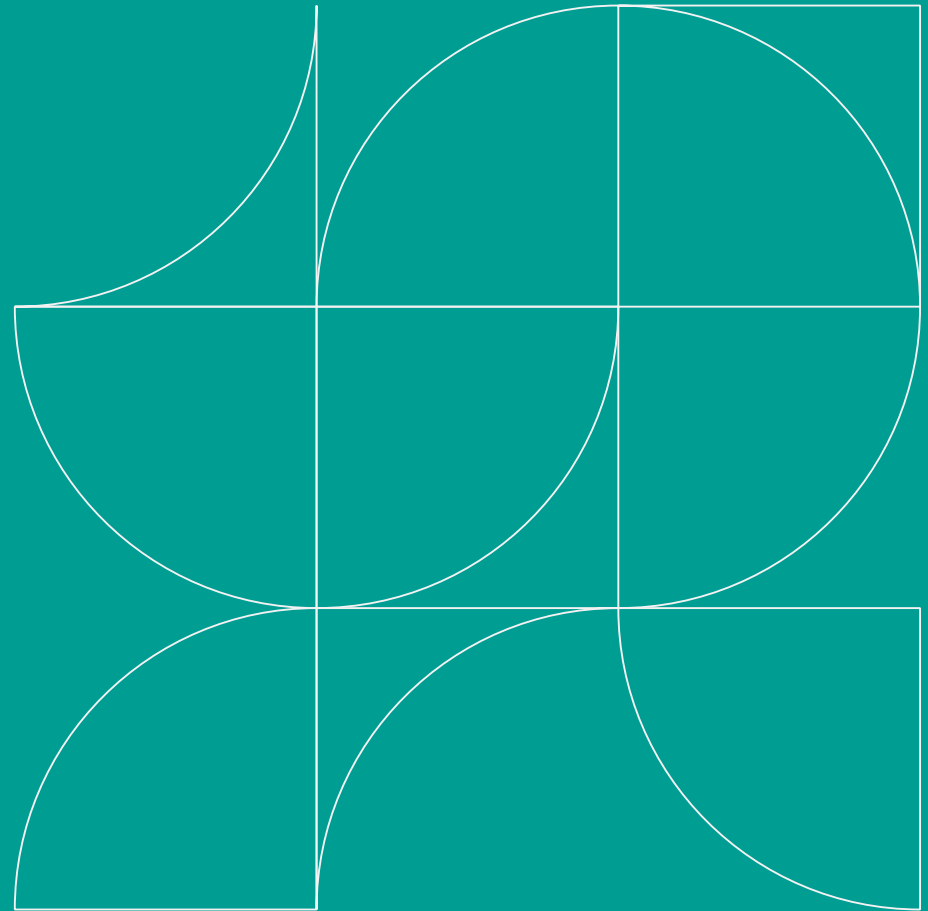
Agenda

- 1 | What you need to know about PBMs
- 2 | J&J litigation
- 3 | Anti-trust litigation
- 4 | Investigating potential litigation paths
- 5 | Action steps to take during an uncertain time

ERISA Welfare Fiduciary Litigation – How Did We Get Here?



Welfare Plan Fiduciary Litigation



ERISA Welfare Fiduciary Litigation - Overview

- *What is happening?*
 - Lawsuit filed against Johnson & Johnson alleging breach of fiduciary duty in structure of pharmacy benefit manager contract
- *How did we get here?*
 - After years of retirement plan litigation, focus of plaintiff's bar has shifted in the wake of the Consolidated Appropriations Act (CAA) transparency guidelines.
- *Why does this matter?*
 - Any employer sponsoring a welfare benefit plan has fiduciary obligations that could put the employer at risk for a similar action.
- *What should I do?*
 - Fiduciary obligations focus more on process than result/outcome.

New Transparency Guidelines = More Publicly Available Info

- Four key provisions usher in a new era of health plan data transparency:
 1. **Fee Disclosures.** Brokers/consultants must disclose direct/indirect compensation at renewal (or upon entering into initial agreement).
 2. **Price Comparison Tool.** Health plans must create online tool for participants to estimate out-of-pocket costs before receiving health services.
 3. **Machine-Readable Files.** Health plans and hospitals must make publicly available data on network and non-network reimbursement rates.
 4. **Gag Clause Prohibition.** Employer plan sponsors are prohibited from entering into contracts that restrict access to price/quality of care data.

Refresher - ERISA Fiduciary Basics

- *What is a Fiduciary?*
 - A person (or organization) that owes a duty to someone else and must act in their interests.
- *Why is this Important:*
 - Under ERISA, the company sponsoring the plan is a fiduciary
 - Vendors may or may not be fiduciaries
 - ERISA plan fiduciaries are subject to greater DOL oversight and litigation
 - ERISA fiduciaries are personally liable for losses

ERISA Fiduciary Basics

- *What is Required of Fiduciaries?*

- Exclusive Benefit 

- Actions must be for the “exclusive benefit” of plan participants
- Cannot engaged in a “prohibited transaction” unless exemption exists

- Duty of Prudence 

- Fiduciary should either have expertise to manage plan or hire someone who does
- Fiduciary should monitor delegates

- Duty to Diversify

- Fiduciary must diversity a plan’s investments to minimize risk of large losses (retirement plans only)

- Duty to Follow Plan Documents

PBM Refresher – What Are They?

PBM Terminology

- **PBM** = Pharmacy Benefit Manager
- **Formulary** = Plan's list of covered drugs
- **Step Therapy** = Requirement to try a generic drug before the plan will cover brand name drug (AKA “fail-first” protocol)
- **Copay Maximizer Program** = Design intended to reduce plan's copay obligation to enable use of drug manufacturer coupons
- **Specialty Drug** = Typically high-cost drugs treating rare, complex and/or chronic conditions

What Do They Do?

- Assist in development plan's **formulary**
- Negotiate drug purchases with drug manufacturers
- Coordinate payment to pharmacies/pharmacists
- Adjudicate prescription drug claims
- Assist in development of “value-based insurance design”
 - **Step Therapy**
 - Mail order pharmacy
 - Care coordination
 - **Copay maximizer programs**
- Important Note: Many PBMs own/are affiliated with a pharmacy and or **specialty pharmacy**

How are PBMs Compensated?

Spread Pricing

- PBM buys the drugs from the manufacturer for one price and resells to the group health plan sponsor for another price (often for the “Average Wholesale Price” / AWP)
- PBM retains some or all of the spread as compensation

Pass-Through Pricing

- PBM resells drug to group health plan sponsor at acquisition cost
- PBM assesses group health plan per-employee per month (PEPM) fee for cost of administrative services

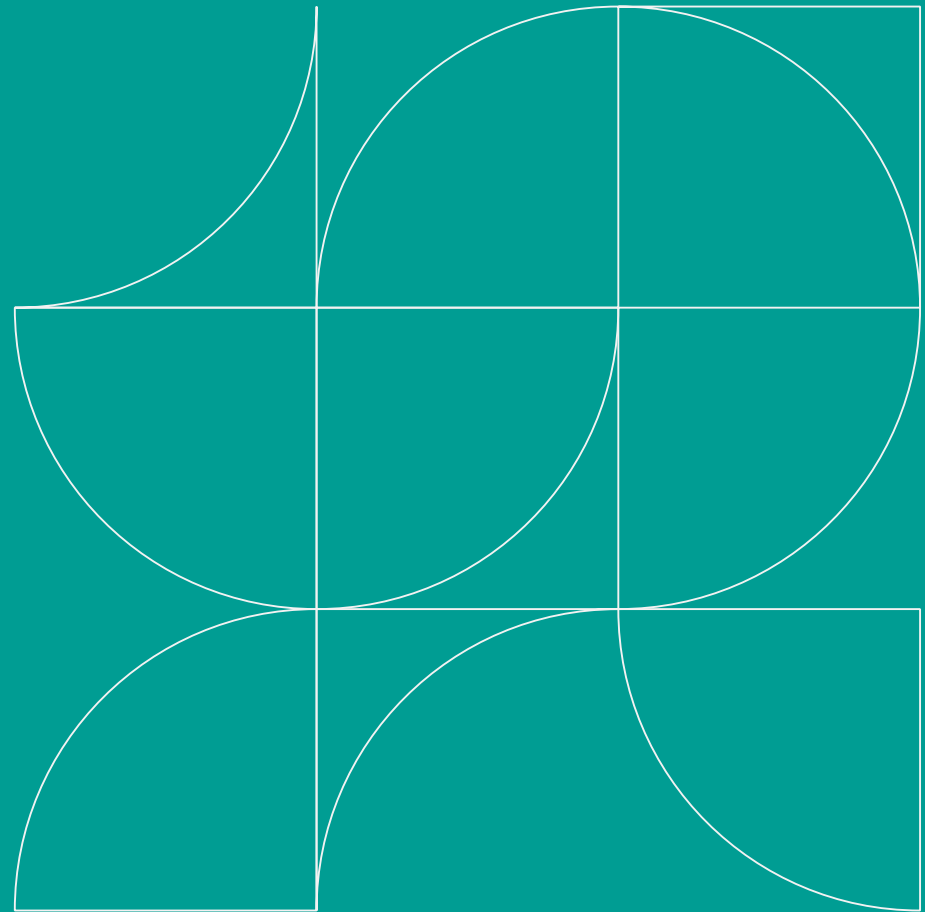
Rebates

- PBM negotiates with drug manufacturers to issue a rebate/refund to the PBM based on bulk purchasing
- PBMs retain some/all of the rebate as compensation

Other?

- Ownership of pharmacy chain/specialty pharmacy
- Retention of portion of amounts recouped on overpayments
- Shared savings models

***Lewandowski v
Johnson and
Johnson, et. al, 24-
cv-00671 (D. N.J.)***



J&J Lawsuit: What are the Allegations?

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- *J&J overpaid for drugs using plan assets*
 - Relied on plan’s price comparison tool and compared to retail pharmacy “uninsured” rates
 - Pass-through pricing is always preferred (over spread pricing/rebates)
 - Plan relied on AWP instead of NADAC, which is a more realistic measure of acquisition cost
 - Reliance on broker/consultant who had conflict of interest
 - Failed to enter into a collective/coalition
 - Failed to consider a non-traditional PBM
 - NOTE: Plan had a trust, which meant most employer contributions also constituted plan assets

J&J Lawsuit: What are the Allegations?

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- *Deference to PBM for key design features*
 - J&J relied on PBM’s proposed formulary rather than developing its own formulary
 - J&J relied on value-based insurance designs pushed by PBM that incentivized participants to seek higher-cost drugs that generated greater revenue for PBM

J&J Lawsuit: What are the Allegations?

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- *Failed to carve out specialty drugs*
 - J&J engaged specialty pharmacy affiliated with/owned by PBM
 - Specialty pharmacy overcharged for drugs and PBM was not incentivized to drive down prices
 - Mail order requirement pushed more business to PBM-owned/affiliated pharmacies

J&J Lawsuit: Key Defenses

- Plaintiff has no standing because the plan is a DB plan and there is no claim that the plan did not pay all benefits it provided.
- Plaintiff does not actually allege she received one of the allegedly overpriced drugs.
- The claim fails on the merits – not proper to infer imprudence from the fact that a few of thousands of drugs were allegedly overpriced, especially where the employer pays most of the cost.
- Not enough to allege a cost dispute without pleading that the cost is excessive based on a fair comparison.

J&J Case: motion to dismiss responses

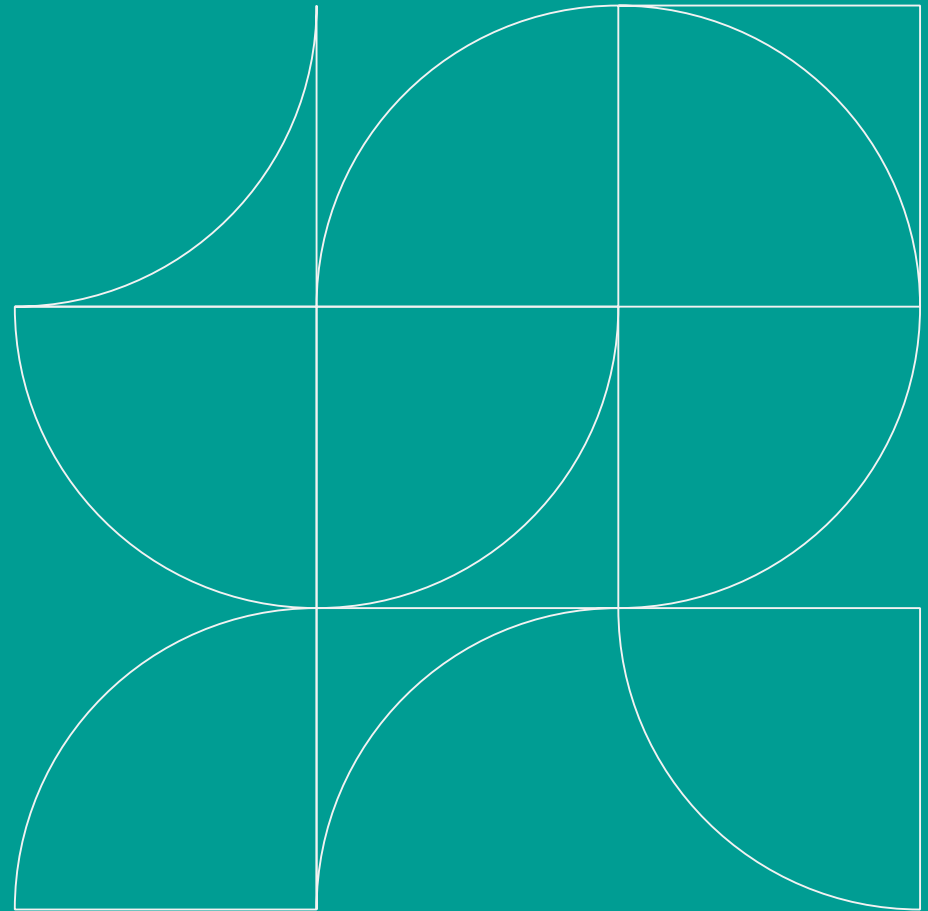
- Plaintiff has standing because alleged breaches caused plan and participants to overpay
- Distinguishes *Thole* because in that case, participants suffered no benefit loss, but here they paid more for drugs and coverage
- Plaintiff argues she has alleged enough to plausibly state a claim for fiduciary breach



Knudsen v. MetLife Group Inc. (D. N.J. 2023)

- Plaintiffs alleged that fiduciaries' failure to use PBM rebates to cover plan benefit costs resulted in higher costs to participants
- Alleged breaches of fiduciary duty and prohibited transactions based on use of rebates to pay plan sponsor costs
- Court dismissed the case (it is on appeal)
 - No standing under the Supreme Court's *Thole* decision because the plan is a defined benefit plan and individual participants have no entitlement to plan assets. The Court also noted that the existence and possible use of rebates was spelled out in the plan
 - Also, plaintiffs alleged only that absent corporate use of rebates, costs "may have been lower"; court found this was speculative and thus insufficient

Anti-trust Litigation



Antitrust Litigation: What are the Allegations?

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- *Alleges anti-trust activity across the pharmaceutical industry*
 - Comes after information released in other multi-district price fixing litigation and a Department of Justice investigation that resulted in significant penalties.
 - Pharmaceutical companies were "systematically and routinely" in communication about bids, pricing, market entries and market exits for hundreds of generic drugs.
 - Divvied up customers to create an artificial equilibrium in the market, known across the pharmaceutical industry as "fair share."
 - Alleges generic medications—which are generally less expensive than brand-name medications—make up about 90% of prescriptions filled in the United States.
 - Alleges that the illegal "fair share" agreements deprived employers (and their employees) of the savings for generic medications.

Antitrust Litigation: What are the Allegations?

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- Employer defendants maintain “self-funded” health plans. They allege they are charged “supra-competitive” prices for the generic drugs they purchase because of defendants’ “collusion and anticompetitive conduct.”
- Complaint asserts that if the marketplace was operating as it should, more generic manufacturers of a certain drug should result in the price of that drug dropping.
- Complaint alleges that between 2009 and 2016 the prices of hundreds of generic drugs instead “increased significantly,” as much as 1,000%.
- On average, the prices of more than 1,000 generic medications rose 448% between July 2013 and July 2014.
- Alleges that there are no market forces that explain this pricing.

Antitrust Litigation: What are the Allegations?

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- *The “Fair Share Conspiracy”*
- Complaint alleges that when a corporate defendant raised the price of a generic drug, under the “fair share conspiracy”, instead of holding or reducing prices to compete, the other pharmaceutical companies would follow the price increase and also not seek to add market share.
- This allowed the price increases to stick and defendants' profits to rise despite actual decreases in market share.
- Points to two major pharmaceutical companies as playing “major roles” in the alleged conspiracy, pointing to records that the companies’ sales executives and pricing/marketing employees “spoke to representatives of every significant competitor by phone and/or text on multiple occasions.”
- Seek to recover damages, restitution, disgorgement of profits, injunctive relief, and court costs and attorney fees.



SCAN ME

CLE: NEW PROCESS

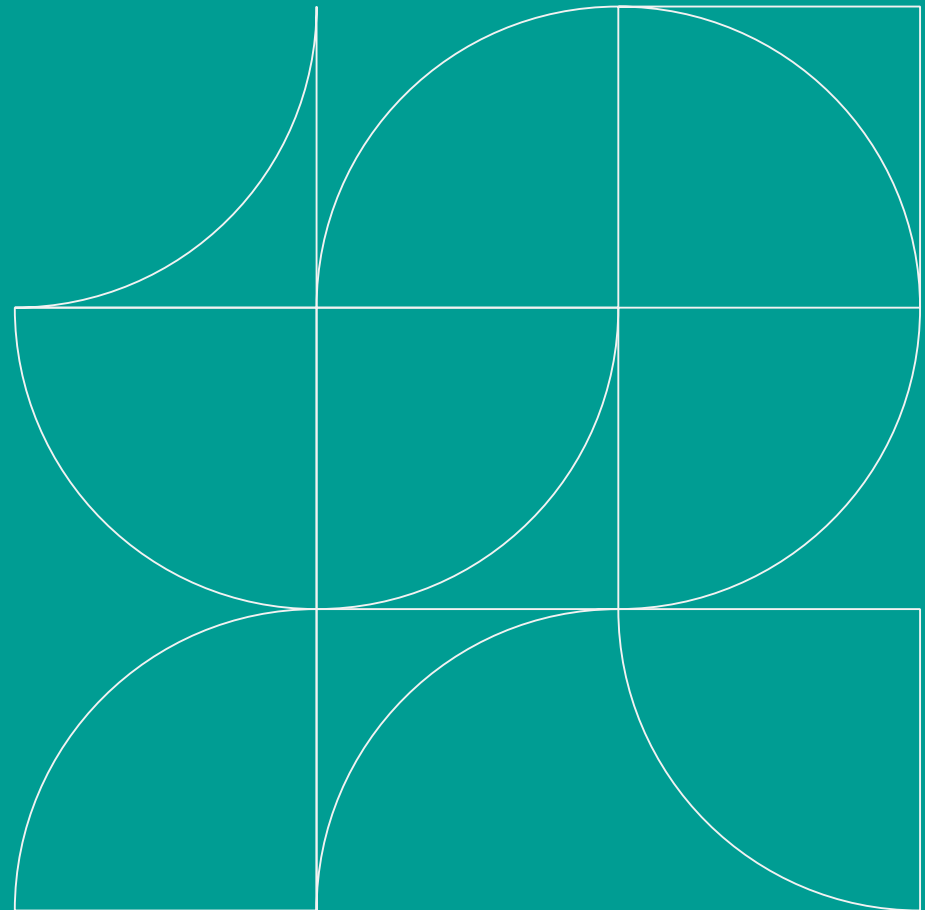
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Recommended Next Steps for Fiduciaries



Where Do Fiduciaries Go From Here?

Key Tenets

- Focus on use of plan assets
- Process matters more than result/outcome
- Decisions may be challenged years after they occur – documentation helps
- Selection of lowest cost vendor *is not* required if you have a reasonable basis for selection

Possible Approaches

- Governance
- Monitoring
- Prudent Selection
- Avoid prohibited transactions



Questions?

**thank
you**

contact information

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