EMPLOYER COALITION OF LOUISIANA ERISA FIDUCIARY ISSUES For Health Plans

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Fiduciary Obligations

- The Employee Retirement Income Security Act of 1974, as amended ("ERISA") imposes the highest standard of conduct on "fiduciaries."

- While historically ERISA focused on retirement plans, the spotlight is expanding to focus on healthcare plans.

Standard of Conduct

- "Prudent person rule" or "prudent *expert*"?
  - ERISA § 404(a)(1): A fiduciary must discharge his duties: *With the care, skill, prudence and diligence under the circumstances then prevailing that a prudent person acting in a like capacity and* ***familiar with such matters*** *would use*
  - "*Procedural prudence*": Courts focus on the fiduciary's conduct in arriving at a decision, not its results

Who is a "Fiduciary"?

- ERISA § 3(21)(A): A person is a fiduciary with respect to a plan to the extent he/she:
  - Exercises any discretionary authority or control over the management of the plan, or the management or disposition of plan assets;
  - Has any discretionary authority or responsibility in the administration of the plan; or
  - Renders investment advice for a fee or other compensation, with respect to plan assets.
- Fiduciary status is based on the functions performed for, or on behalf of, the plan, and include committees or individuals that oversee employee benefits and administer the group health plan.

Increasing ERISA Litigation Fiduciary Claims

- In a class action suit, plaintiffs claim that Johnson & Johnson did not meet its obligation to negotiate favorable pricing and, as a result, plan participants and their beneficiaries paid increased costs and premiums. *Lewandowski et al v. Johnson & Johnson* (D. Ct. NJ 2024).
- Plaintiffs claim J&J failed to act prudently in:
  - negotiating contract pricing terms,
  - selecting pharmacy benefit managers (PBM), and
  - designing the prescription drug plan.

  The suit claims these three breaches of fiduciary duty led to increased premium rates and cost-sharing for plan participants, and a rise in overall expenses relating to prescription drug costs—which, in turn, increased the premium rates that participants (employees) contribute.

ERISA Litigation (cont'd)
Johnson & Johnson Suit

- The Complaint attempts to support these allegations by focusing on a specific and small subset of drugs covered by the Plan – specifically asserting that the Plan overpaid for 42 specialty generic drugs. For example, with respect to one of these drugs, teriflunomide (a generic drug used to treat Multiple Sclerosis), the Complaint alleges the following:

  [S]omeone with a 90-pill prescription for the generic drug teriflunomide (the generic form of Aubagio, used to treat multiple sclerosis) could fill that prescription, without even using their insurance, at Wegmans for $40.55, ShopRite for $41.05, Walmart for $76.41, Rite Aid for $77.41, or from Cost Plus Drugs online pharmacy for $28.40. Defendants, however, agreed to make their ERISA plans and their beneficiaries pay $10,239.69—not a typo—for each 90-pill teriflunomide prescription.

- The Complaint goes on to provide a number of other examples of specialty generic drugs that it alleges the Plan agreed to overpay as compared to the given drug's cash cost at a retail pharmacy.

COMMENT: Plaintiffs select specific aspects of the PBM agreement without looking at the arrangement in its totality. Established case law and DOL guidance support a fiduciary prudence standard that assesses the overall economics of the service provider arrangement versus a more limited focus on any specific item or service.

ERISA Litigation (cont'd) Johnson & Johnson Suit

- Plaintiffs claim that:
  - there is no definitive set of objective factors that help determine whether a drug is a specialty drug, meaning the classification of certain drugs as "specialty drugs" should have been discussed by PBMs and plan fiduciaries.
  - formulary management practices were not prudent. Plaintiff claims prudent fiduciaries replace brand-name drugs with FDA-approved, lower-cost options when available.
  - J&J did not use negotiation power to get better rates from its PBM or an alternative PBM.
  - J&J could have transitioned its Rx plan to a "pass-through" PBM that sets its prices on actual acquisition costs instead of inflated benchmarks.
  - J&J did not evaluate service providers for possible conflicts of interest and promote greater transparency.

ERISA Litigation (cont'd) Preemption

- In 2020, the Supreme Court held that ERISA did not preempt a state law regulating the maximum allowable costs lists that PBMs use to set Rx reimbursement rates. *Rutledge v. Pharmaceutical Care Management Association*. Since then, lower courts have struggled with the implications of *Rutledge* for other state laws, including other laws regulating PBMs' interactions with pharmacies.

- The 10th Circuit recently held that ERISA does preempt an Oklahoma law regulating PBMs under the Oklahoma Patient's Right to Pharmacy Choice Act. The Court held that a "state law can affect ERISA plans even if it does not nominally regulate them," and that "state laws can relate to ERISA plans even if they regulate only third parties."

- On 5/31/24, the Ninth Circuit Court of Appeals issued an opinion which has significant implications for state law causes of action arising from pre-service coverage communications between medical providers and health plan administrators. *Bristol SL Holdings, Inc. v. Cigna Health and Life Insurance Company.* The court held ERISA preempted an out-of-network provider's state law claims arising from verification of benefit and preauthorization communications with a health plan administrator under both the "reference to" and "connection with" prongs of ERISA preemption analysis. The opinion also distinguished prior Ninth Circuit case law finding no preemption of state law claims on the ground the member was not covered by an ERISA plan at the time services were rendered. This opinion stands to health plans as it will limit the ability of health care providers to "plead around" ERISA preemption or expand the scope of ERISA benefits actions by asserting non-derivative state law claims.

ERISA Litigation (cont'd)
Arbitrability of ERISA Benefits Claims

- Whether ERISA § 502(a)(2) fiduciary-breach claims may be arbitrated continues to be a frequently litigated issue.
- Ninth Circuit decision in *Dorman v. Charles Schwab Corp.*, 934 F.3d 1107 (9th Cir. 2019), overturned decades of case law that had held that ERISA fiduciary-breach suits could not be arbitrated. In response, companies have increasingly incorporated arbitration provisions into their ERISA plans.
- The 3rd Circuit held a class action waiver in a plan arbitration clause to be unenforceable because it "purport[ed] to waive plan participants' rights to seek remedies expressly authorized by" ERISA § 409(a). *Henry ex rel. BSC Ventures Holdings, Inc. ESOP v. Wilmington Trust*, 72 F.4th 499 (3d Cir. 2023).
- The 2nd Circuit ruled that a plan arbitration provision limiting the relief available in an arbitration proceeding to remedies impacting only the participant's own account and forbidding any relief that would benefit any other employee, participant, or beneficiary was unenforceable. *Cedeno v. Sasson*, 2024 WL 1895053 (2d Cir. May 1, 2024).

Health Plan Compliance Updates

Legislative and Regulatory Changes
To
Health Plan Compliance

1. Reproductive Health Care New HIPAA Privacy Protections

- New HIPAA regulations expand the prohibitions on the use or disclosure of PHI involving "reproductive health care" to include any of the following purposes:
  - To conduct a civil, criminal, or administrative investigation into any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care;
  - To impose liability on a person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care; or
  - To identify any person described in the above two bullet points.
- These prohibitions only apply if:
  - The activity relates to a person seeking, obtaining, providing, or facilitating reproductive health care; and
  - The health plan or any of its business associates that receives a request for PHI reasonably determines that:
    - the reproductive health care was lawful in the state where it was provided;
    - the reproductive health care was protected by federal law; or
    - the reproductive health care was presumed to be lawful.

1. Reproductive Health Care New HIPAA Privacy Protections (cont'd)

- Presumption that care was lawful unless actual knowledge it was unlawful or factual information that provides a substantial basis that it was unlawful. Therefore, it is likely the expanded prohibitions will apply in the majority of circumstances.

- An additional attestation is required in circumstances where the use or disclosure of reproductive health-care-related PHI is deemed not to be a prohibited use or disclosure.

- Compliance Deadlines:
  - **12/23/2024** – Update BAAs, privacy polices & procedures, and forms for compliance and train those with access to PHI on rules.
  - **2/16/2026** – Update Notice of Privacy Practices

2. Prohibition of Gag Clauses

Plan Sponsor agreements with service providers must provide access to provider-specific cost or quality information for the Fiduciary to:

- Show that employee costs related to claims are expended in an efficient manner
- Provide enrollees with access to information to make informed, cost-effective healthcare decisions
- Share information with the Plan Sponsor to identify waste through comparative analytics

Gag Clause Prohibition Compliance Attestation (GCPCA) first required by **12/31/23** and annually thereafter.

3. Nonquantitative Treatment Limitations (NQTLs)

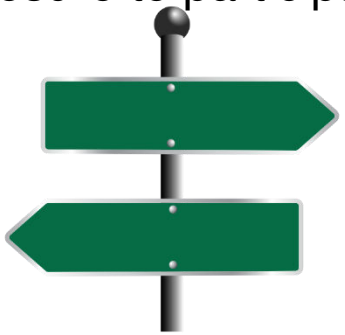
- The Mental Health Parity and Addiction Equity Act generally prohibits group health plans from imposing NQTLs (e.g., pre-authorizations, medical management techniques, standards related to network composition, or methodologies to determine out-of-network reimbursement rates) on services that are more restrictive than those applied to ally all medical/surgical benefits. Plan Sponsors have to provide NQTL analysis "reports" showing compliance upon request.
- DOL, IRS, and HHS issued final regulations 9/9/24 that apply to most all group health plans. These regs require Plan to provide any requested NQTL report:
  - within 10 business days of its request by the government, and
  - within 30 days of its request by plan participants "who have received an adverse benefit determination."
- Failure to provide the required analysis is likely to trigger the $100 a day penalty per plan participant.
- If the plan is not in compliance, it must detail remedial action within 45 days. If unable to bring the plan into compliance, plan sponsor will have 7 days to notify participants that coverage is non-compliant and federal regulators will report the plan to the state where the employer is located or licensed to do business.

4. Transparency Requirements

- The No Surprises Act requires a number of disclosures, claim adjudication requirements, determination of the amount to be paid for out-of-network health care providers, and the dispute resolution process for determining the amount to be paid.

- Self-insured health plan sponsors should ask the health plan's TPA to provide assurances of their compliance with the Act.

- The Transparency in Coverage rules were issued in November 2020 and had a phased implementation process. Self-insured health plan sponsors should request that their TPA provide them with a status update on the disclosure of fees and cost-sharing information because as of 1/1/24, all covered items and services must be part of the disclosure to participants.



5. Cybersecurity Compliance

- On 9/6/24, the DOL issued guidance confirming that cybersecurity compliance applies to all types of plans governed by ERISA, including health and welfare plans. Guidance has 3 parts:
  - Tips for Hiring a Service Provider (directed toward plan sponsors and fiduciaries);
  - Cybersecurity Program Best Practices (directed toward recordkeepers and other service providers responsible for plan-related IT systems and data); and
  - Online Security Tips (directed toward plan participants and beneficiaries).

5. Cybersecurity Compliance (cont'd)

The guidance recommends that Health Plan fiduciaries do the following:

1. Select and monitor service providers with an eye towards cybersecurity.
2. Conduct periodic reviews of the cybersecurity programs of recordkeepers and other service providers.
3. Review the terms of agreements with service providers to ensure they contain best practice provisions and require ongoing compliance by the service provider with cybersecurity and information security standards.
4. Educate participants and beneficiaries who manage their benefit accounts online about online security.
5. Inquire if the service provider has any insurance that would cover losses caused by cybersecurity and identity theft breaches.

While described as "recommendations" and "assistance" Plan Sponsors are well-advised to implement these practices as good fiduciary hygiene for their plans.

6. Rx Disclosures

Plan Sponsors must report to HHS, DOL, and Treasury, the following information:

- Top 50 brand drugs most frequently dispensed
- Annual amount spent by top 50 most costly Rx drugs by total plan/coverage spend
- Amount spent for the top 50 Rx drugs with the greatest prior year plan spend
- Total healthcare spend
- Premiums and rebates

RxDC Reporting Deadline: 6/1 for the preceding year.

7. Compensation Disclosures

ERISA § 408(b)(2)(B) requires brokers and consultants expecting $1,000 or more in direct and indirect compensation for services provided to group health plans to make detailed disclosures to the "responsible plan fiduciary" regarding their services and compensation.

The disclosure requirement applies to contracts and arrangements entered into, extended, or renewed after 12/27/21. Because they are part of an exemption from the ERISA-prohibited transaction rules, liability for failure to comply with these disclosure requirements could fall primarily on the group health plan fiduciaries.

Fee disclosures have played a significant role in the explosion of litigation alleging excessive service provider compensation in the retirement plan context.

7. Compensation Disclosure (cont'd)

Based on the types of claims and allegations raised in retirement plan fee litigation, there are several action items health plan fiduciaries may consider to mitigate risk:

- Establish a written fee policy statement or update plan governance documents to address service provider compensation.
- Review compensation disclosures from service providers providing brokerage and consulting services. Designate a point person who is responsible for obtaining such disclosures, assessing the disclosures, and reporting to the plan fiduciaries.
- Benchmark service provider fees, whether through a request for proposals process or otherwise.
- Document your disclosure and compensation review process, including by recording the steps taken to assess the compensation and any decisions resulting from that assessment, and maintain documentation for at least 6 years.
- Pay close attention to contracts coming up for renewal and negotiations with new service providers. Consider requesting service provider fee proposals rather than simply approving the extension of a preexisting agreements.
- Obtain representations in contracts for covered services that the provider has furnished all required disclosures under Section 408(b)(2)(B).

Fiduciary Liabilities and Penalties

- Fiduciary Liability penalties:
  - Lost profits plus 20% penalty (negligence)
  - Criminal penalties for willful violation
  - Civil actions by participants
  - Can lose personal assets, home and business
- DOL Health Plan audit activity increasing:

  The DOL reviewed over 200 mental health parity analyses. NONE of the analyses reviewed were found to meet the requirements.
- Increased Class Action Litigation:
  - See next slide

Questions?