



Washington Update: Health Care Policies of Candidates, Self-Insurance Hot Topics and Fiduciary Concerns

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Hot Topics for Self-Insured Health Plans

- ***Fiduciary Issues***
- ***Access to Health Claims Data & Audit Rights***
- ***Fees Paid To – and Paid By – Plan Service Providers***
- ***408(b)(2) Disclosures***
- ***Transparency/Data-Sharing/PBM Reforms***
- ***Level-Funded Arrangements***
- ***Health Care Policy In Next Administration?***
- ***Other Issues***
 - ***Cost of Rx Drugs and Specialty Drugs***
 - ***Artificial Intelligence***

Lawsuits: Claims Data, Fees, Fiduciary Breach

Lawsuits Filed to Access Claims Data

- Lawsuits filed by 2 union plan sponsors and separate lawsuit by single-employer plan sponsor
 - *Argument #1:* Gag Clause Prohibition requires access to the plan's claims data
 - *Argument #2:* Carrier-Owned TPA is a fiduciary and violated fiduciary duties for failing to share claims data

Lawsuit Filed by the DOL

- DOL filed a lawsuit against BCBS of Minnesota for charging improper fees to self-insured plan clients
 - Arguing that BCBS of MN improperly collected plan assets, making it a fiduciary

Lawsuit Filed By Employee-Participant Against Employer-Plan Sponsor

- 2 similar lawsuits involving Johnson & Johnson and Wells Fargo as plan sponsors and individual fiduciaries
 - Arguing that J&J and Wells Fargo (as plan sponsors) and individuals (as plan fiduciaries) breached fiduciary duty to the employee by allowing the plan to over-pay for covered Rx drugs
- Employee lawsuit against the Mayo Clinic for underpaying out-of-network health claims
 - Alleging RICO violations, failure to provide an accurate EOB and SPD, and breach of the fiduciary duties of loyalty and care

J&J Lawsuit...and Now Wells Fargo

- Ever since the early 2000s, hundreds of lawsuits have been filed by retirement plan participants against employer plan sponsors and the retirement plan's fiduciaries claiming fiduciary breach
 - For paying excessive fees to the retirement plan's investment managers and/or service providers
 - For investment losses on account of investment decisions made by the plan's fiduciaries
- Most practitioners thought we would see similar fiduciary breach lawsuits against health plans, but no lawsuits materialized...UNTIL RECENTLY
- The J&J and Wells Fargo lawsuits are significant for a number of reasons:
 - First, future lawsuits will likely involve other service providers, beyond PBMs
 - Second, future lawsuits could shine a brighter light on the CAA's compensation disclosure rules for brokers and consultants (because if the complaint is about excessive fees, well then...)
 - The best defense against this type of lawsuit is that J&J/Wells Fargo – as the plan sponsor – is the victim, and J&J's/Wells Fargo's PBM is the bad actor
 - Regardless of whether the plan sponsor is the real victim, plan sponsors MUST step-up their game on monitoring their service providers and paying attention to how much the plan is paying for benefits

Adhering to Fiduciary Duties

- As long as the plan sponsor undertakes reasonable steps – or develops a “process” – for determining whether things like:
 - What to benefits to cover and not cover under the plan
 - The cost of covered benefits
 - The fees paid to – and paid by – the plan’s service providersare in the best interest of the plan participants, the plan sponsor will generally satisfy their fiduciary duties
- Plan sponsors must continually monitor the plan’s service providers and their costs/fees
 - This can be done by establishing a “Health Plan Committee” to review plan-related information and make decisions about the operation and management of the plan
 - Documenting any reviews, discussions, deliberations, and communications is recommended to keep a record that illustrates that the plan sponsor undertook reasonable steps and engaged in a “process” to make the best decision for the plan and its participants

408(b)(2) Disclosure Requirement

- Plan sponsors must obtain a 408(b)(2) disclosure from their brokers and benefit consultants prior to the execution or renewal of the service agreement with the broker or consultant
 - Disclosing the total amount of fees paid to the broker or consultant directly by the plan (i.e., “direct compensation”)

AND

- Disclosing the amount of fees, if any, paid to broker or consultant by any entity other than the plan that the plan sponsor opted to contract with to provide services to the plan (i.e., “indirect compensation”)
- Plan sponsors must also obtain a 408(b)(2) disclosure from their TPAs and PBM partners disclosing BOTH direct and indirect compensation
 - TPAs and PBMs take the position that they are NOT subject to the 408(b)(2) disclosure requirement
 - BUT, a letter sent by Congress to the DOL on Dec. 14, 2022 confirms that Congress always intended to subject TPAs and PBMs to the 408(b)(2) disclosure requirement if they performed services such as:
 - Developing a provider network or an Rx drug formulary
 - Processing claims and maintaining records
 - Negotiating rates

House: Transparency, Data-Sharing, PBM Reforms

House-Passed Legislation

- House passed the *Lower Costs, More Transparency Act* on December 11th with 320 votes
- Highlights:
 - **Transparency:** Codifies Hospital Transparency and Transparency in Coverage (TiC) Rules, along with requirement to publicly disclose Prescription Drug Prices on a Machine-Readable File
 - Increase penalties for non-compliance with the Hospital Transparency Rule
 - Require disclosure of prices and fees paid at ambulatory surgical centers, imaging centers, and labs
 - **Data-Sharing:** Require owners of the provider networks to share claims data for “auditing” their claims administrator
 - **Gag Clause:** Allow plan sponsors to tell the Federal government that they *cannot* “attest” that “gag clauses” have been removed from their agreements and why
 - **PBM:** Require PBMs to disclose prices of Rx drugs, rebates and discounts, and other PBM practices to the plan administrator

Senate: Transparency, Data-Sharing, PBM Reforms

S. 1339, the *Pharmacy Benefit Manager Reform Act*

- S. 1339 would require PBMs to disclose to the plan administrator detailed information about:
 - Pricing practices
 - Fees charged
 - Rebate amounts and discounts
 - Steering patients to pharmacies owned by the PBM
- Consideration of S. 1339 could involve an amendment strategy to make PBMs a fiduciary
- Some Transparency/Data-Sharing provisions from the House-passed bill will likely be added

Lame Duck

- Negotiations between House and Senate staff during the Spring broke down
- Expectation is that House and Senate will consider Transparency/Data-Sharing/PBM Reforms after the November elections during “lame duck”
 - Also, look out for clarifying that 408(b)(2) applies to TPAs and PBMs and deeming PBMs an ERISA fiduciary

Level-Funded Arrangements

- On March 28th, the Federal Departments finalized proposed regulations that were issued back in July 2023 which focused primarily on short-term health and fixed indemnity plans, but also included a Request for Information (RFI) on "Level-Funded Plan Arrangements"
 - An RFI does NOT propose new requirements; rather the Departments asks for "input" from the public that the Departments may consider if they decide to develop proposed regs
- The recently issued finalized regulations did NOT address any issues related to level-funded arrangements
 - The preamble to these final regs did say that the Departments intend to consider all of the comments received to "determine whether additional guidance or rulemaking is warranted in the future"

Health Care Policy In The Next Administration?

- **Harris-Walz Administration**

- *The “Enhanced Premium Subsidies” and ACA Exchange Enrollment*
- *Medicaid Expansion*
- *Prescription Drug Negotiations and Limits on Drug Spending*
- *Mental Health and Substance Use Disorder Benefits*
- *Eliminating Medical Debt*
- *Family Paid Leave*

- **Trump-Vance Administration**

- *No “Repeal and Replace,” but Alternatives to the ACA (e.g., AHPs, Short-Term Plans, Catastrophic Plans)*
- *Medicaid Reform*
- *Price Transparency*
- *Health Care Claims Data-Sharing*
- *PBM and Patent Reforms*
- *Expand HSAs, Direct Primary Care, and Telehealth*

Other Issues

- *Cost of Rx Drugs and Specialty Drugs*
- *Artificial Intelligence*