

ERISA, the Johnson & Johnson case, and how employers can protect themselves

March 12, 2024

Lockton Compliance Consulting

Presented by

Beth Latchana, J.D.

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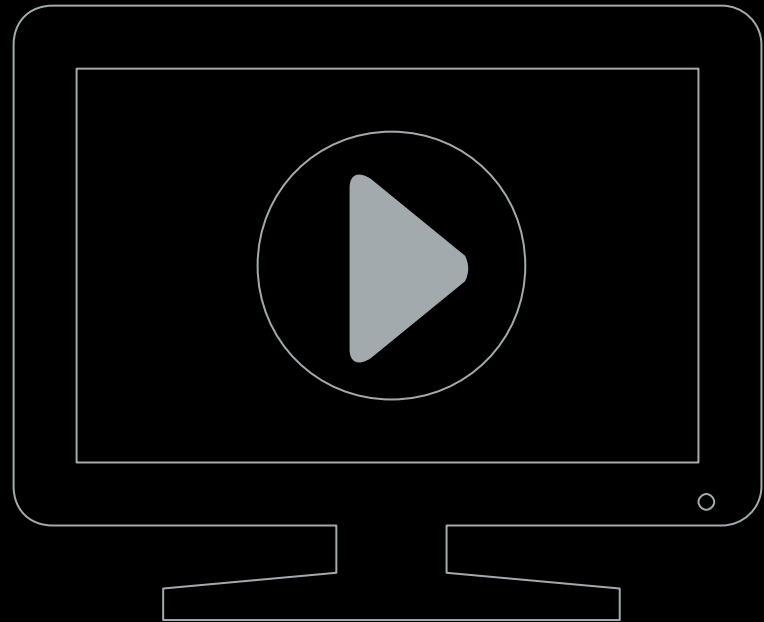
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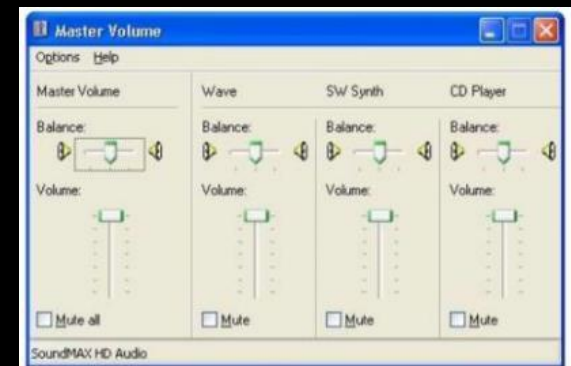


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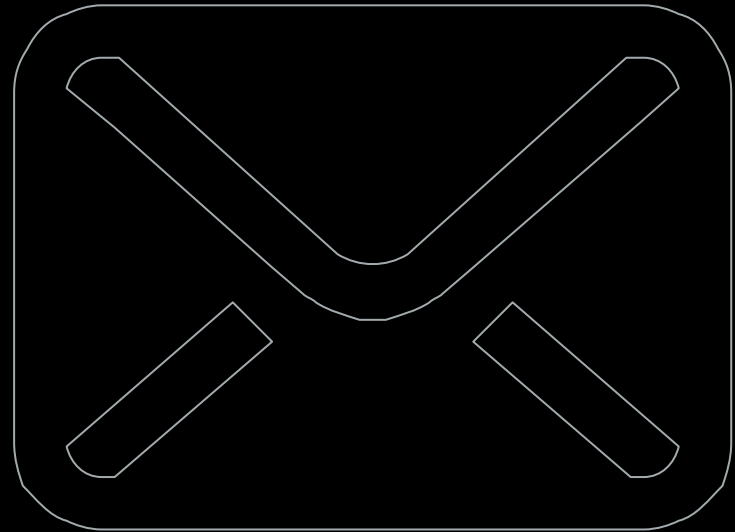
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We may attempt to answer some questions during the Q&A portion, near the conclusion of the presentation, if time permits.



Our upcoming webcasts

ERISA is still our friend – 50 years later

March 19, 2024 | 2-3 p.m. CT

Speakers: Rory Akers, JD, Suzanne Bach, JD and Ethan McWilliams, MBA

[Register here!](#)

April showers bring... annual HIPAA training!

April 18, 2024 | 2-3 p.m. CT

Speakers: Ruhe Wadud, JD and Jeff Lowry, JD

[Register here!](#)

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Today's speakers



Beth Latchana, J.D.
*SVP, Director
Compliance Consulting*



Julayna Meyer, RPh, MBA
*SVP, Director
Pharmacy Analytics*



Suzanne Bach, J.D.
*VP, Senior ERISA Attorney
Compliance Consulting*

Agenda

Overview & why it's important

Johnson & Johnson - unique facts


Understanding fiduciary duties

How can employers protect themselves?

Questions

Overview & why it's important





Johnson & Johnson lawsuit overview – what got us here?

- Overview of the lawsuit
- Overview of ACA and CAA transparency rules
 - *See Appendix A for specific transparency rules, obligations, and effective dates*
- Impact on employer plan sponsors
 - Concern about future class action lawsuits by participants vs. employers
 - Ensuring appropriate fiduciary governance
 - Monitoring of other fiduciaries and service providers
 - Ensuring payment of only necessary and reasonable plan expenses

Johnson & Johnson – unique facts



J&J unique facts

- J&J is a leading drug manufacturer
 - Bargaining power
- Pension and benefits committee oversees the plans
 - No health and welfare committee
- ERISA trust
 - Plan assets
 - What does this mean?
- Crux of the complaint
 - Mismanagement and breach of fiduciary duties with respect to prescription drug plan
 - What was claimed / considerations to make



J&J - pharmacy discussion

Items cited	Considerations
Specialty generic price discrepancies between specialty pharmacy and retail	Separate specialty generic discount guarantee vs. overall guarantee
Open RFP not conducted	Most pharmacy contracts are three years long, so recommend clients review the market on a regular basis
Contracted with consultant coalition; coalition commission incentivized consultant's recommendation	With Lockton's independence , we don't offer a pharmacy coalition but work with many different PBMs to find the best fit for our clients
No PBM Oversight	Review contractual terms, contract compliance

J&J - pharmacy discussion

Items cited	Considerations
Steering to PBM pharmacies	Exclusive network often provides greater client savings; must evaluate total savings and not individual drugs
Pass-through or NADAC would solve issue	Must look at the total cost of the benefit; no mention of dispensing fee, admin fees, or total cost
Direct to CostPlus Pharmacy	No mention of # of drugs they can't fulfill or impact to other drug prices if CostPlus is added to the network
Plan should determine own formulary	Plans do not have clinical expertise to make these decisions
Specialty carve-out	Be strategic; savings not guaranteed as stated in lawsuit

Understanding fiduciary duties

Who is a fiduciary and what are their responsibilities?



Act only for the benefit of participants/beneficiaries *exclusive purpose rule (duty of loyalty).*



Monitor other fiduciaries and service providers.



Perform duties with the care, skill, and diligence of a subject matter expert.



Follow the terms of the plan.



Diversify plan assets to minimize the risk of large losses.



Pay only necessary and reasonable plan expenses.

How can employers protect
themselves?





How employers can protect themselves

1. Understand their fiduciary duties
2. Implement good plan governance
3. Identify and mitigate primary compliance risks
4. Understand consequences for breaching fiduciary duties

What goes into a fiduciary governance program?

Written plan governance policies and procedures

- Plan documents and other policy documents (e.g., ACA measurement policies, QMCSO procedures, HSA employer contribution policy)
- Identify named and functional fiduciaries





What goes into a fiduciary governance program?

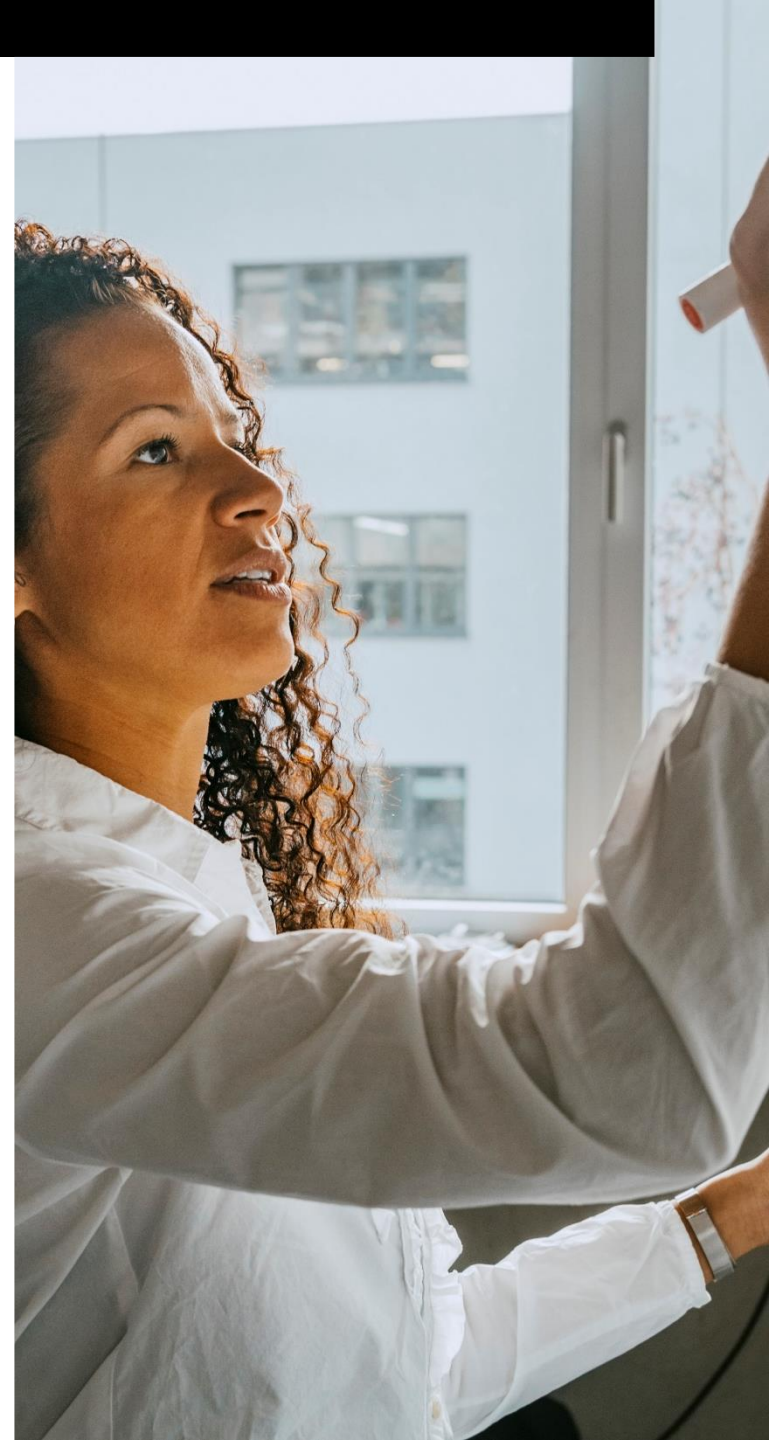
Establishment of a plan governance committee

- Handle routine and novel plan matters
- Identify and complete plan administration tasks (claims adjudication, notices, Form 5500, ACA reporting, etc.)
- Deliberate, decide and act on plan matters
- Service provider selection and oversight

What goes into a fiduciary governance program?

Regular committee meetings and minutes

- Document the prudence process
- Formal deliberations on plan matters
- Highlight facts and circumstances
- Memorialize decisions



Fiduciary governance best practices

Follow plan terms

- Keep plan document terms updated
- Notice to participants

Ensure plan operations follow plan terms

- Dependent audits
- Claims and appeal decisions

Complete routine compliance tasks

- Compliance calendar (e.g., Form 5500, RxDC reporting, notices)
- Compliance audits

Fiduciary governance best practices

Select or renew service providers

- Market research (e.g., RFP)
- Reasonableness of costs/fees

Monitor service providers

- Implementation audits
- Performance guarantee audits for service providers

Identify conflicts of interest

- Service providers
- Between plan sponsor and plan



Fiduciary governance in the future

- New plan designs, administration policies, service providers
- New rules (e.g., transparency)
- New litigation decisions shape the law (e.g., J&J case)
- Technological advances (e.g., vendors using AI to adjudicate claims)
- New threats (e.g., increase in HIPAA breaches)

How Lockton can help



Lockton's Fiduciary Governance Toolkit

- Free for Lockton clients (ask your Lockton account team)
- Continual access to Lockton compliance attorneys who can address questions about fiduciary matters
- Sample plan governance checklist
- Sample benefits committee charter
- Sample plan policies and procedures
- Sample meeting minutes



Stay informed of industry trends and happenings.

Today's "best practices" will quickly become industry standard

Questions

Independence changes everything.



UNCOMMONLY INDEPENDENT

Appendix A



Transparency Rules

Transparency: *What's already happened*

Requirement	Original effective date	New date
ID cards showing cost sharing	CAA: Plan years beginning on or after Jan. 1, 2022	Deadline is not deferred; however, until guidance is issued, plans should implement the requirements applying a good faith interpretation of the law.
Continuity of care	CAA: Plan years beginning on or after Jan. 1, 2022	Deadline is not deferred; however, until guidance is issued, plans should implement the requirements applying a good faith interpretation of the law.
Accurate network directories	CAA: Plan years beginning on or after Jan. 1, 2022	Deadline is not deferred; however, until guidance is issued, plans should implement the requirements applying a good faith interpretation of the law and apply only in-network cost sharing if a member receives out-of-network care due to an error in the network directory.
Broker/consultant compensation disclosure	CAA: Applies to brokerage and consulting contracts, relating to ERISA healthcare plans, entered into, extended or renewed on or after Dec. 27, 2021	Deadline is not deferred.

Transparency: What's already happened

Requirement	Original effective date	New date
<p>Surprise billing for out-of-network ER care, care by an out-of-network provider at an in-network facility, and care supplied by an out-of-network air ambulance provider</p>	<p>CAA:</p> <ul style="list-style-type: none"> • Limiting member responsibility to in-network amounts: Plan years beginning on or after Jan. 1, 2022. • Arbitration process: Plan years beginning on or after Jan. 1, 2022 • Disclosure obligations: Plan years beginning on or after Jan. 1, 2022 	<p>Deadlines are not deferred; interim final rules have been issued on both the limitation of member cost sharing, and on the dispute resolution process; final rule in Aug. 2022 along with FAQs but still awaiting more regulations</p> <p>Litigation against the latter is ongoing.</p>
<p>Three machine-readable files</p> <ul style="list-style-type: none"> • In-network rates (the "In-Network Rate File") • Historical allowed amount data (the "Allowed Amount File") • Prescription drug pricing information (the "Prescription Drug File") 	<p>TiC: For all three files, plan years beginning on or after Jan. 1, 2022</p>	<p>For in-network and OON data, the deferred enforcement date is the later of the original date and July 1, 2022.</p> <p>For prescription drug data, the enforcement date is no longer deferred.</p>
<p>Healthcare plan cost reporting</p>	<p>CAA: First filing due Dec. 27, 2021, and annually thereafter by June 1</p>	<p>Federal authorities did not require reporting by Dec. 27, 2021, nor will they by June 1, 2022, but expect to require the first filing by Dec. 27, 2022, reflecting relevant reportable data for 2020 and 2021.</p>
<p>Price comparison tool</p> <p>Free, self-service tool, on internet website with real-time responses based on information that is accurate at the time of the request</p>	<p>TiC/CAA: Plan years beginning on or after Jan. 1, 2022</p>	<p>The deferred enforcement date is the first day of the plan year beginning on or after Jan. 1, 2023.</p>

Transparency: What's already happened

Requirement	Original effective date	New date
Gag Clauses Prohibition Attestation	CAA: Effective Dec. 27, 2020	No delayed effective date. First attestation of compliance due Dec. 31, 2023 for the period from Dec. 27, 2020 through Dec. 31, 2023. Subsequent attestations due each Dec. 31 st .

Transparency: What's coming

Requirement	Original effective date	New date
Advance explanation of benefits	CAA: Plan years beginning on or after Jan. 1, 2022	The enforcement deadline for both providers' obligations to supply the good faith estimate of charges, and plans' obligation to supply the advance EOB upon receipt of that estimate, are deferred until federal regulators issue and implement guidance.