Health Legal and Regulatory Update

National Coordinating Committee for Multiemployer Plans Lawyers and Administrators Meeting

Elena Lynett, Senior Vice President, Segal
Ryan Temme, Principal, Groom Law Group

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Segal

Agenda

Administration and Agency Updates

Preemption of State PBM Laws

Mental Health Parity

PBM Spread-Pricing Litigation

Other Hot Topics

Outgrowth of Executive Orders That May Impact Group Health Plans

- **Making America Healthy Again by Empowering Patients with Clear, Accurate, and Actionable Healthcare Pricing Information**
- **Lowering Drug Prices by Once Again Putting Americans First**
  - RFI regarding RX machine readable files
  - FAQ 70
- **Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients**

A Leading Priority: Pharmacy Benefit Reform

- Lowering Drug Prices
- Transparency in Pharmacy Pricing and Operations
  - Bans or limits on spread pricing
  - Pass through rebates
  - PBM Contracting Reforms
- Banning the use of affiliated or consolidated pharmacies/ supporting independent pharmacies
- State legislative activity continues

Examples of PBM Reform Legislation

S.882 *Patients Before Middlemen Act*

S 526 *Pharmacy Benefit Manager Transparency Act of 2025*

S 527 *Pharmacy Pricing for the People Act of 2025*

HR 4317 *Pharmacy Benefit Reform Act of 2025*

Outgrowth of Executive Orders That May Impact Group Health Plans

Establishing the President's Make America Healthy Again Commission

- Child Health Assessment Report Issued May 22, 2025
- A Make Our Children Healthy Again Strategy within 180 days (i.e., by August 12, 2025)

Expanding Access to In Vitro Fertilization

https://www.segalco.com/consulting-insights/executive-order-creates-health-commission

Drivers of Childhood Chronic Disease

The shift to ultra-processed foods

- Closer look at ultra-processed food
- Government programs compounding the issue

The crisis of childhood behavior in the digital age

- Decline of physical activity
- Psychosocial factors and mental health crisis

The cumulative load of chemicals in our environment

- Chemical exposures
- Unique vulnerability of children
- Corporate influence

The over-medicalization of our kids

- Kids on too much medication
- Growth of childhood vaccine schedule
- Mechanisms of corporate capture

MAHA Report

On May 22, 2025, the Administration released the child health assessment report required by the Executive Order

Strategy released September 9, 2025

MAHA Commission Strategy to Make Children Healthier Again

- Key Focus Areas
  - Expanding NIH and agency research
  - Reforming dietary guidelines
  - Streamlining organic certification to ease barriers to farm-to-school and direct to consumer sales
  - Public awareness and education initiatives
  - Private Sector Collaboration

What We Are Watching on Preventive Care

Turmoil in vaccine policy

- FDA approval changes
- Changes to ACIP vaccine recommendations
- Plans must continue ACA preventive service coverage through the end of the plan year

US Preventive Services Task Force

- July meeting cancelled;
  Next meeting November

Executive Orders Relevant to Group Health Plans

Biological Sex (Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government)

Regulatory Freeze Pending Review

Initial Recissions of Harmful Executive Orders

Protecting Children from Chemical and Surgical Mutilation

Ending Radical and Wasteful Government DEI Programs and Preferencing

Impact of OBBBA on the ACA and Medicaid

- The Congressional Budget Office (CBO) estimates that the health sector will lose $1.1 trillion and that the Act will result in more uninsured people in the year 2034 than would otherwise be the case, including:
  - 10 million more uninsured resulting from Medicaid changes and changes to the ACA Exchange
  - 5.1 million more uninsured with the expiration of the enhanced premium tax credits because of increase in premium costs
- Largest Medicaid cuts will occur in limitations on state provider taxes, work requirements for working-age adults without disabilities or dependents

Impact of OBBBA on the ACA and Medicaid

- Act also includes a five-year, $50 billion relief fund for rural hospitals and a Medicare reimbursement increase for physicians in 2026
- Group health plans may see increased enrollment and requests for special enrollment as a result of cuts
- Cost impact on plans could be significant

Hot Topics in the Administration and Congress

Unlocking Benefits for Independent Workers

Unlocking Benefits for Independent Workers Act (S. 2210)

Modern Worker Empowerment Act (S. 2228)

Association Health Plan Act

Independent Retirement Fairness Act (S. 2217)

Expansion of HSAs

Hearing on Restoring Trust: Enhancing Transparency and Oversight at EBSA

Health Savings Account

Three changes that will expand the use of HSAs

- Permanent and retroactive extension of provision that permits High Deductible Health Plans (HDHP) to cover telehealth and other remote services before the deductible is met
- Bronze and catastrophic ACA Exchange plans qualify as HDHPs for HSA compatibility
- Direct Primary Care Service Arrangements do not bar HSA participation

HSA changes that were not in the Act

- "Other health plans" that would have no longer barred HSA eligibility:
  - Enrollment in Medicare Part A
  - On-Site Clinics
  - Coverage under a spouse's Health Flexible Spending Arrangement (FSA)
- Additional changes that were not included:
  - Increases in HSA contribution limits for certain individuals based on income
  - Allowing HSA to reimburse expenses 60-days before establishment of the HSA
  - Allowing both spouses to make catch up contributions to same HSA
  - Allowing HSA to pay for qualified sports and fitness amounts
  - Allowing limited rollovers of amounts in HRAs and FSAs to HSAs

EBSA Enforcement Under Scrutiny

- The House Education and Workforce Committee on Wednesday approved a package of bills that, among other things, seek to provide greater transparency surrounding the investigative and enforcement efforts of the Department of Labor, as well as create a safe harbor for fiduciaries when appraising shares in ESOPs.

Agency Leadership Update

Department of Health and Human Services

- Robert F. Kennedy, confirmed
- CMS Administrator, Dr. Oz, confirmed

Department of Labor

- Secretary, Chavez-DeRemer, confirmed
- Deputy Secretary, Keith Sonderling
- Employee Benefits Security Administration, Assistant Secretary, Daniel Aronowitz, confirmed
- Solicitor of Labor, Jonathan Berry, pending

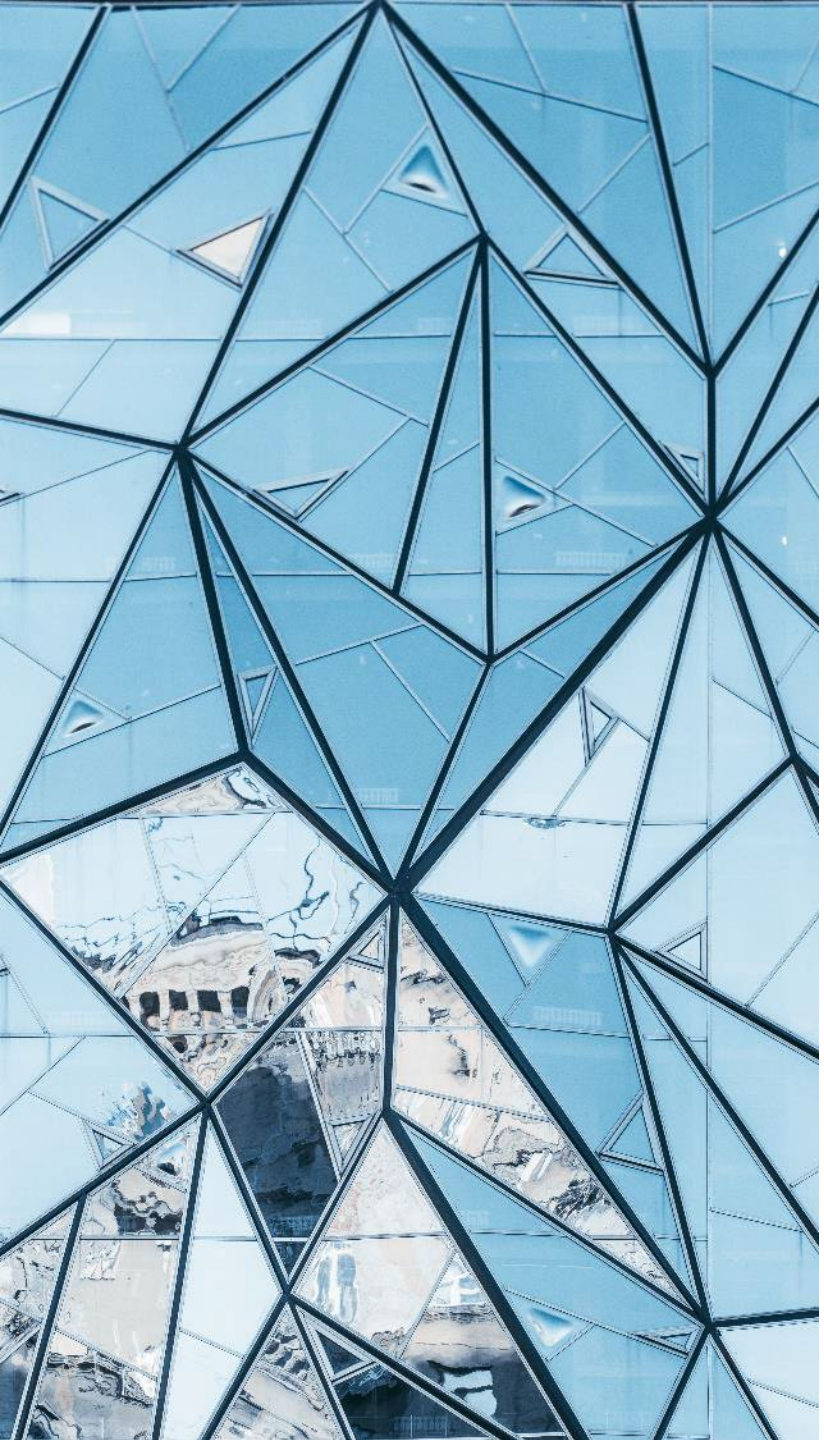
Department of Treasury/Internal Revenue Service

- Secretary of Treasury, Scott Bessent, confirmed
- Commissioner of the IRS, Scott Bessent. acting

EBSA Opinion Letter Program

- On June 2, 2025, the U.S. Department of Labor (DOL) announced a significant expansion of its compliance assistance tools by launching an Opinion Letter Program across five key enforcement agencies, including the Employee Benefits Security Administration (EBSA). This initiative aims to provide employers, plan sponsors, and other stakeholders with clear, tailored guidance on complex issues related to employee benefit plans.

Preemption of State PBM Laws



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Background

- State regulation of PBMs, TPAs, and group health plans continues to accelerate.
- Persistent high drug and medical costs create strong incentives for state activity
- The contours of ERISA preemption are more important than ever for group health plans and their service providers

ERISA Preemption

- **ERISA shall "supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan."** ERISA 514(a).
- Two flavors of state laws:
  - "Reference to"
  - "Connection with"
- Connection with prong is usually at issue

The "In Connection With" Test

Governs a central matter of plan administration

Upsets nationally uniform plan administration

Binds a plan sponsor to a specific plan design choice

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ERISA - Insurance "Savings Clause" and "Deemer Clause"

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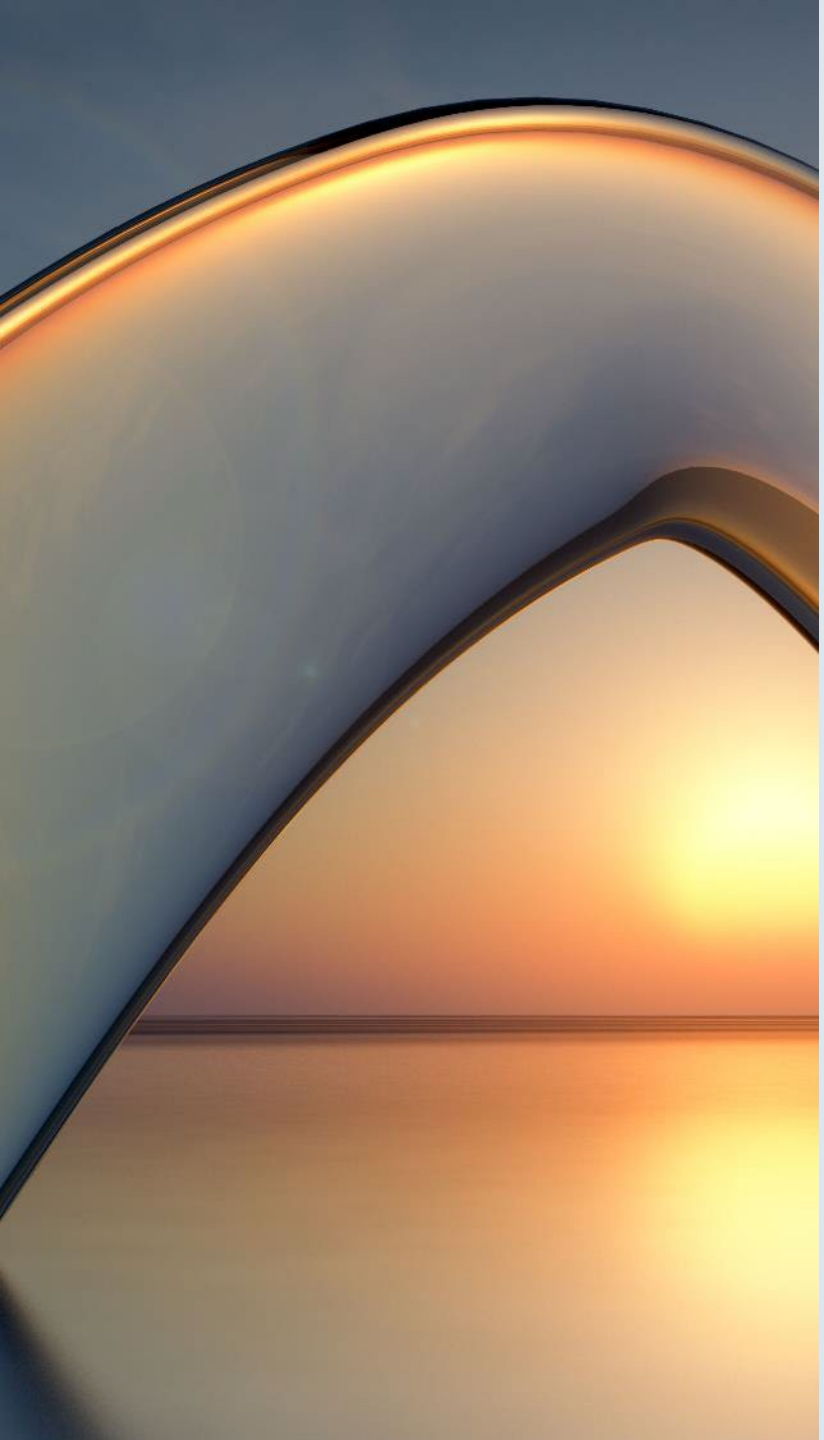
- ERISA's "**savings clause**" provides that "nothing in this title shall be construed to exempt or relieve any person from any law of any State which regulates insurance, banking, or securities." ERISA 514(b)(2)(A)
- ERISA's "**deemer clause**" provides that no benefit plan under ERISA "shall be deemed to be an insurance company or other insurer ... for purposes of any law of any State purporting to regulate insurance companies [or] insurance contracts." ERISA 514(b)(2)(B)
- **Under this framework state laws are preempted as applied to self-funded group health plans, but states can regulate the insurance policies that insurers issue to employers.**



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Limits on Preemption: Economic Effects/Cost Regulation

- *Travelers:*
  - An **indirect economic effect** does not bind plan administrators to any particular choice
  - Nor does it upset uniform plan administration

Limits on Preemption - *Rutledge vs. PCMA*

- **State rate regulation imposes indirect, non-acute economic burdens**
  - No connection with
- What is an acute economic burden?
- At what point does the rate regulation become direct?
- *Rutledge* reaffirmed the other forms of "connection with" preemption

PCMA v. Mulready

- OK any willing preferred provider law and other network limitations:
  - Regulated a "central matter of plan administration"
  - Mandated benefit structures
  - Interfered with "nationally uniform plan administration."
- SCOTUS denied OK's cert petition following DOL brief.

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Ongoing Legislative Efforts

Network regulation – Limits on steering to preferred/affiliated pharmacies, mail-order, and specialty

Integration – Newer efforts to void licensure of PBMs integrated with insurers, or pharmacies affiliated with PBMs

Contracting – Prohibitions on spread pricing, point-of-sale PBM pass through, mandatory fee structures

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Overview of Tennessee PBM Law

- Any willing pharmacy requirement
- Prohibition on cost-sharing differentials
- 340B pharmacy non-discrimination

McKee Foods v. BFP Inc.

- Complex procedural history, *but* the court ultimately addressed whether ERISA preempted TN's any-willing pharmacy law and prohibition on steering to certain pharmacies.
- These laws are preempted by ERISA, notwithstanding *Rutledge*.
- Any willing provider laws regulate plan networks and prohibitions on financial incentives dictate plan design (*i.e.*, cost shares).
- As a result, both have an impermissible connection with the plan, and are preempted.
- Currently on appeal to the Sixth Circuit Court of Appeals.

Overview of Florida PBM Law

- Network adequacy
- Spread pricing prohibition
- Greater transparency
- Specifically applies to self-insured group health plans with participants resident or working in Florida

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Recent State Enforcement

- Florida: OIR is conducting comprehensive market conduct examinations of PBMs and requesting all Rx claims (with fully identified information) across all PBMs.
  - Raises both HIPAA and preemption concerns
  - *Gobeille* appears fully aligned and so preemption appears to be a sound defense
- Some PBMs are allowing an "opt-out" but not clear how OIR will respond.

Arkansas Rule 128

- State requires reimbursement reporting by ***self-insured group health plans***
- Direct application to the plan (instead of PBM) strengthens the preemption argument
- Authority to directly mandate minimum dispensing fees also outside the bounds of *Rutledge*
- *Central States, Southeast and Southwest Areas Health and Welfare Fund v. McClain*, No. 1:25-cv-03938 (N.D. IL)
  - The court appears to have created a *de minimis* standard for "connection with" which is a novel theory.

Non-PBM State Regulation

- States are beginning to apply the same theories at the heart of *Rutledge* to non-PBM services
- But, these laws may have different profiles because of differences between PBMs and medical TPAs
  - In a traditional TPA arrangement, the pass-through payment to the plan falls directly on the ERISA-covered plan, unlike the PBM spread-pricing model

Mental Health Parity

MHPAEA Background

- Final regulations published in 2013 provide requirements regarding parity in quantitative and nonquantitative treatment limitations
- MHPAEA was amended December 27, 2020, through the Strengthening Parity provisions of the Consolidated Appropriations Act of 2021
- Proposed rules published on August 3, 2023
- Proposed rules receive over 9,500 comments
- Final regulations published September 23, 2024
  - Staggered applicability dates for plan years on or after January 1, 2025, and January 1, 2026

2013 Regulations General Rule for Parity in NQTLs

GHPs (and health insurance issuers) prohibited from:

Imposing **a nonquantitative treatment limit** on mental health/substance use disorder benefits **unless** processes, strategies, evidentiary standards or other factors used to apply it to MH/SUD are **comparable and not more stringently applied** than standards used for med/surg

Compare within each classification.

Strengthening Parity Mental Health/Substance Use Disorder

- Enacted December 27, 2020 through CAA 2021
- Requires group health plans to perform and document comparative analyses of the design and application of nonquantitative treatment limitations (NQTLs)
- Plans were required to be prepared to make these comparative analyses available to the Departments of Labor and/or Health and Human Services upon request beginning 45 days after the date of enactment (February 10, 2021)
- Included a sunset for the nonfederal governmental plan opt out

MHPAEA Litigation

- The ERISA Industry Committee (ERIC) filed litigation challenging the 2024 final regulation on January 17, 2025, against the US Departments of Health and Human Services, Labor, and Treasury in the United States Court of Appeals for the DC Circuit
- The lawsuit alleges that the rule exceeds the Departments' authority under the MHPAEA and CAA, violates the Due Process Clause of the Fifth Amendment, is arbitrary and capricious, and otherwise violates the Administrative Procedure Act
  - Also alleges that the effective date for many of the Final Rule's provisions is arbitrary and capricious because it did not leave enough time for plans to come into compliance with the entirely new, vaguely worded regulations
- The federal Departments responded seeking an abeyance

MHPAEA Nonenforcement Agreement

- On May 12th the court granted an abeyance (stay) based on the Departments stating it will reconsider the final regulations, including potentially issuing a proposed rulemaking rescinding or modifying the current regulations
- On May 15th the Departments issued a statement regarding enforcement of the 2024 MHPAEA final regulations. Specifically, the Departments indicate that they will not enforce the provisions of the 2024 Final Rule that were set to become applicable for plan years beginning on or after January 1, 2025 and 2026 or otherwise pursue enforcement actions, based on a failure to comply with those provisions that occurs prior to a final decision in the litigation, plus an additional 18 months
- The statutory provisions and 2013 final regulations remain in effect and enforceable

https://www.segalco.com/consulting-insights/mhpaea-litigation-and-enforcement-news

MHPAEA Litigation

Key Areas Challenged by the Litigation

- "Meaningful Benefits" rule
- Meaningful Differences in Access
- Fiduciary Certification
- Comparative Analysis
- 1/1/25 Applicability Date

2021 CAA Statutory Amendments and 2013 Final Regulations continue to apply even if 2024 regulation re-visited.

New Core Treatment Rule

Meaningful benefit requirement

- Includes the requirement to provide “core treatments” with respect to MH/SUD benefits in classifications where Med/Surg benefits are provided
- A core treatment is a standard treatment, indicated by generally recognized, independent standards of current medical practice

Data Collection and Evaluation

Plans are required to collect and evaluate outcomes data in a manner reasonably designed to assess the NQTL's impact on access to MH/SUD benefits

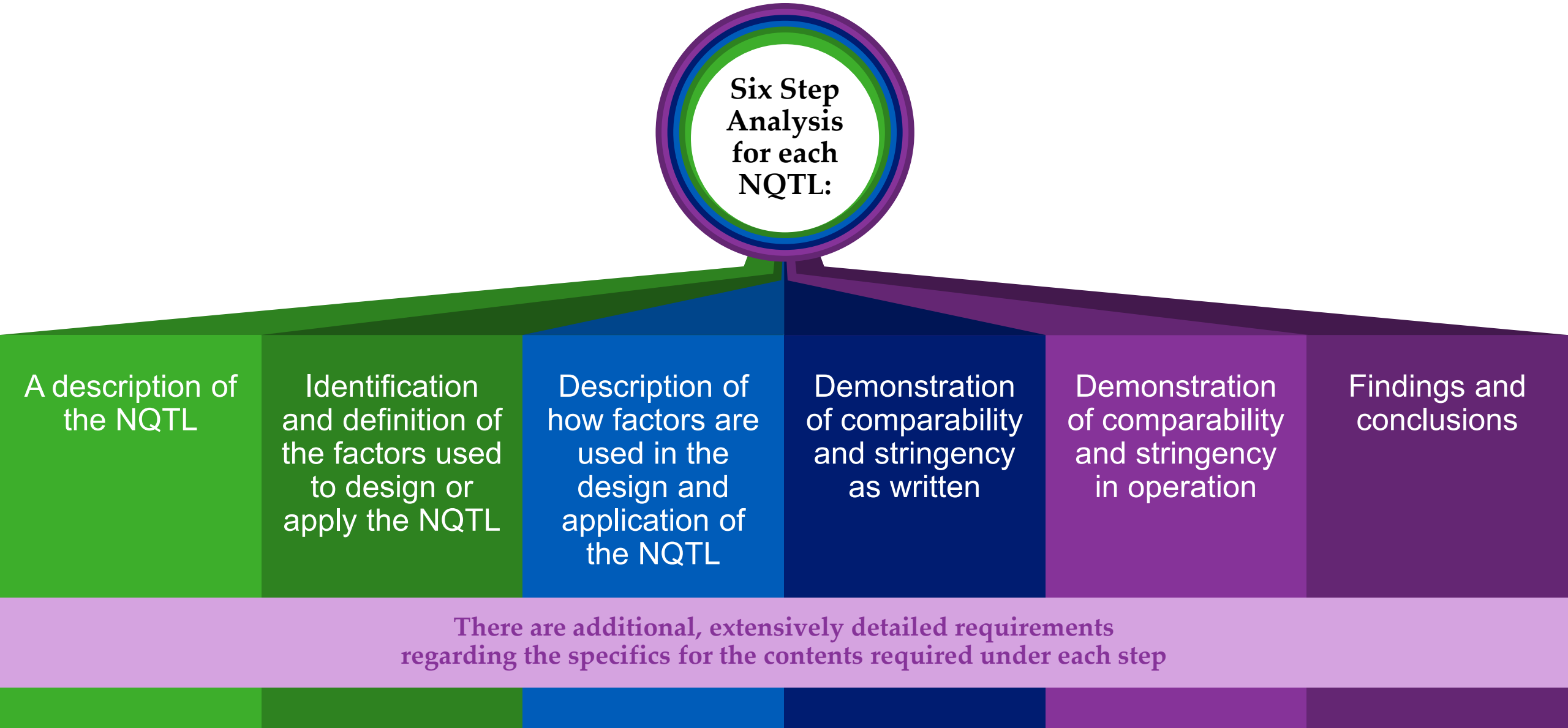
- Plans have a duty to identify and substantiate or remedy "material" differences. De facto noncompliance based on outcomes is not included in the final regulations.
- No exhaustive list of outcomes data
- More guidance is anticipated

Documented Comparative Analysis Including Fiduciary Certification

- Documented comparative analysis content, timing, findings of noncompliance
  - The Departments provide additional detail regarding the comparative analysis content.
  - Plans may be asked to cease unsupported NQTLs in the context of findings of noncompliance.
  - Strict timing expectations were retained.
- Named Fiduciary Certification

  Revised to require a certification that the fiduciary engaged in a prudent process to select a qualified service provider to perform and document a comparative analysis and satisfied the duty to monitor the service provider

Content Requirements for NQTL Comparative Analyses Reports



Requests and Findings of Noncompliance

10 business days to respond to an initial request

10 business days when an initial response is found insufficient and DOL or HHS requests supplemental information

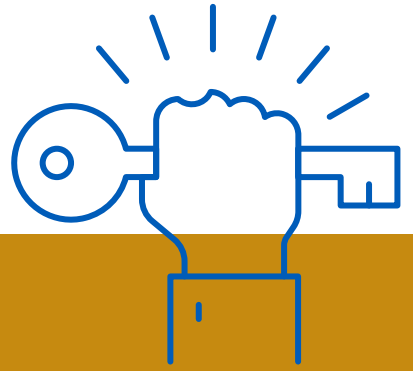
7 days to notify participants and beneficiaries when a final determination of noncompliance is issued.

Significant enforcement is anticipated once rules are finalized.

Definitional Changes

- New Definitions have been added to help differentiate among factors, evidentiary standards, and strategies
- For purposes of defining MH/SUD conditions the Departments define these according to the most current versions of the Diagnostic and Statistical Manual (currently the DSM-5) and the International Classification of Diseases (currently the ICD-10)

Additional Key Elements of the Final Rule



Plans must have a list of the NQTLs applicable under the plan.

The Departments reiterate that the comparative analysis is an instrument of the plan.

Key Concerns Persist

- Continued subjectivity in the general standards as well as in the new “meaningful benefits” rule
- Reasonable timing to allow for implementation
- Network composition standards
- Data collection and evaluation standards
- Cost estimates
- Named fiduciary certification though revised presents challenges

PBM Spread-Pricing Litigation

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Three Complaints:
Johnson & Johnson, Wells Fargo & JP MorganChase

- Putative class action complaints alleging breach of fiduciary duty in **management and design of prescription drug benefit** by:
  - Overpaying for drugs
  - Overpaying for PBM services
  - Failing to engage in a prudent process for selecting PBM
  - Failing to carve out specialty drug benefit from PBM
  - Steering members to PBM pharmacies with higher prices

Lewandowski v. Johnson & Johnson, No. 3:24-cv-00671, 2025 WL 288230 (D.N.J. Jan. 24, 2025)

- **No Article III standing**
  - **Payment of Higher Premiums**
    - Plaintiff's allegations were speculative "at best."
    - Conclusory allegations that plaintiff "paid more" insufficient to allege standing.
  - **Higher Out-of-Pocket Costs**
    - *Injury-in-fact*: Plaintiff alleged that she paid higher prices for specific drugs as a result of employer's fiduciary breaches.
    - *Redressability:* Plaintiff would have hit the MOOP anyway.

Lewandowski v. Johnson & Johnson – Amended Complaint

- **Higher Premiums**
  - Employer charged participants a "consistent ratio" of plan costs
  - No allegation that plan required employer to use a rigid formula when calculating participant contributions
- **Higher Out-of-Pocket Costs**
  - Reduction in cash position
  - New plaintiff – did not hit the MOOP

Navarro v. Wells Fargo & Co., No. 24-cv-03043, 2025 WL 1136091 (D. Minn. Mar. 24, 2025)

- **No Article III Standing**
  - 502(a)(2) Claims:
    - *Injury-in-fact*: No link between contributions and administrative fees
    - *Causation*: Selective allegations re: markups of certain drugs insufficient
    - *Redressability*: Employer had "sole discretion" to set participant contributions
  - 502(a)(3) Claims:
    - Prospective Relief: No standing because not current plan participants
    - Retrospective Relief: Allegations of individual harm too speculative

What's next?

- 408(b)(2) rulemaking could materially alter the information plan fiduciaries access, which could bolster plaintiffs arguments of a fiduciary breach.
- As plaintiffs' counsel continue to develop standing arguments, de-risking strategies include delinking cost-share from amounts paid and fixing participant premium equivalents at a fixed dollar amount.

Other Hot Topics

Reproductive Health Privacy Rule Vacated

- On June 18, 2025, in *Purl v. Department of Health and Human Services*, the U.S. District Court N.D. Texas vacated the final rule. The court ruled that the final rule's protections for reproductive healthcare exceeded the statutory authority of the Department of Health and Human Services (HHS). The court struck down nationwide the final rule's protections for PHI related to reproductive healthcare.

Updated Privacy Notice Requirements Struck Down

- The final rule on reproductive healthcare prohibited covered entities from disclosing protected health information (PHI) related to lawful reproductive healthcare in certain situations.
  - Specifically, it restricted covered entities (e.g., health plans, healthcare clearinghouses or healthcare providers) and business associates from using or disclosing an individual's PHI for the purpose of conducting a criminal, civil or administrative investigation into or to impose criminal, civil or administrative liability on any person for the "mere act of seeking, obtaining, providing or facilitating lawful reproductive healthcare."
  - The final rule also required covered entities to obtain a signed written attestation from the person requesting reproductive health PHI that the use or disclosure is not for a prohibited purpose.

Privacy Notice SUD Updates Remain

- The final rule also required covered entities to revise their Notices of Privacy Practices by February 16, 2026, to address new privacy protections under the Part 2 Rule for the Confidentiality of Substance Use Disorder Patient Records, published on February 16, 2024. This portion of the rule was not vacated.
- If a plan's Notice of Privacy Practices has not yet been updated to include the additional protections and consent requirements for records pertaining to substance use disorder services, it must be updated no later than February 16, 2026.

Insulin Litigation

- In these cases, the plan argues that the PBMs intentionally incentivize manufacturers to inflate their insulin list prices
- The consolidated cases are not a class action, so every plan would have to file its own litigation which is then consolidated in New Jersey
- Remains unclear how the damages are measured
- Plans and their legal counsel need to make the decision whether to file the lawsuit and it seems it may be resource intensive because they would need to devote resources to monitoring the litigation and putting together the damages

Telehealth

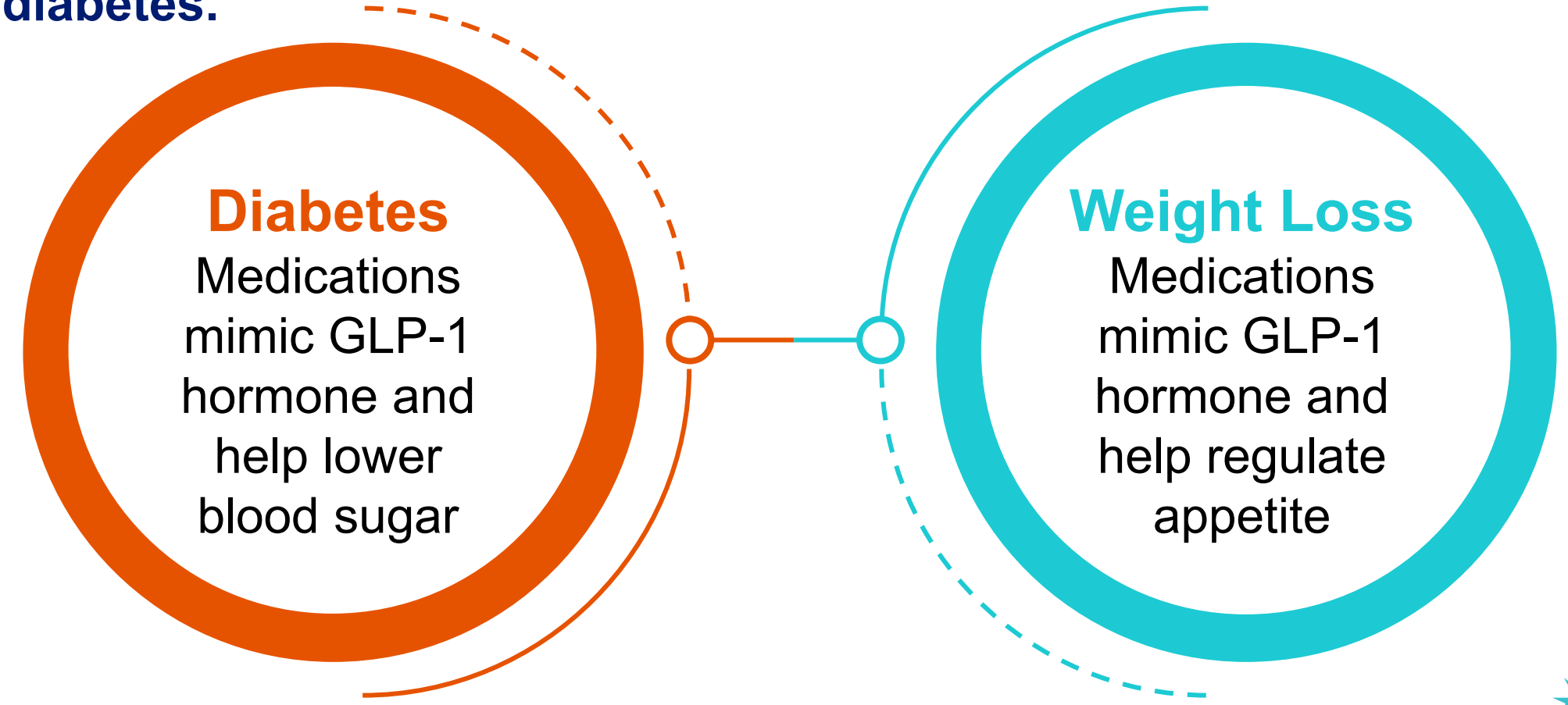
During the COVID-19 pandemic, the CARES Act allowed HDHPs to cover telehealth services before the participant has met their deductible. This relief expired at the end of 2024

The Act permanently and retroactively extended the opportunity for HDHPs to have telehealth services covered first-dollar before the deductible is met for plan years beginning after December 31, 2024

Plan sponsors can choose whether to permit coverage for telehealth before the deductible is met

What are GLP-1 Medications?

GLP-1 is a hormone found naturally in our bodies that targets the area of the brain that regulates appetite and is insufficient in people who have type 2 diabetes.



Utilization Concerns

- Off label use of diabetes GLP-1 therapies (i.e. Ozempic) for weight loss
- Discontinuation of therapy remains a concern (either due to shortage or tolerance of side-effects)
- PBMs are offering utilization management programs to curb off-label spend for the GLP-1 medications
- GLP-1s are in the top drug spend for many plan sponsors in 2024

Compliance considerations should be reviewed with respect to GLP-1 UM

Questions?