Segal

NCCMP Annual Conference

Healthcare Legal and Legislative Forecast

March 31, 2026 / Kathy Bakich

Agenda

The One Big Beautiful Bill Act and its Consequences

The PBM Requirements in the Consolidated Appropriations Act of 2026

The One Big Beautiful Bill Act and its Consequences

Budget and Tax Legislation Enacted

On July 4, 2025, the President signed into law tax and budget reconciliation legislation called the One Big Beautiful Bill Act (OBBBA or the Act) (Public Law 119-21)

What's not in the OBBBA?

- No changes to the taxation of group health benefits or retirement income benefits
- No extension of enhanced subsidies for ACA Marketplace (Exchange) coverage
- No changes to allow individuals flexibility to purchase health insurance through Individual Coverage Health Reimbursement Arrangements (ICHRAs)

Changes to Health Savings Accounts

- Three changes that will slightly 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
- Act did not allow Medicare beneficiaries to contribute to HSA accounts

Impact of Act on Healthcare Financing

- Over $800 Billion in Medicaid cuts over the next 10 years
- The Congressional Budget Office (CBO) estimated that the health sector will lose $1.1 trillion and that the Act would 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

What we're seeing

- In 2026, one million fewer people signed up for the exchange than in 2025 – From 24.2 million to 23 million. When premium bills come due more people may drop coverage
- Group health plans may see increased enrollment and requests for special enrollment as a result of cuts
  - KFF survey shows that some people are moving into employment-based coverage from the Exchange
- Lack of financing for rural healthcare will impact access to care

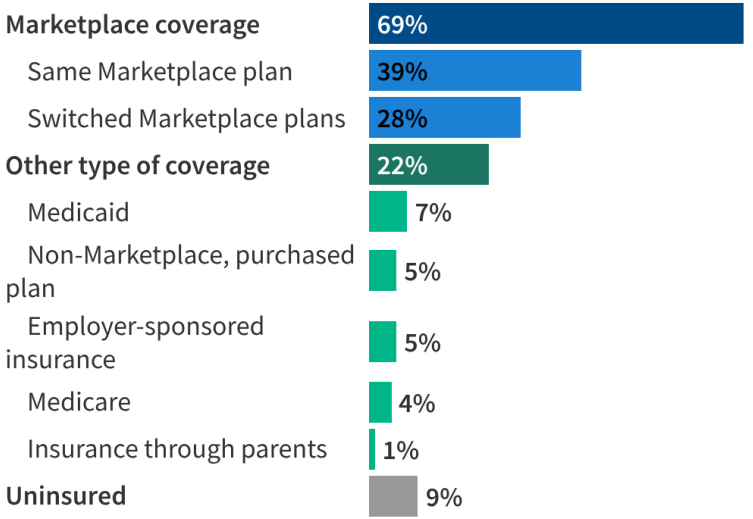
Exchange Enrollment Down

- Enrollment is down
- One in ten formerly covered are uninsured
- Some people have moved to employment-based coverage

Figure 2

Most 2025 Marketplace Enrollees Still Have Marketplace Coverage, Though One in Ten Are Now Uninsured

Current health insurance coverage for 2025 Marketplace enrollees:



Note: Among 2025 Marketplace enrollees. See topline for full question wording.

Source: KFF Follow-Up Survey of Marketplace Enrollees (February 12-March 2, 2026)

Trump Accounts

- The OBBBA created a new tax-preferred savings account for children under age 18 called the “Trump Account”
- These accounts will operate like individual retirement accounts that allow earnings to grow on a tax-free basis
- Parents, relatives or other entities may contribute up to $5,000 annually after tax (indexed for inflation) up to age 18, with exceptions to the maximum for certain entities
- Children who are born from 2025 through 2028 will be automatically enrolled and receive a one-time deposit of $1,000 from the federal government into their account
- The accounts must be held by a financial institution and invested in a qualified equity index fund

Contributions to Trump Accounts

- Under a new IRC Section 128, employers may contribute to an employee's child's Trump Account on a tax-free basis beginning in 2026
- The employer must have a separate written plan document to make such contributions, and the plan is subject to nondiscrimination rules under IRC Section 129
- Employers may contribute up to $2,500 for each employee, and that amount is indexed beginning in 2027
- Exploring whether multiemployer group health plans would be able to offer access to Trump accounts through this new law

The PBM Requirements in the Consolidated Appropriations Act of 2026

Consolidated Appropriations Act of 2026

- The Consolidated Appropriations Act of 2026 (CAA 2026) was passed by Congress and signed by the President on February 3, 2026
- The Act funded five government agencies, including the Department of Health and Human Services
- The HHS portions contain significant new rules affecting pharmacy benefit managers

CAA 2026: Lowering Prescription Drug Costs

- Law amends ERISA, the Internal Revenue Code, and the Public Health Service Act to add requirements applicable to group health plans, insurers, and entities providing pharmacy benefit management services
- Effective for plan years beginning on or after August 2028 (January 1, 2029, for calendar year plans)
- $10,000 Civil Monetary Penalty/day for violations

CAA 2026: Lowering Prescription Drug Costs

Semiannual Reports

PBMs must submit reports at least every six (6) months (or quarterly upon request) to large self-insured plans and employers with over 100 participants

Summary Documents

PBMs must provide annual reports to all insured and self-insured plans regardless of size

Written Disclosure

Plans must provide annual disclosure to participants about the PBM information and their rights to access claims information

Four Categories of Information Disclosure

1. A list of each drug for which a claim was filed during the reporting period
2. A list of each therapeutic class of drugs for which a claim was filed during the reporting period
3. High-cost drugs with gross spending exceeding $10,000 during the reporting period
4. Information regarding affiliated pharmacies or pharmacies under common ownership of the PBM

CAA 2026: Lowering Prescription Drug Costs

A list of each drug for which a claim was filed during the reporting period

- Compensation paid by plan to PBM, by PBM to pharmacy, and the difference
- Drug name, NDC, and dispensing channel
- For each dispensing channel, whether drug is brand or generic, price (WAC for brand and AWP for generic), total number of claims, participants, dosage units
- Net price to the plan after rebates, other remuneration
- Total amount of OOP spending by Participants
- Total net spending on the drug
- Total amount received by PBM in rebates, fees, other remuneration, including the amount related to utilization

CAA 2026: Lowering Prescription Drug Costs

A list of each therapeutic class of drugs for which a claim was filed during the reporting period

- Total gross spending by the plan before rebates, price concessions, discounts, or other remuneration
- Net spending in each class after rebates and other remuneration
- Total amount received by the PBM in rebates or other remuneration related to drug utilization or drug spend
- Average net spending by plan per 30- and 90-day supply
- Number of participants who filled a prescription for a drug in the class
- A description of formulary tiers and utilization management for the class
- Total OOP spending by participants

CAA 2026: Lowering Prescription Drug Costs

With respect to drugs for which gross spending exceeded $10,000 during the reporting period*

- A list of all other drugs in the same therapeutic class
- If applicable, the rationale for the formulary placement of the drug in that therapeutic class
- Any change in formulary placement compared to the prior plan year

* If gross spending exceeded $10,000 for fewer than 50 drugs, the information must be provided for the top 50 drugs with highest spend

CAA 2026: Lowering Prescription Drug Costs

For affiliated pharmacies or pharmacies under common ownership of the PBM, including mandatory mail and specialty home delivery programs, retail and mail auto-refill programs, and cost-sharing assistance incentives funded by the entity providing PBM services

- An explanation of all benefit design parameters that encourage using services
- The percentage of total prescriptions dispensed by affiliated pharmacies
- A list of all drugs dispensed by these pharmacies
  - The amount charged per dosage unit to the plan and to participants
  - The median amount and interquartile range per dosage unit, per 30- and 90-day supply, when the same drug is dispensed by other non-affiliated pharmacies that are in the network
  - The lowest cost per dosage unit, per 30- and 90-day supply, including amounts charged to plan and participant, that is available from any pharmacy included in the network of the plan

CAA 2026: Full Pass-Through of Rebates

- Only applies to ERISA plans, but could be useful to governmental plan sponsors
- Requires that contracts with PBMs must require the PBM to remit 100 percent of rebates, fees, alternative discounts, and other remuneration to the group health plan or insurer
- Rebates must be paid quarterly, within 90 days after the end of the quarter
- Records must be available for audit

CAA 2026: Full Pass-Through of Rebates

Responsible plan fiduciaries that did not know the fees were not remitted or upon discovering, request the fees in writing, and if there is no compliance, notify the Secretary of the failing, are considered “Innocent Plan Fiduciaries”

Effective for new contracts or renewals entered into for plan years beginning on or after August 2028 (January 1, 2029, for calendar year plans)

CAA 2026: Fee Disclosure

CAA amends ERISA Section 408(b)(2) to require PBMs, TPAs and any other entity providing services to group health plans to disclose all direct and indirect compensation received by the service provider to the group health plan sponsor

CAA 2026 Additional Provisions

Additional PBM reforms would apply to **Medicare** and **Medicaid**

For **Medicare Part D** law contains delinking provision preventing PBMs from receiving compensation based on drug prices or rebates

Extends existing **public health programs** and funding for programs such as **pediatric cancer research** and **HIV prevention**

CAA 2026 Additional Provisions

Extends coverage of **telehealth services** for Medicare

Contains site neutral reforms that require billing with **separate National Provider Identifier numbers** for services in **separate facilities**

Would **speed generic drug reviews** by the FDA

Plan Sponsor Action Needed to Comply with CAA 2026

Important to have fiduciary monitoring processes in place – the new law makes it clearer what the processes must include

- Exercise due diligence in PBM contracting
- Monitor PBM reporting obligations and follow through if standards not met
- Require compensation disclosure
- Revise PBM contracts no later than 2029 plan years

Congress Considering Amending ERISA

- Congress is considering legislation that would amend ERISA in order to address lawsuits filed against fiduciaries
- US Supreme Court decided *Cunningham v. Cornell* in 2025 that makes it easier for participants to sue plans for everyday plan transactions with service providers
- The “ERISA Litigation Reform Act” was recently reported out of the House Committee on Education and Workforce

Thank You and Questions

HEALTH CARE LITIGATION UPDATES

NCCMP Annual Conference

March 31, 2026

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HEALTH CARE LITIGATION UPDATES TOPICS:

- Mental Health Parity Addiction Equity Act (MHPAEA) 2024 Final Rule litigation update
- Fiduciary liability cases concerning compensation paid to Pharmacy Benefit Managers (PBMs)
- ERISA preemption challenges to state PBM legislation

MHPAEA - BACKGROUND

- Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) generally requires that, where a group health plan provides mental health and/or substance use disorder (MH/SUD) benefits, those benefits must be provided in a manner that is no more restrictive or limited than the medical/surgical (M/S) benefits offered. In 2010 and 2013, a Final Rules were issued by the Departments of Labor, the Treasury, and Health and Human Services (the "Departments).
  - Six categories in which parity must be maintained (Inpatient, in-network, Inpatient, out-of-network, Outpatient, in-network, Outpatient, out-of-network, emergency, and Rx).
  - Applies to financial requirements, quantitative treatment limitations (QTLs), and non-quantitative treatment limitations (NQTLs).
- The Consolidated Appropriations Act of 2021 (CAA) required group health plans and insurers to perform and document a comparative analysis for all NQTLs. The CAA also: (i) required the DOL to review at least 20 comparative analyses per year and submit an annual report to Congress; and (ii) directed the Departments to issue guidance to help plans properly document the NQTL analysis.
- In September 2024, the Departments issued a Final Rule implementing the requirements of the CAA. Some provisions of the Final Rule were effective for plan years beginning on or after January 1, 2025, and others for plan years beginning on or after January 1, 2026.

MHPAEA - 2024 FINAL RULE

- Key requirements of 2024 Final Rule:
  - **"Meaningful Benefits" Standard**: Plans must provide "meaningful benefits" for each covered MH/SUD condition or disorder in each classification in which it offers M/S benefits, including at least one "core" treatment for such MH/SUD condition.
  - **NQTL Requirements**: A plan may not impose a NQTL on MH or SUD benefits that is more restrictive, as written or in operation, than the predominant NQTL that applies to substantially all M/S benefits in the same classification.
    - Design and Application: Plans must examine the processes, strategies, evidentiary standards, and other factors used in designing and applying an NQTL to MH/SUD benefits in each classification to ensure they are comparable to, and applied no more stringently than, those used in designing and applying the NQTL to M/S benefits in the same classification. Discriminatory factors and evidentiary standards may not be used to design MH/SUD NQTLs (biased or not objective in a way that discriminates against MH/SUD benefits as compared to M/S benefits).
    - Data Evaluation : Plans must collect and evaluate relevant data to assess the impact of NQTLs on relevant outcomes related to access to MH/SUD benefits and M/S benefits. The comparative analysis must include an analysis of the impact of each NQTL.
  - **"Material Differences in Access" Standard**: If relevant data indicates that there are material differences in access to MH/SUD benefits resulting from application of any NQTL, plans must take reasonable steps to address these material differences. The comparative analysis must evaluate compliance with this standard for each NQTL.
  - **Plan Fiduciary Certification Requirement**: Comparative analysis must include a certification that the plan's fiduciary engaged in a prudent process to select one or more qualified service providers to perform and document the comparative analysis and satisfied their duty to monitor the service provider.
  - **Disclosure Requirements**: Comparative analysis must be provided upon request and following an adverse benefit determination.

MHPAEA – 2024 FINAL RULE LITIGATION

- On January 17, 2025, the ERISA Industry Committee (ERIC) filed a lawsuit, *The ERISA Industry Committee v. United States Department of Health and Human Services et al.,* challenging the Final Rule.
- Among other things, the complaint alleges that the "meaningful benefits" standard exceeds the Departments' authority under the statute because it mandates that plans provide certain additional benefits even though MHPAEA indicates it is not a benefits mandate.
- The complaint also alleges that numerous parts of the Final Rule, including the material differences in access standard, and fiduciary certification requirement, rely on vague terms and impose unreasonable and unnecessary burdens on plans.
- The lawsuit seeks to vacate the Final Rule in its entirety or at least the challenged provisions.

MHPAEA – 2024 FINAL RULE LITIGATION AND NON-ENFORCEMENT POLICY

- On May 9, 2025, the Departments filed a motion to hold the lawsuit in abeyance pending the Departments' reconsideration of the Final Rule, and the court granted the motion.
- On May 15, 2025, the Departments issued a statement that they will not pursue enforcement actions based on a failure to comply with the Final Rule that occurs prior to a final decision in the lawsuit plus 18 months.
- The Departments made clear that the enforcement relief "applies only with respect to those portions of the 2024 Final Rule that are new in relation to the 2013 final rule." The Departments note that the obligation to maintain an NQTL comparative analysis, as required by the CAA, remains in effect.
- Plans and issuers may continue to refer to the 2013 final rule, the 2021 *FAQs About Mental Health and Substance Use Disorder Parity Implementation and the Consolidated Appropriations Act, 2021 Part 45*, and other sub-regulatory guidance issued by the Departments under MHPAEA including the MHPAEA Self-Compliance Tool on the DOL's website.

MHPAEA COMPLIANCE BEST PRACTICES

- The CAA requires the Departments to review at least 20 NQTL comparative analyses annually, and the DOL is still actively auditing plans for compliance with MHPAEA.
- Audits can also be triggered by participant complaints and solicitation of “non-compliant” client lists from TPAs and insurers.
- Plans should maintain a compliant, up-to-date comparative analysis that complies with the 2013 regulation and applicable guidance.
- Focus on DOL-identified priorities:
  - Network adequacy
  - ABA therapy for autism
  - Nutritional counseling
  - Inaccurate provider lists
  - Speech and occupational therapy
- Continue to monitor legal developments.

BREACH OF FIDUCIARY DUTY CASES

- **Standing in suits against health plans**

Derives from U.S. Constitution, Article III, which limits federal courts to resolving actual cases and controversies, not political questions, which are reserved to Congress or the Executive Branch (or to the states).

To have standing to bring suit in federal court, the plaintiff must demonstrate that:

- they suffered injury fact that was concrete and particularized or is in immediate danger of sustaining such an injury if the court doesn't intervene,
- defendant's action caused the injury, and
- the injury can be redressed by a favorable judicial decision.

BREACH OF FIDUCIARY DUTY CASES (CONT.)

- *Lewandowski v. Johnson & Johnson* (D.N.J., Nov. 26, 2025)
  - Complaint alleged that J&J mismanaged its Rx benefit program resulting in higher costs due to PBM contract terms, among other reasons.
  - Court dismissed fiduciary breach claims for lack of standing –
    - Court found Plaintiff's claim that she was directly harmed by the alleged overpayments to the PBM through higher participant contribution rates was too speculative because there were many other factors that went into contribution amount.
    - Court found there was concrete injury through higher out of pocket costs but still no standing -- court could not redress injury because plaintiff had exceeded the OOP maximum through other expenditures, so excess cost was paid by plan not by her.
  - Plaintiffs appealed dismissal to the Third Circuit, and parties are briefing the case.

BREACH OF FIDUCIARY DUTY CASES (CONT.)

- *Navarro v. Wells Fargo & Co.* (D. Minn. Mar. 24, 2025)
  - Complaint alleged failure to control specialty drug costs, asserted claims focusing on excessive fees paid to PBM and conflicts of interest. Wells Fargo entered into traditional PBM agreement with Express Scripts (ESI).
  - Motion to dismiss granted in March 2025 due to lack of standing because Plaintiffs did not demonstrate increased contributions or out-of-pocket costs due to alleged mismanagement.
  - Plaintiffs filed an amended complaint in May 2025. They argued that they had standing because they were injured by paying higher contributions for their health insurance coverage and higher out of pocket costs for their Rx drugs, which higher costs were traceable to Wells Fargo's failure to negotiate a better deal with ESI.
  - Court granted defendants' motion to dismiss amended complaint on **March 3, 2026**, again finding Plaintiffs' assertions related to standing were too speculative because participant contributions amount may be affected by a number of factors having nothing to do with Rx benefits.

BREACH OF FIDUCIARY DUTY CASES (CONT.)

- **Standing in suits against health plans (cont.)**

Lewandowski and *Navarro* courts both relied in part on *Thole v U.S. Bank N.A.* (U.S. 2020) for standing analysis. In *Thole,* the Court found that participant-plaintiffs in a lawsuit alleging mismanagement of plan investments in a defined benefit retirement plan lacked standing because their benefits were unaffected by the alleged mismanagement. *Lewandowski* and *Navarro* courts held that health plans are analogous to defined benefit plans because they consist of a general pool of assets rather than individual accounts.

BREACH OF FIDUCIARY DUTY CASES (CONT.)

- *Stern v. JPMorgan Chase & Co.* (S.D.N.Y. March 9, 2026):
  - ERISA class action brought by current and former employees alleging that JP Morgan breached its fiduciary duties by imprudently failing to negotiate terms with its PBM to protect the Plan from excessive costs, allowing Caremark to use a traditional PBM model characterized by opaque pricing, which allegedly inflated costs to the plan and its participants.
  - Case recently survived motion to dismiss in part and will proceed to discovery.
  - Unlike in *Lewandowski* and *Navarro* cases, court here held that, at the pleading stage, the plaintiffs had identified a cognizable injury -- in the form of higher out-of-pocket costs -- sufficient to confer standing.
  - Court dismissed the fiduciary breach claims, however, because it held that the employer's decisions about the structure of the pharmacy benefit was a settlor function not a fiduciary function.

BREACH OF FIDUCIARY DUTY CASES (CONT.)

- *Stern v. JPMorgan Chase & Co.* (S.D.N.Y. March 9, 2026) (cont.)
  - Court did not dismiss Plaintiffs' claims that JPMorgan engaged in "prohibited transactions" under ERISA Section 406, to the extent the company failed to ensure that service providers, including the PBM, received no more than "reasonable" compensation for their services.
  - Court relied on *Cunningham v. Cornell University,* in which Supreme Court held that plaintiff need only allege that the plan fiduciary engaged in a prohibited transaction under ERISA sec. 406 and did not have to plead facts showing that the transaction was not exempt under ERISA sec. 408(b)(2), which provides a prohibited transaction exemption for a contract with a party in interest for services necessary for the operation of the plan if no more than reasonable compensation is paid for the service.

BEST PRACTICES FOR AVOIDING LAWSUITS RE PBM RELATIONSHIPS

- Work with fund counsel to carefully review proposed agreements with PBMs and demand transparency into the PBM's indirect compensation.
- Compare options in the market – what are other PBM's offering?
- Consider moving from traditional PBM arrangement to pass-through model.
  - Traditional arrangement is where PBM is paid primarily through spread between what it pays the pharmacy and what it charges the plan, which creates conflict of interest between PBM and plan
  - Pass-through model: PBM bills the plan what it pays the pharmacy as well as a flat fee for administrative services
- Avoid allowing PBM to steer specialty drug prescriptions to their own specialty pharmacies.
- Question the reason for Plan formulary changes, don't just accept the PBM's recommendation.
- Continue to monitor legal developments.

ERISA PREEMPTION CHALLENGES TO STATE PBM LEGISLATION

- *What is ERISA Preemption?*
  - Employee Retirement and Income Security Act of 1974, as amended ("ERISA") "shall supersede any and all State laws insofar as they . . . relate to any employee benefit plan" governed by ERISA.
  - A state law "relate[s] to" an employee benefit plan if it has (1) a connection with, or (2) reference to such a plan.

The Access Standards tell plans they can't use mail-order pharmacies to serve members living in rural areas with few nearby retail pharmacies, the Discount Prohibition stops plans from giving m

ERISA PREEMPTION CHALLENGES TO STATE PBM LEGISLATION (CONT.)

- *Rutledge v. Pharmaceutical Care Management Association* (U.S. 2020)
  - PBMs developed a practice of setting reimbursement rates for generic drugs using internal price lists called Maximum Allowable Cost (MAC) lists. Pharmacies argued these MAC lists were secretive, arbitrary, and often paid them less than their own cost to acquire the drug, which they said put immense financial pressure on community pharmacies, threatening their survival.
  - In response, Arkansas adopted Act 900, which, among other things, prohibited PBMs from reimbursing a pharmacy less than what the pharmacy paid to buy the drug from a wholesaler.
  - In *Rutledge*, the Supreme Court held that Act 900 was not preempted by ERISA, stating, "Act 900 is merely a form of cost regulation" that may cause ERISA plans to pay more for drug prescription benefits, but the effect of Act 900 was not "so acute that it will effectively dictate plan choices."
  - *Rutledge* was viewed as opening the door to state regulation of PBMs.

The Access Standards tell plans they can't use mail-order pharmacies to serve members living in rural areas with few nearby retail pharmacies, the Discount Prohibition stops plans from giving m

ERISA PREEMPTION CHALLENGES TO STATE PBM LEGISLATION (CONT.)

- *PCMA v. Mulready*, 78 F.4th 1183 (10th Cir. 2023)
  - Court of Appeals found that ERISA preempted provisions in Oklahoma's Patient's Right to Pharmacy Choice Act that:
    - set minimum geographic requirements for network pharmacies,
    - prohibited PBMs from requiring or incentivizing use of mail order, and
    - required PBMs to admit into the PBM's preferred network every pharmacy that is willing to accept the PBM's preferred-network terms.
  - The Tenth Circuit held that these Oklahoma provisions were preempted by ERISA because "[f]unctionally, the network restrictions mandate benefit structures" and eliminate at least one method of structuring prescription drug benefits.
  - Oklahoma sought review by Supreme Court. Ultimately, the Supreme Court declined review, allowing the 10th Circuit decision to stand.

ERISA PREEMPTION CHALLENGES TO STATE PBM LEGISLATION (CONT.)

- *Central States, Southeast and Southwest Areas Health & Welfare Fund v. McClain*, (N.D. Ill. 2025)
  - Central States Fund sued the Arkansas Insurance Commissioner seeking a declaration that the Department's Rule 128 is preempted by ERISA.
  - Rule 128 allows the Commissioner to impose a dispensing fee payable to the pharmacy if the pharmacy's compensation is "not fair and reasonable." It also contains a reporting provision that requires health benefit plans to submit certain pharmacy compensation information.
  - On September 2, 2025, the Court dismissed the ERISA preemption claim because rule appears to operate without regard to the existence of an ERISA-governed plan and regulates health benefit plans whether or not they are governed by ERISA. Court found it to be a cost regulation statute akin to that at issue in *Rutledge*.
  - Fund appealed to Seventh Circuit. Case is pending.

ERISA PREEMPTION CHALLENGES TO STATE PBM LEGISLATION (CONT.)

- *ERISA Industry Committee v. Minnesota Department of Commerce* (filed D. Minn. Dec. 2024)
  - Minnesota law regulates PBMs by imposing network adequacy standards, disclosure requirements, and controls on pricing between PBMs and pharmacies. Law specifies that plans may not select networks that require enrollees to obtain covered maintenance drugs from a PBM-owned mail-order pharmacy, must instead permit enrollees to fill prescriptions at independent retail pharmacies.
  - Lawsuit brought by ERIC and the National Labor Alliance of Health Care Coalitions challenged law on grounds that, in effect, it regulates plan sponsors and the Rx benefits they choose to offer through networks maintained by the PBMs; accordingly, it is preempted by ERISA.
  - Two provisions of law that *Mulready* court found to be preempted are also challenged here.
  - Lawsuit seeks injunction against enforcement of Minn. law. Case is in discovery.

ERISA PREEMPTION CHALLENGES TO STATE PBM LEGISLATION (CONT.)

- Injunctive relief
  - What is an injunction?

  A court order that directs a person to do something or to stop doing something. It is an equitable remedy issued in situations where monetary compensation would be inadequate, typically to prevent irreparable harm. Courts must consider the facts and balance the relative harms to the parties involved.

  - What is a preliminary injunction?

  An injunction that may be granted before or during a trial, with the goal of preserving the status quo before a final judgment. Preliminary injunctions may only be granted after a hearing. Courts consider the extent of the irreparable harm, each party's likelihood of prevailing at trial, and any other public or private interests implicated by the requested injunction. Parties may appeal the judge's decisions on whether to award a preliminary injunction.

ERISA PREEMPTION CHALLENGES TO STATE PBM LEGISLATION (CONT.)

- *Iowa Assoc. of Business and Industry v. Ommen* (S.D. Iowa Jul. 21, 2025)
  - Lawsuit brought by coalition of Iowa employers and employee benefit plans governed by ERISA seeking declaratory and injunctive relief to prevent enforcement of Iowa statute that regulated PBMs.
  - Law prohibits discrimination against pharmacies by PBMs and health plans, requiring open networks. Law restricts PBMs' ability to steer patients toward preferred pharmacies, bars requirements for exclusive use of mail-order pharmacies, and mandates equal cost-sharing between retail and mail-order options. Law imposes mandatory reimbursement standards and mandates that PBMs transfer 100% of manufacturer rebates to health plans.
  - Lawsuit alleged that statute was preempted by ERISA.
  - Court grants partial preliminary injunction because the Court finds that some of the law's provisions "cross the line from permissible cost regulation into impermissible structural mandates that govern central matters of plan administration." State filed appeal with 8th Circuit. Appeal is pending.

QUESTIONS?

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