The Latest in Pharmacy Benefit Legislation

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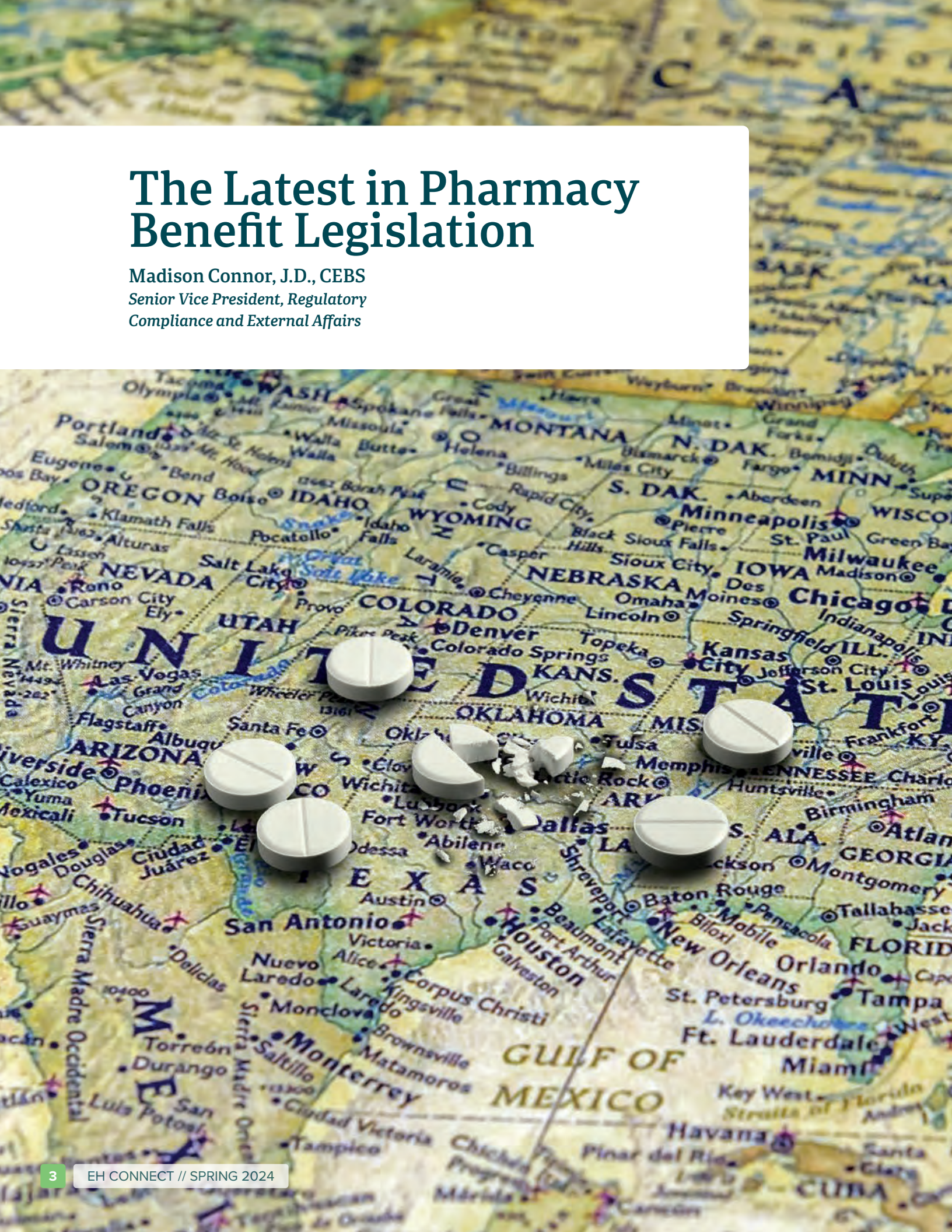
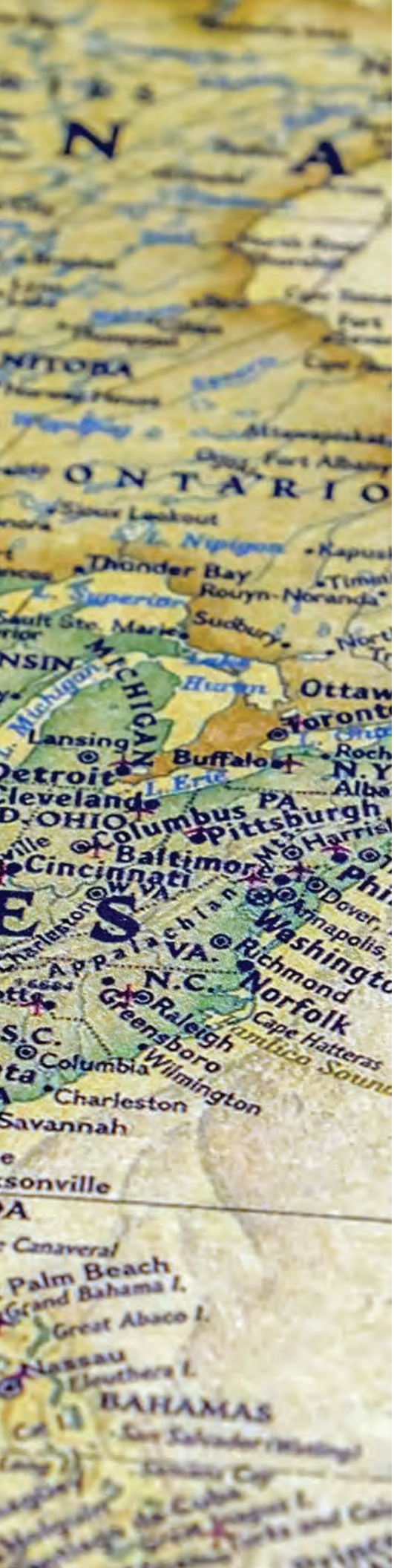




In the past year, state legislatures introduced hundreds of bills regarding pharmacy benefit plans, while congressional committees held an unprecedented 20 hearings scrutinizing various stakeholders in the pharmacy benefit industry. This momentum has only continued into the 2024 legislative sessions.

Prescription drug pricing remains a strong bipartisan priority for Congress. In early December of 2023, the House of Representatives passed the Lower Costs, More Transparency Act. The bill bans spread pricing in Medicaid contracts, strengthens existing transparency rules from the Trump administration including requirements for machine-readable file publication and member cost-comparison tools and requires site neutrality for Medicare payments. While the measure has yet to be considered in the Senate, Congress could pass some form of health care transparency-related package by the end of the year. What ultimately passes may be a stand-alone bill or included as part of a broader appropriations package or spending bill.

The most significant industry developments continue to be driven by state-level efforts. Some noteworthy trends from last year that have continued into 2024 include:

- Restrictions on utilization management.
- Any willing pharmacy provisions.
- Regulatory action through administrative rulemaking.
- Copay accumulator restrictions.
- Traditional (spread) pricing bans.
- Regulation of self-funded ERISA plans.

State Regulatory Activity

In addition to introducing bills through the formal legislative process, states have begun to advance meaningful pharmacy benefit changes through regulatory rulemaking via state departments of insurance. States may pass laws that require pharmacy benefit managers (PBMs) to register as regulated entities with the state's department of insurance and grant the department the authority to draft implementing rules for that state law. The department then has the power and discretion to further regulate PBMs and, by extension, plan sponsors' underlying benefit plans. Such state regulatory actions add another avenue for plan sponsors to monitor when considering changes that may need to be made to their pharmacy benefit plans.

Last year, New York undertook extensive regulatory rulemaking that went far beyond what was originally included in the bill passed by the legislature. The legislation initially focused on setting licensure and disclosure requirements for PBMs, while the proposed rules included several additional provisions impacting benefits design such as anti-steerage provisions, minimum pharmacy reimbursement levels plus a statutory dispensing fee of $10.18 and restrictions on plan communications regarding pharmacy network options. The department rules were ultimately withdrawn last year, however, similar proposed rules were reintroduced this February.

Extraterritorial Enforcement

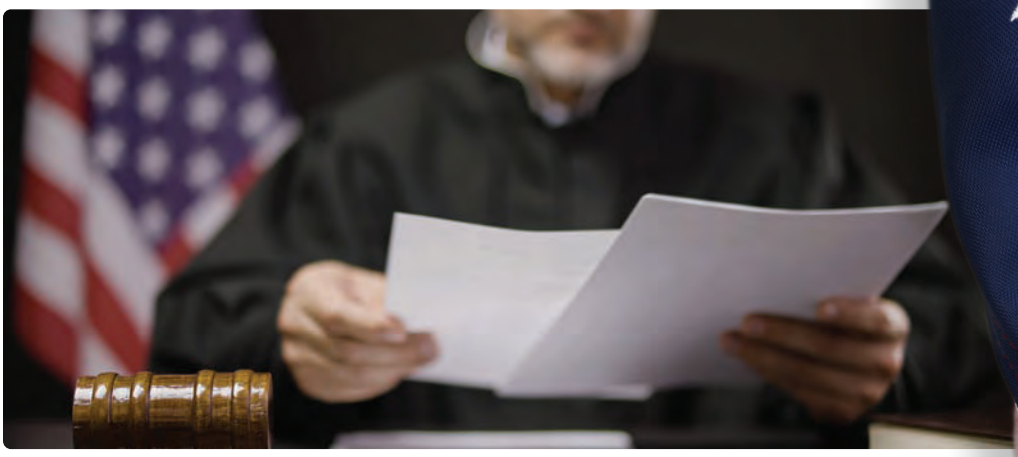
Arguably the most alarming trend observed in 2023 was the extraterritorial enforcement of state pharmacy benefit laws. **Extraterritorial enforcement occurs when a state seeks to enforce its law against out-of-state plans that have participants residing within that state.** For example, Oklahoma law prohibits plans from incentivizing participants to use mail-order pharmacies via lower copayments or reductions in cost-sharing. Historically, such a law was assumed to only apply to plan sponsors operating an Oklahoma-domiciled health benefit plan. However, in 2021, Oklahoma argued that 1) its law applied to self-funded ERISA plans and 2) its law extended to out-of-state plans by nature of a plan providing coverage to participants living in the state of Oklahoma. So, while a Kansas-based plan may select a national plan design that incentivizes mail-order pharmacies, that plan design would not be permissible for its participants based in Oklahoma.

In addition to Oklahoma, other states that have sought extraterritorial enforcement of their laws include Florida, Tennessee and Minnesota. These laws have created operational challenges and inefficiencies for plans seeking to operate uniform benefits schemes across state lines. Fortunately, solutions are available to accommodate some of these inefficiencies. For example, participants in certain states may be covered by a state-specific broad retail network to ensure participants are not incentivized to use a preferred or exclusive network. This state-specific network can operate independently without disrupting a plan sponsor's national plan design offered in other states.

These state laws present a novel issue that could be met with legal challenges based on the commerce clause of the U.S. Constitution. A long-standing judicial interpretation of the commerce clause forbids states from passing laws that regulate out-of-state activity. Similar arguments have been made in previous cases challenging state generic drug pricing laws.

ERISA Preemption Concerns

Plan sponsors monitoring the unique laws of every state in which they provide coverage to participants is part of the fundamental issue that the Employee Retirement Income Security Act (ERISA) sought to solve. An ongoing case challenging the enforcement of state pharmacy benefit legislation against ERISA plans is PCMA v. Mulready. This case challenges the Oklahoma Patient's Right to the Pharmacy Choice Act, the same law discussed previously, based on ERISA preemption grounds and is the most significant legal development in the industry since the Supreme Court's consideration of Rutledge v. PCMA in 2020. The Oklahoma law in question prohibits the utilization of preferred pharmacy networks and incentivizing the use of mail-order pharmacies via cost-sharing discounts or reductions in copayments.



In August 2023, a three-judge panel for the 10th Circuit Court of Appeals held that the Oklahoma law was preempted by ERISA, meaning the law was unenforceable against self-funded ERISA plans. Shortly after the circuit court's ruling, the Oklahoma insurance commissioner filed a motion for a rehearing and a motion to stay the ruling pending appeal to the U.S. Supreme Court — this effectively would suspend the court's latest ruling while Oklahoma filed a petition for review by the U.S. Supreme Court. The court denied both motions.

Since the 2020 ruling in Rutledge, plan sponsors have been left in a state of uncertainty as to the extent of state laws that apply to their benefit plans. Rutledge involved an Arkansas pharmacy reimbursement statute which the U.S. Supreme Court said was not preempted by ERISA. States have broadly interpreted this ruling to allow for complete state regulation of PBMs without considering how the law impacts the underlying benefits plan. If the Supreme Court decides to reconsider the extent of ERISA preemption in the PBM space, it could provide welcomed clarification on the extent of the Rutledge decision's applicability and distinction between laws that mandate reimbursement levels and laws that dictate network composition, copay structure and other plan design features.

Considerations for Plan Sponsors

So far this year, new legislation that would impact network design has been introduced in Alabama, Indiana, Illinois, Kentucky, Massachusetts and Pennsylvania. With 2024 being an election year, much of the legislatures' time will be consumed with election business. The highest potential for bill passage will be before primary elections and after the general election during lame duck sessions.

Employers should remain aware of developments in the states where they have covered lives. Certain state laws may apply to out-of-state pharmacy benefit plans based on where a plan's participants are physically located. As this year marks the 50th anniversary of ERISA, discussions around the sustainability of ERISA preemption will be prevalent in the employee benefits industry. Employers Health will continue to monitor state and federal developments and advocate for strong protection of employer-sponsored health plans.

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