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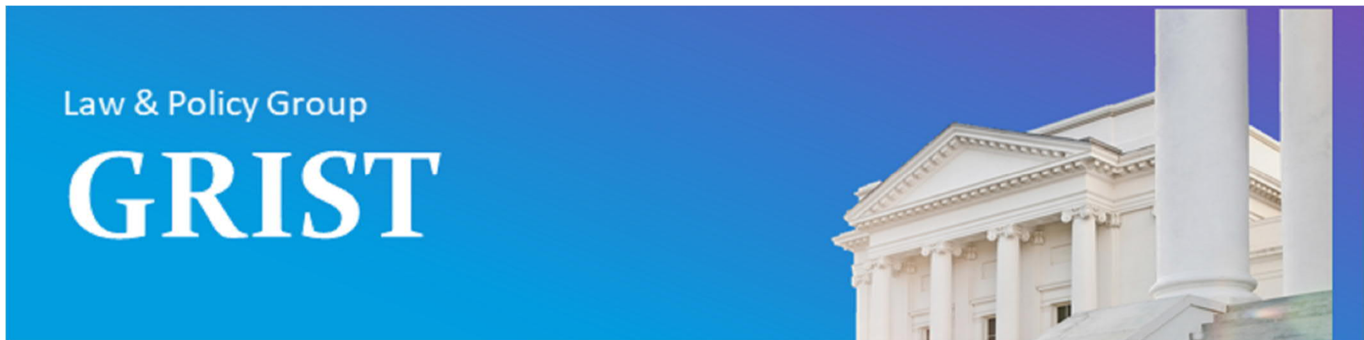

States seek to rein in Rx costs and pharmacy benefit managers

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Oct. 26, 2021

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Prescription drug costs and their impact on medical coverage have drawn the attention of state and federal lawmakers. While Congress continues to debate the best approach to control these costs, states have moved ahead with an assortment of measures in recent years. Since the US Supreme Court in late 2020 upheld a state law regulating certain contract terms between pharmacy benefit managers (PBMs) and network pharmacies, more states have taken the opportunity to regulate PBM contract provisions that lawmakers view as abusive to pharmacists and/or their patients.

Rutledge recap

In *Rutledge v. Pharmaceutical Care Management Association* (140 S. Ct. 812 (2020)), the US Supreme Court unanimously held that "ERISA does not pre-empt a state law that merely increases costs." The Arkansas statute at issue regulates only the relationship between PBMs and pharmacies. The law does not make "reference to" or have an "impermissible connection with" ERISA plans. Nor does the statute regulate plans themselves or their relationships with PBMs, pharmacies, or plan participants. Therefore, the court concluded that ERISA did not preempt the law.

This ruling has raised concerns among self-funded and fully insured group health plan sponsors that their prescription drug plans will have to comply with multiple and varied state regulations that may effectively reduce cost savings. Two competing perspectives have emerged post *Rutledge*:

- **Narrow scope.** The decision only impacts state laws — like the Arkansas statute — that merely increase PBMs' reimbursement costs. Other more expansive laws are preempted by ERISA.
- **Broader scope.** The decision could signal a trend where courts conclude that other types of state PBM laws are not preempted by ERISA.

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PBM overview

In general, PBMs serve as intermediaries between prescription drug plans and the pharmacies that plan participants use. PBMs develop and maintain formularies of covered medications on behalf of health insurers and self-funded plan sponsors. These lists affect which drugs plan enrollees use and determine out-of-pocket costs. PBMs contract directly with individual pharmacies to reimburse them for drugs dispensed to participants. PBMs also use their purchasing power to negotiate drug manufacturer rebates, discounts and other price concessions.

To lower costs, PBMs design strategies that may, in part, require or incentivize use of mail-order drugs for maintenance medication, steer patients to a particular pharmacy, or require the use of generics or specific preferred brands. PBMs may also include certain reimbursement restrictions in contracts with pharmacies and limit network availability to pharmacies owned or affiliated with the PBM. While these strategies may control costs, the PBM may realize added benefits — especially when it owns the preferred venue.

State objectives

Like lawmakers at the federal level, state legislators are concerned with prescription drug costs. Some PBM approaches are viewed as unfairly disadvantaging local pharmacies and hindering patient choice. Proposed and enacted state laws have attempted to end or limit these practices.

Post-*Rutledge* efforts

The *Rutledge* ruling has spurred states to study how they can regulate these PBM practices while avoiding ERISA preemption. Here are some of the common provisions:

- **Regulation.** A number of states now require PBMs to obtain a license and/or registration to operate in the state. This may lead to PBMs being treated as insurers in the future.
- **Transparency.** Some states require PBMs to report aggregated rebate or other information to the health plan and/or a state agency. To some extent, these requirements may overlap with federal requirements under the 2021 Consolidated Appropriations Act (Pub. L. No. 116-260) and/or the 2020 transparency in coverage regulations.
- **Any willing pharmacy (AWP).** These measures permit any pharmacy willing to comply with the plan's terms to join the network.
- **Maximum allowable cost (MAC) pricing standards.** These standards require PBMs to disclose to plan sponsors and pharmacies how MAC pricing is determined and updated and to establish an appeals process.
- **Spread pricing bans.** These measures bar a PBM from paying a pharmacy less than the PBM's cost for the drug.

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- **Mail-order limits.** These laws prohibit mandatory use of mail-order drugs.
- **Affiliate restrictions.** These measures require reimbursement parity between affiliated and nonaffiliated pharmacies so pharmacies owned by a PBM don't receive a higher reimbursement rate than other network pharmacies.
- **Anti-specialty.** These provisions prohibit a PBM from requiring a pharmacy to purchase a specialty drug directly from the PBM as a condition for participating in the PBM's network contract or for any other reason.
- **Anti-steering**. These laws limit a PBM's ability to require or encourage the use of a PBM-owned affiliated or other specific pharmacy.
- **Manufacturer rebate restriction.** These provisions require PBMs to pass any rebates from a manufacturer along to the health plan

Other state prescription drug laws

In addition to enacting PBM restrictions, state lawmakers have worked to increase transparency, including annual pharmacy cost and usage reports. Several states have or are attempting to hold prescription drug manufacturers accountable for price increases. These measures may include:

- Pharmacy cost review boards
- Cost-sharing restrictions
- Certain required drug plan designs

The National Association for State Health Policy (NASHP) has posted a chart of state drug-pricing laws from 2017 to 2021 across multiple categories, including PBMs, transparency, importation and cost sharing. PBM laws accounted for 111 laws across 46 states, according to the report. As of Oct. 14, 2021, 18 states imposed pharmacy cost-sharing restrictions during those years.

Interaction with group health plans

Many of the drug plan restrictions will directly affect insured health plans. Health insurers also may have to provide reports to regulators. How these laws apply to self-funded ERISA plans is less clear. Some laws, such as price review boards, have a very tangential application to health plans. However, to the extent that a prohibited (or required) activity applies to the PBM rather than the plan itself, a self-insured plan may see an impact because of the way the PBM must do business in a particular state. That could affect many programs that PBMs use to save plan sponsors money.

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Plan sponsor considerations

In many cases, a state law is silent on whether it applies to self-funded plans. Other state laws are specifically limited to fully insured plans. In a few cases, the law or related regulatory guidance may clearly indicate that a requirement applies to PBMs, regardless of fully insured or self-funded status. Where the law is unclear, its applicability to self-funded plans ultimately depends on how it is enforced by state regulators — like the state department of insurance — or interpreted by the courts. Any penalties related to a state PBM law typically apply to PBMs, not employer plan sponsors. However, plan sponsors should confirm PBM compliance as part of their ERISA fiduciary duties.

Some laws can have a material financial impact on plan sponsors, even though the laws are aimed at PBMs. As a result, how each law applies to self-funded plans is a relevant consideration. However, a plan sponsor's ability to mitigate the law's impact will vary by each measure. Plan sponsors will need to determine what, if any, actions are feasible to address the possible impact while remaining compliant.

Clinical considerations

PBMs typically have a provider-credentialing process that has clinical, operational and financial criteria to participate in the PBM's network and provide services to members. While all providers must meet minimum licensing criteria, a PBM's criteria may be more specific on one or more criteria. PBMs may seek an exception for certain performance guarantees if all providers are not subject to the same credentialing metrics. This variability is a greater concern regarding services for chronic care patients whose therapy includes specialty biotech medications. These medications often have more rigorous dispensing requirements so assuring the provider meets or exceeds these requirements is important. However, plan members usually will not have this information.

Chart: Recent state laws regulating drug costs

The chart starting on the next page offers a sampling of recently enacted state laws regulating prescription drug costs.

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State	Summary	Self-funded ERISA impact
Alabama	Act 2021-341, SB 227 • Expands the state's existing PBM regulation (AL Code § 27-45A) • Prohibits certain PBM practices in contracts with pharmacies and insured health plans: — Reimbursing a pharmacy an amount less than the PBM reimburses its own affiliated pharmacies — Paying a pharmacy an amount other than the contracted amount — Requiring or steering an insured to use a mail-order pharmacy or a PBM's affiliated pharmacy — Limiting pharmacy choice through incentives or disincentives — Restricting a pharmacist's ability to provide services to insureds — Using spread pricing • Requires a PBM to act as a fiduciary for its clients • Includes certain disclosure obligations • Applies to any covered individual who works in or is a resident of Alabama and to PBM contracts on and after Oct. 1, 2021	Unclear
Illinois	2021 Pub. Act 101-0452, HB 465 • Requires PBMs to obtain licenses to operate in Illinois • Sets contract requirements with health insurers and between PBMs and pharmacies that regulate: — Pricing — Reimbursement — Disclosure — Appeals — Gag clause ban • Grants plan sponsors certain disclosure and annual audit rights	No
Indiana	2021 Pub. L. No. 196, HB 1405 • Prohibits limiting a pharmacy's access to medication by imposing quantity or refill frequency restrictions that differ from those that apply to a PBM affiliate	Unclear
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State	Summary	Self-funded ERISA impact
Louisiana	2019 Act 124, SB 41 • Requires every PBM that does business in the state to obtain state licenses • Uses a PBM monitoring advisory council to oversee implementation • Limits spread pricing • Prohibits: — Any "unfair and deceptive trade practice" — Patient steering — Inducements, including incentives — such as variations in premiums and cost sharing — to use specific retail or mail order pharmacy — Retroactive denial or reduction of a pharmacist's or a pharmacy's claim — Reimbursements to a local pharmacist or a local pharmacy in an amount less than what chain, mail-order, specialty or affiliate pharmacies receive — Failure to honor MAC prices along with pharmacist and patient protections — Requirements for a pharmacy to purchase drugs from any particular wholesaler — Failure to comply with established payment standards — Restrictions on early refills of maintenance drugs	Unclear
Minnesota	2019 Ch. 39, SB 278 • Requires PBMs to obtain a license to do business in the state • Imposes standards for: — Network adequacy — Transparency — Conflict of interest — Handling of specialty drugs — Audit performance — MAC pricing • Prohibits — Gag clauses — Certain retroactive claim adjustments — Limits on synchronization of prescription drug refills	No

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State	Summary	Self-funded ERISA impact
Montana	2021 Ch. 501, SB 395 • Requires PBM licensure • Requires: — Transparency MAC reporting — Network adequacy standards — Disclosures to insurers and plan sponsors that include information on certain rebates and fees received, exclusivity arrangements, utilization data, and claim information	No
New Hampshire	2019 Ch. 320, SB 226 • Requires PBMs that operate in the state to register • Designates the Insurance Commissioner to issue rules and provide oversight • Includes: — Pharmacy contract stipulations related to pricing, reimbursements and pharmacist appeals — Reporting requirements and regulatory examination	No
Oklahoma	2019 HB 2632 • Sets network adequacy standards with specific requirements for preferred retail pharmacies • Requires AWP preferred participation status • Prohibits: — Certain steering — Retroactive claim denials — Gag clauses • Authorizes PBM regulation by Insurance Commissioner	No
South Carolina	2019 Act 48, SB 359 • Requires: — State licenses — Appeals process • Bans gag clauses • Provides for state-run audits	No

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State	Summary	Self-funded ERISA impact
Tennessee	2021 Ch. 569, HB 1398 • Prohibits PBM from interfering with a patient's right to choose a pharmacy, including through inducements, steering, or financial or other incentives • Requires patients to have the option to receive covered drugs and devices without additional cost sharing or limitations from a physician's office, a hospital outpatient infusion center providing and administering the drug, or a pharmacy • Limits spread pricing • Imposes on PBMs a fiduciary responsibility to report to the health plan and the patient any benefit percentage that either the plan or the patient is entitled to receive as a benefit • Imposes on health plans an obligation to provide on request certain prescription drug cost, benefit and coverage data • Builds on the state's existing PBM law (TN Code Ann. § 56-7-3101 *et seq.*) • Applies to "self-insured entities," according to Bulletin 21-01	Yes
Texas	2021 HB 1763 • Tightens restrictions on PBMs • Prohibits reducing pharmacy payments after adjudication, except as part of an audit • Bans PBMs from paying an affiliated pharmacy or pharmacist more than the amount paid to a nonaffiliated pharmacy	No

Texas	2021 HB 1919
	• Bans PBMs from requiring a patient to use an affiliated pharmacy to receive the maximum benefit
	• Prohibits implementing a plan that requires or induces a patient to use an affiliated pharmacy
	• Prohibits PBMs from engaging in the following practices:
	  – Soliciting a patient to transfer a prescription to an affiliated pharmacy
	  – Requiring an unaffiliated pharmacy or durable medical equipment provider to transfer a patient's prescription to one affiliated with the covered entity
		No

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State	Summary	Self-funded ERISA impact
West Virginia	2021 Ch. 164, HB 2263 • Requires PBM licenses • Adds a "freedom of consumer choice for pharmacy" provision to the state's existing pharmacy law (WV Code art. 33-51) • Adds pharmacy reimbursement restrictions • Requires PBMs to allow patients to select a pharmacy of choice • Imposes AWP requirement • Bans gag clauses • Provides pharmacists the right to participate the plan if the Prohibits mail-order pharmacy cost benefit and mail-order only benefits • Requires reducing patients' cost sharing by any rebates	Unclear

Related resources

Non-Mercer resources

- *PCMA v. HHS*, No. 1:21-cv-02161 (D.DC Aug. 12, 2021)
- 2021 state legislative action to lower pharmaceutical costs (NASHP, July 7, 2021)
- Legislative approaches to curbing drug costs targeted at PBMs: 2017–2021 (NASHP, June 14, 2021)
- Pub. L. No. 116-260, the Consolidated Appropriations Act, 2021 (Dec. 27, 2020)
- *Rutledge v. Pharm. Care Mgmt. Ass'n*, 140 S. Ct. 812 (2020)
- Transparency in coverage regulations (Federal Register, Nov. 12, 2020)
- *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 US 645 (1995)

Mercer Law & Policy resources

- Supreme Court upholds Arkansas law regulating PBMs (Dec. 10, 2020)
- US Supreme Court declines to hear Maryland drug-pricing case (March 1, 2019)

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