Gallagher

Compliance Directions

A Balancing Act: State PBM Laws and ERISA Preemption

Gallagher

Over the past decade, individual states have taken their own stances on regulation of pharmacy benefit managers (PBMs), primarily to increase transparency in the market, lower prescription drug prices for their residents, and protect brick-and-mortar pharmacies. Today, all 50 states have some form of law regulating PBMs. Below are the major targets of state PBM laws, listed from most to least common.

- Prohibitions on gag clauses
- Limitations on participant cost sharing
- Licensing of PBMs to do business in the state
- Disclosures on rebates and requirements to share rebates
- Prohibiting discrimination against 340B entities and out-of-network pharmacies
- Standardizing maximum allowable cost (MAC) lists[1]
- Prohibitions on clawbacks and spread pricing[2]
- Establishing state ability to audit PBM and enforce law
- Instituting network standards (e.g., no exclusion of brick and mortar pharmacies)
- Placing fiduciary duty on PBM to insurer

While some of the state law provisions have no impact on the associated health plan (e.g., licensing), other provisions have a direct or indirect impact. For instance, a state law might prohibit a PBM from offering a health plan with more favorable participant cost sharing when using a mail order network pharmacy. If a PBM is prohibited from selling that plan feature in states with such a prohibition, then that law impacts the design of the PBM clients' health plans. Whether and how the state PBM laws apply to employer-sponsored health plans is a multi-prong consideration, as further discussed below.

[1] MAC lists are produced by PBMs and list the products that the PBM covers with a maximum amount it will pay for generic and brand name drugs with generic versions available.

[2] Spread pricing is the difference between what a PBM charges a health plan for a particular drug and what it pays the pharmacy for dispensing that drug. The PBM keeps the difference, which is the "spread."

Fully Insured Health Plans

While ERISA preempts state laws that relate to ERISA plans, the statute also includes a "savings" clause which permits states to regulate insurance, including fully insured ERISA plans. A fully insured health policy issued in a state with a PBM law is subject to that PBM law when the law is written to apply to plans written or issued in that state. This is generally true no matter who the sponsor is – a private, public, or church employer. As such, a fully insured health policy received by any employer in that state will include the state-required provisions, and the insurer (or PBM) will typically comply with any necessary requirements associated with the law.

There are potential arguments for ERISA preemption of some PBM state laws because the "savings" clause is meant to "save" clauses that regulate insurance, not plan service providers, such as PBMs. In reality, fully insured plan sponsors are subject to whatever laws their insurer or PBM interpret to be applicable.

Self-Insured Health Plans

Governmental and Church Plans

A state PBM law will apply to a state or local government plan in that state unless the terms of the particular law exempt such plans from the requirements. Health plans sponsored by churches are subject to the same consideration – if the state law incorporates the plan type (e.g., all self-insured plans), then it applies to church plans, unless the plan has elected to be an ERISA plan. In that case, see ERISA plans below.

ERISA Plans

Private employers that sponsor group health plans for their employees are subject to ERISA. ERISA, a federal benefits law, preempts a state law that "relates to" ERISA plans, including when the law has an *indirect* impact on ERISA plans, if it affects a central matter of plan administration and interferes with nationally uniform plan administration. Preemption of a state law is not an easy, clear cut determination. There are hundreds of ERISA preemption cases since the passage of ERISA in 1974, and a handful of cases that provide a roadmap on ERISA preemption of certain provisions of state PBM laws. To determine whether a law or provision is preempted by ERISA, a court must analyze how each specific provision relates to ERISA plans and whether it creates an impermissible connection.

PBM Laws that Merely Increase Plan Costs

The U.S. Supreme Court decision in *Rutledge v. Pharmaceutical Care Mgmt. Ass'n (PCMA)* determined that Arkansas Act 900, enacted in 2015, was not preempted by ERISA. The Act requires PBMs to reimburse Arkansas pharmacies at rates that are equal to or higher than the pharmacy's acquisition cost for the drug (i.e., prohibition of spread pricing) by requiring PBMs to update MAC lists when wholesale prices increase, permits pharmacies to decline selling a drug with a low reimbursement rate, and provides pharmacists the ability to appeal to obtain higher reimbursement rates.

The potential impact on ERISA plans of eliminating spread pricing in Arkansas (and other states with similar restrictions) would be increased costs of doing business in the state if the PBM charged those increased reimbursements back to the plan. As noted by the Court, the Act is "merely a form of cost regulation" that does not "effectively dictate plan choices" and thus does not "interfere with nationally uniform plan administration." Although ERISA plans are likely to adjust their plan designs to limit the economic effect, the Court determined that such decisions are immaterial, as ERISA does not preempt state laws that merely increase costs.

After the Rutledge decision, the Supreme Court also vacated and remanded an 8th Circuit decision that found a North Dakota law to be preempted in *PCMA v. Wehbi*. In that case, the PBM law requires PBMs to abide by various requirements (e.g., reporting, sharing information with the plan or participants, network adequacy). Upon rehearing, the 8th Circuit reversed their decision, finding that the entire law was not preempted by ERISA because the requirements were a noncentral matter of plan administration, with de minimis economic effects, that did not prevent national uniformity in administration.

PBM Laws that Impact Plan Networks and Design

After *Rutledge*, states began to pass more complex PBM laws. For example, Oklahoma's PBM law requires PBMs and insurers to provide retail pharmacy access (i.e., prohibiting mail-order only plans), admit willing pharmacies into their networks, and prohibit requiring or incentivizing participants to use network pharmacies through reduced cost sharing or copay discounts. The law also prevents insurers and PBMs from denying network contracts to pharmacists on probation with the pharmacy board.

Soon after its passage, PCMA (a national association of PBMs) sued Oklahoma in *PCMA v. Mulready*, arguing that the entire law should be preempted because it has an impermissible connection to ERISA plans. The lower court, incorrectly relying on *Rutledge*, found that the law was not preempted, but on appeal, the 10th Circuit agreed

with PCMA on the majority of the provisions, except for the prohibition on exclusions of pharmacists on probation. Oklahoma appealed to the U.S. Supreme Court, but in June 2025, the Court denied the petition for review, allowing the 10th Circuit decision to stand. As a result, state PBM laws in the 10th Circuit that dictate plan design, including network adequacy considerations, are preempted by ERISA. However, considering the 8th Circuit's decision in *Wehbi*, which determined the preemption status of a North Dakota PBM law which included network adequacy standards (along with other provisions that do not directly or indirectly impact ERISA plans), it is unclear how sweeping the *Mulready* decision is.

PBM Laws that Require Reporting or Attestation

Another type of PBM law is one that requires reporting or attestation of compliance. For example, Arkansas Rule 128 requires fully insured and self-insured health plans to submit pharmacy compensation data, though it also includes an exemption for federally regulated plans (e.g., ERISA plans). By its own language, it is unclear if it applies to ERISA plans, but the state is taking the position that it applies, unless the plan covers fewer than 5,000 Arkansas residents. Other states, like Florida, require an annual PBM attestation of compliance with the network adequacy standards.

There is no specific case law on state PBM reporting or attestation requirements yet; however, an older Supreme Court case – *Gobeille v. Liberty Mutual Ins.* – guides the preemption analysis. In that case, Vermont enacted an all-payers database and required insurers and self-insured plans to submit claims information on an ongoing basis. The Court determined the reporting requirement was preempted for self-insured ERISA plans because the administrative tasks required by the law intruded on the extensive federal reporting already required under ERISA and if other states passed similar requirements, it would "create wasteful administrative costs and threaten to subject plans to wide-ranging liability." Fully insured plans remain subject to the law.

Florida anticipated that the stakeholders would argue that the attestation requirement is preempted by ERISA and spent time in the bill's fiscal analysis attacking the preemption argument under *Rutledge*, arguing that the requirement is merely a form of cost regulation. While the Arkansas and Florida laws may not create equally onerous tasks as the Vermont law, as more states enact similar requirements, ERISA plans would be subject to a growing number of administrative costs and liability.

There is an argument these provisions are preempted under *Gobeille*, but unfortunately, until the courts opine, the risk of avoiding compliance in the absence of a clear court decision is facing state enforcement and liability.

Action Steps

For now, we know that *Rutledge* does not preempt PBM regulations that merely increase the cost of doing business in the state. *Mulready* preempts plan design requirements, including network adequacy, in PBM laws in the 10th Circuit, but network considerations are likely not preempted pursuant to *Wehbi* in the 8th Circuit. Finally, *Gobeille* provides an argument that ongoing reporting and attestations are preempted but the court in *Wehbi* did not preempt the North Dakota reporting requirement on PBMs in the 8th Circuit. All in all, the only thing that is clear is that PBM laws that merely increase plan costs, without more, are not preempted. Most other types of provisions, because of disagreements amongst the circuits, are still up for debate.

Any state PBM law preemption discussion should involve outside counsel and the plan's PBM. At times, PBMs have taken conflicting positions on a law or chosen to mitigate potential risk for plan sponsors by submitting to the law despite the preemption argument. It is important to have these discussions with your PBM, so you know which state laws the PBM is complying with (and which ones it isn't) on the plan's behalf.

The intent of this article is to provide general information on employee benefit issues. It should not be construed as legal advice and, as with any interpretation of law, plan sponsors should seek proper legal advice for application of these rules to their plans.