Legislative Trends in State Regulation of PBMs

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In recent years, nearly 40 states have passed a multitude of laws that regulate pharmacy benefit managers (PBMs) and, by extension, employer-sponsored health plans. The most prevalent topics of state legislation occurred in the areas of drug price transparency and reimbursement, pharmacy audit standards and copay accumulator programs. Employers Health recognizes the challenges that plan sponsors face in light of these regulations and recently filed an amicus curiae brief with the Supreme Court of the United States to protect the interests of its plan sponsors.

Certainly, non-Employee Retirement Income Security Act (ERISA) groups must take heed of state regulatory efforts, but ERISA groups that have long benefited from ERISA's shield from state regulatory efforts must keep a watchful eye on existing and proposed regulations given the mechanisms of application and recent legal challenges. Success of such legislation may give rise to a patchwork of state regulation that undermines consistent national plan design and negatively disrupts the economic model that a plan sponsor's pharmacy benefit is based upon. One such state law, Rutledge v. PCMA, has made it all the way to the Supreme Court of the United States.

State Regulation of Pharmacy Reimbursement by PBMs

Rutledge v. PCMA involves an Arkansas statute (Act 900) that prohibits negative reimbursement by requiring PBMs to reimburse pharmacies at or above pharmacies' drug acquisition costs. Additionally, the statute requires PBMs to:

- **update maximum allowable cost (MAC) lists within 7 days of an increase in a pharmacy's acquisition cost,**
- **establish an appeal process for pharmacies to challenge and re-rebill claims at a higher rate and**
- **allow a pharmacy to decline to dispense prescriptions at the point of sale, if the pharmacy believes that it would lose money on the transaction.**

The Pharmaceutical Care Management Association (PCMA) challenged this law as violating ERISA. On June 8, 2018 the U.S. Court of Appeals for the Eighth Circuit ruled that Act 900 was preempted and thus unenforceable as applied to ERISA covered health plans. The Arkansas Attorney General appealed the Eighth Circuit's decision on whether Act 900 is preempted by ERISA. The Supreme Court agreed to hear the case this term.

As ERISA is a federal law that regulates employer-sponsored benefit plans and provides express federal preemption of state laws that relate to an employee benefit plan, ERISA is essential to protecting plan sponsors from having to comply with an irregular patchwork of state laws that create disparities and administrative inefficiencies.

TO THAT END, ON APRIL 1, EMPLOYERS HEALTH FILED AN AMICUS CURIAE, OR FRIEND OF THE COURT, BRIEF SUPPORTING THE EIGHTH CIRCUIT'S HOLDING THAT ACT 900 IS PREEMPTED BY ERISA.

Employers Health believes it is vitally important that ERISA plans continue to be protected from state laws that interfere with benefit plan administration. State specific pricing and reimbursement legislation that override network contracts create inconsistency within the benefit plan. The ability for an in-network pharmacy to decline to dispense a participant's medication creates access issues. Moreover, the ability to reverse and rebill below-cost transactions if the pharmacy concludes that the MAC rate is below the pharmacy's acquisition cost is especially concerning for participant and plan cost sharing. If laws like Act 900 are upheld, ERISA plans would be forced to comply with the laws of every state in which participants and their beneficiaries fill prescriptions. In order to ensure plan viability, these extra hurdles will force plans to reevaluate plan design such as benefit coverage and participant cost sharing.

With similar laws pending in many states, the Supreme Court's decision will have important legal and practical implications for ERISA plans and the employees they cover. This case is the Supreme Court's first opportunity to consider the scope of ERISA preemption since its decision four years ago in Gobeille v. Liberty Mutual Insurance Company, where the Court took a helpfully broad approach to ERISA preemption. Oral arguments are expected to occur later this year.

AT LEAST 38 STATES HAVE ENACTED LAWS REGULATING THE CONDUCT OF PBMS IN A VARIETY OF WAYS.

State Regulation of PBM Operations

Another development in state legislation is that some states are considering requiring PBMs to act as fiduciaries in their administration of pharmacy benefits. Nevada has implemented a law specifying that a PBM has a fiduciary duty to a third party with which it has entered into a contract to manage that party's pharmacy benefit plan. This legislation means that the PBM must act in the best interest of the consumers it serves, rather than the underlying health plan. Similar legislation is being considered in Florida, Hawaii and Illinois.

A majority of states have enacted some form of a fair pharmacy audit bill, which subjects PBMs to audit standards by placing guidelines on when and how pharmacy audits are conducted by PBMs. These standards may include:

- **providing a pharmacy at least 10 days' notice of a PBM's intent to audit,**
- **allowing PBMs to recoup costs from pharmacies only if errors are substantive and not merely typographical or clerical in nature and**
- **limiting audit look-back periods.**

As states face rapid growth in prescription drug spending, transparency in the pharmacy supply chain is increasingly seen as an approach to mitigate cost. Many state laws attempt to mandate transparency by requiring PBMs to report certain cost information about rebates and pricing methodology.

TO DATE, 36 STATES AND COUNTING HAVE ENACTED LEGISLATION REGULATING PBMS' PHARMACY REIMBURSEMENT PRACTICES.

Copay Accumulator Regulation

Many states drafted bills similar to the Department of Health and Human Services' (HHS) proposed federal rule regarding the prohibition of copay accumulator programs. As readers may recall, the HHS proposed rule was finalized April 25, 2019, but a few months later, the Department of Labor (DOL), HHS and Department of the Treasury (USDT) collectively announced that the Departments would not enforce the regulation in 2020 amid confusion about the rule's application. The rule, as originally drafted, would have potentially required drug manufacturer coupons for drugs without a generic equivalent to accumulate toward a participant's annual out-of-pocket spending requirements.

On May 14, 2020 HHS finalized the Notice of Benefit and Payment Parameters for 2021. Effective July 13, 2020, this new finalized notice revises the 2019 proposed rule and clarifies that direct support offered by a drug manufacturer for specific prescription drugs may be counted toward an enrollee's annual limitation on cost sharing provided the support does not conflict with any state law. Thus, at the objection of manufacturers and certain advocacy groups, the language does not require the coupon be counted towards participant cost sharing and removes the language narrowing the application of the notice to brand drugs with a generic equivalent.

The intersection with state law contemplated in this notice must be noted. To that end, several states such as Arizona, Illinois, Virginia and West Virginia have passed laws banning certain copay accumulator programs while many other states have followed suit with pending legislation. However, Rhode Island and Kentucky have pending bills that would enforce the opposite; these bills prohibit manufacturer cost assistance from being applied toward any cost sharing owed by the plan participant.

The impact and applicability of such regulations varies based on the mechanism of regulatory action. Legislation specifically regulating insurance and plan design should be viewed very differently than legislation governing PBMs and how claims are adjudicated. For example, many stated have passed legislation or have existing laws that cap insulin cost sharing. As such laws regulate insurance and benefit design, these laws generally do not impact self-funded ERISA plans. However, to the extent states seek to accomplish their aims by regulating the PBM or the PBM-pharmacy relationship, ERISA plan sponsors must take notice.

Final Thoughts

Given the complexity of the pharmacy benefit ecosystem, there are a myriad of different components that states may seek to regulate. Prudent plan sponsors should continue to monitor state regulatory efforts and proceed with the knowledge that these efforts will only increase. Employers Health will continue to advocate for its plan sponsors and will continue to monitor developments as they arise.

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