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EMPLOYEE BENEFITS

Florida Prescription Drug Act

On May 3, 2023, Florida Governor Ron DeSantis signed the Florida Prescription Drug Reform Act ("the Act") into law. The Act can potentially impact many group medical/prescription drug plans and the employers that sponsor them. This article identifies the key effects the Act could have on employers and their medical/prescription drug plans, discusses the issues plan sponsors should review/consider when determining the scope of the impact and suggests some next steps plan sponsors should consider taking.

While the Act will impact fully insured and self-insured plans, this article is primarily relevant to employers sponsoring self-insured plans.

Regulation of Contracts with PBMs

The Act directly impacts employers that sponsor self-insured group medical/prescription drug plans because one section of the Act regulates the content of the contract between the group medical/prescription drug plan and the plan's pharmacy benefits manager (PBM). This portion of the Act:

- Requires the contract between the plan and PBM to use pass-through pricing and prohibits the use of spread pricing.²
- Requires the contract between the plan and PBM to include provisions ensuring funds received in relation to providing services for a plan or a pharmacy are used or distributed only pursuant to the contract with the plan or pharmacy or as required by applicable law.
- Requires the contract between the plan and PBM
 to provide that the PBM will pass through 100% of
 manufacturer rebates (if the contract delegates the
 negotiation of rebates to the PBM) and that those
 rebates will be used for the sole purpose of offsetting
 defined cost sharing and reducing premiums of
 participants.
- Requires the contract between the plan and PBM to include network adequacy requirements that meet or exceed Medicare Part D program standards for convenient access to network pharmacies.

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¹ See FL Stat. § 626.8825(2). The term "pharmacy benefit manager" is defined as "a person or an entity doing business in this state which contracts to administer prescription drug benefits on behalf of a pharmacy benefits plan or program."

² "Spread pricing" occurs when the health plan payment to the PBM exceeds actual amounts paid to the pharmacy by the PBM.

- Requires the contract between the plan and PBM to:
 - » Extend the network beyond pharmacies affiliated with the PBM.
 - » Include provisions that require the PBM to offer contracts to licensed pharmacies physically located at the site of certain specified providers for the administration or dispensing of drugs that are "administered through infusions, intravenously injected, or inhaled during a surgical procedure or are covered parenteral drugs, as part of onsite outpatient care."
 - » Permit participants to receive prescription drugs through retail pharmacies without requiring participants to use the PBM's mail order service unless the drug cannot be acquired at any retail pharmacy in the plan's network. However, the PBM may operate a mail-order program on an opt-in basis so long as the participant is not penalized for not using the mail-order program.
 - » Not require a covered person to receive pharmacist services from an affiliated pharmacy or healthcare provider with respect to in-person administration of covered prescription drugs.
 - » Prohibit (1) offering pharmacy networks that require or provide incentives (other than a reduced costsharing amount or enhanced quantity limits) for the use of affiliated pharmacies or healthcare providers for in-person administration of prescription drugs and (2) advertising, marketing or promoting an affiliated pharmacy (except that the PBM can include affiliated pharmacies in communications regarding all network pharmacies if treated equally).
- Requires the contract between the plan and PBM to prohibit the PBM from conditioning participation in a pharmacy network on participation in any other pharmacy network and from penalizing a pharmacy for not agreeing to participate in a specific network.
- Requires the contract between the plan and PBM
 to prohibit the PBM from instituting a network that
 requires a pharmacy to meet accreditation standards
 inconsistent with or more stringent than applicable
 federal and state licensing requirements. However, the
 PBM may specify specialty networks that require certain
 enhanced standards for participation if certain specified
 conditions are met.
- Requires the contract between the plan and PBM to require the PBM and the group medical/prescription plan to provide a 60-day continuity of care period following revision of the formulary (with limited exceptions).

The Act also requires pharmacy benefit plans to annually submit to the State an attestation that the plan is compliant with the Act. Fully insured plan sponsors with plans administered through Florida-licensed insurance carriers may request their insurer to complete the annual attestation on their behalf. Self-funded pharmacy benefit plan sponsors may be responsible for submitting the attestation directly with the Florida Office of Insurance Regulation (OIR), attesting that the pharmacy benefit plan is compliant with the law. The Act is unclear when the due date of the attestation is, but a best practice could be submitting the attestation to OIR by the end of each calendar year. The Florida OIR has made available a template attestation and provides some basic instructions for submitting the attestation on its website. Some third-party administrators (TPAs) and pharmacy benefit managers (PBMs) have suggested that a self-funded pharmacy benefit plan need only file an attestation if the self-funded plan is ERISAexempt (e.g., church or non-federal governmental plans). We recommend that plan sponsors consult with their legal counsel to determine whether they are subject to the attestation requirement.

The Act includes a variety of other provisions outside this article's scope. For example, the Act also regulates the content of contracts between PBMs and participating pharmacies³ and prohibits PBMs from engaging in certain practices.⁴

³ FL Stat. § 626.8825(3).

⁴ FL Stat. § 626.8827.





Application to an Employer and Its Plan

Whether the Act will impact a particular plan sponsor and its group medical/ prescription drug plan will depend on a couple of key factors:



Who does the plan cover?

The Act specifically applies to all contractual arrangements between a PBM and a "pharmacy benefits plan or program." The Act defines the term "pharmacy benefits plan or program" to mean "a plan or program that pays for, reimburses, covers the cost of, or provides access to discounts on pharmacist services provided by one or more pharmacies to covered persons *who reside in . . . this state.*" Accordingly, the Act applies to any group medical/prescription drug plan covering any individuals residing in Florida regardless of where the plan sponsor is located and whether the plan is fully insured or self-insured.

The scope of the Act is potentially broader. The Act also refers to covered persons who "are employed by or receive pharmacist services from this state." The meaning of this phrase is unclear. The State could interpret it to mean that the Act applies if a group medical/prescription drug plan covers individuals working in Florida who reside elsewhere and if a group medical/prescription drug plan provides benefits for prescription drugs obtained from a pharmacy located in Florida (regardless of where the individual resides or works).



Does the PBM contract have provisions that conflict with the requirements of the Act, or is the PBM contract missing provisions required by the Act?

Given the broad scope of the Act, most current PBM contracts likely will not be fully compliant with the Act, but the number of conflicting or missing provisions will vary from contract to contract.

Effective Date

The provision of the Act regulating the content of the contract between the group medical/prescription drug plan and the plan's PBM is effective with respect to contracts executed, amended, adjusted or renewed on or after July 1, 2023, that apply to pharmacy benefits covered on or after January 1, 2024. For many plan sponsors, the Act will apply beginning January 1, 2024. In some cases, the applicable date could be later, depending on the term of the existing contract with the PBM and whether it is amended or adjusted on or after July 1, 2023.⁶





⁵ FL Stat. § 626.8825(1)(u).

 $^{^{\}rm 6}$ For example, the contract with the PBM may be adjusted as the result of an annual market check.

ERISA Preemption

Section 514 of ERISA generally preempts the application of a state law to a self-insured ERISA plan when the state law has a connection with or a reference to an ERISA plan. We previously wrote an article regarding the application of Section 514 to state PBM regulation in light of the Supreme Court's decision that ERISA did not preempt an Arkansas law regulating PBMs. Following that Supreme Court decision, some courts have determined that ERISA does not preempt state laws regulating PBMs, while the Tenth Circuit recently issued an opinion determining that some provisions of an Oklahoma law regulating PBMs (including some provisions that could be characterized as being similar to provisions found in the Act) are preempted by ERISA.

At present, the scope of ERISA preemption with respect to state laws regulating PBMs and their relationships with self-insured group medical/prescription drug plans is unclear and in flux. As a result, it is unclear whether any of the Act's requirements identified above that relate to the content of the PBM contract are preempted and unenforceable against a self-insured group medical/prescription drug plan subject to ERISA. Ultimately, a court will need to make that decision, and until that occurs, the state of Florida may take action to enforce the law against PBMs and self-insured group medical/prescription drug plans.

Next Steps

An employer that sponsors self-insured medical/prescription drug plans should consider taking the following actions related to the Act:

- Determine whether and when the Act will apply to its group medical/prescription drug plan and its contract with the PBM. The Act clearly applies if the plan covers any residents of Florida. If an employer's plan does not cover any residents of Florida, the application of the Act is unclear. As noted above, the State could take the position the Act applies to plans that do not cover Florida residents if certain other conditions exist. Employers will need advice from qualified legal counsel in this situation.
- Have legal counsel review its PBM contract to determine what, if any, changes would need to be made to the contract to bring it into compliance with the Act and evaluate the impact of making those changes.
- Obtain information about the PBM's position regarding the application of the Act to the contract. Is the PBM taking the position the contract must be modified to comply with the Act, or is it acknowledging the possibility the ERISA may preempt certain portions of the Act?
- If the PBM is not automatically adjusting its contracts to comply with the Act and is giving plan sponsors some discretion regarding the changes to be made, consult qualified legal counsel for advice about how to proceed and the risks associated with not conforming the terms of its PBM contract to the requirements of the Act.







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