
DeSantis Signs Florida Prescription Drug Reform Act

May 2023

Florida Governor Ron DeSantis signed into law the Prescription Drug Reform Act (the Act) regulating pharmacy benefit managers (PBMs), their contracts with pharmacies, and nearly all sponsors of health plans in Florida.

The Act will affect self-funded ERISA-governed, fully insured, and governmental health plans, as well as state-funded, Medicaid, Medicare Advantage, and Medicare Part D plans. Florida residents and plans with Florida employees, and participants receiving pharmacy benefits within Florida, will also be affected.

This Aon bulletin addresses the Act's provisions regarding:

- Regulation of PBM contracts with group health plans;
- ERISA preemption and the Act;
- Regulation of PBM contracts with pharmacies;
- Price transparency reporting required for drug manufacturers;
- Florida licensing of PBMs; and
- Enforcement provisions.

Regulation of PBM Contracts With Group Health Plans

The Act regulates the PBM's relationship with a group health plan by defining the PBM as an "administrator" of the plan. The Act requires contract terms between the PBM and the plan that will affect the structure of pharmacy networks, the choice of networks available to a plan, the delivery and availability of certain prescription drugs, and potentially the cost-sharing for participants.

The Act sets out additional terms for a contract between a PBM and a group health plan that is executed, amended, or renewed on or after July 1, 2023, which applies to pharmacy benefits covered on or after January 1, 2024. Such contracts must:

- Use a pass-through pricing model, such that a plan payment is paid in its entirety to the pharmacy or provider;
- Prohibit financial clawbacks, reconciliation offsets, or offsets to adjudicated claims;
- Exclude spread pricing practices, direct or indirect;
- Require the PBM to pass to the plan 100 percent of any manufacturer rebates it receives to offset cost-sharing and reduce premiums of participants;
- Include network adequacy requirements that meet or exceed Medicare Part D standards and that:

- Prohibit “steering” (limiting a network to only affiliated pharmacies);
 - Require a PBM to offer network contracts to pharmacies on certain specialized sites;
 - May not require participants to use mail order, but may permit participants to opt into mail order, provided that the participant is not penalized through the imposition of any additional retail cost-sharing obligations or a lower allowed quantity limit for choosing not to select the mail order or delivery programs;
 - Prohibit requiring use of an affiliated pharmacy or provider for in-person administration of covered drugs; and
 - Prohibit pharmacy networks that provide incentives to participants to use an affiliated pharmacy or health care provider.
- Prohibit conditioning participation in one pharmacy network on participating in another or penalize choice of a network;
 - Prohibit networks from imposing pharmacy accreditation standards inconsistent with, or more stringent than, federal and state requirements for operation in Florida; and
 - Require that a plan annually attest to compliance with the contract provisions between a PBM and the plan.

A PBM must commit to updating “maximum allowable cost” pricing information regularly. PBMs and group health plans must provide patient protections upon midyear changes in formularies, such as a 60-day continuity-of-care period without change in cost-sharing, unless the applicable drug has been made available over-the-counter, withdrawn, or recalled from the market.

PBMs will be subject to the limitations on step therapy that apply to Florida insurers, which require procedures for protocol exemptions, yet do not require an insurer to change its formulary. Insurers must also prohibit a PBM from requiring an insured to pay more for a prescription drug at the point of sale than the lesser of the cost-sharing amount or the retail price.

ERISA Preemption and the Act

ERISA generally preempts state laws that relate to benefit design, interfere with uniform plan administration, or refer to ERISA plans. In *Rutledge v. Pharmaceutical Care Management Association (PCMA)*, however, the Supreme Court limited the scope of ERISA preemption, holding that ERISA did not preempt an Arkansas PBM law that only increased costs or altered incentives for an ERISA plan without forcing the plan to adopt any particular scheme of substantive coverage. A similar Oklahoma law is on appeal to the 10th Circuit in *PCMA v. MulReady*. Whether the Act can meet this standard and avoid ERISA’s preemption provisions is likely to be the subject of litigation.

Regulation of PBM Contracts With Pharmacies

The Florida law also regulates the contractual relationship between PBMs and pharmacies. The Act:

- Requires remittance detail information upon adjudication or reimbursement, including network and plan information;
- Prohibits clawbacks or reconciliation offsets, including by charging remuneration or dispensing fees, or making brand name or generic rate adjustments, except in limited circumstances;
- Prohibits a PBM's unilateral change of terms of the contract;
- Prohibits a PBM from prohibiting a pharmacy from charging a shipping or handling fee to a covered person if certain conditions are satisfied;
- Requires a PBM to disclose to a pharmacy a list of benefit plans for which the pharmacy is in-network, which the pharmacy may make public;
- Provides for a reasonable administrative appeal procedure to allow a pharmacy to challenge maximum allowable cost-pricing and reimbursements;
- Allows the pharmacy to disclose certain information to participants, including information related to treatment, alternative drugs, plan coverage and cost-sharing relative to retail prices and alternatives;
- Allows the pharmacy to disclose certain information to the state, including related to incentives or claim adjudication;
- Prohibits the PBM from disclosing to a pharmacy protected health information for non-plan commercial purposes;
- Requires the PBM to make pharmacy reimbursements during the contract term; and
- Prevents retaliation.

The effective date of this provision of the Act is the same as the effective date for the provision regulating a contract between the PBM and a group health plan.

Price Transparency Reporting Required for Drug Manufacturers

The Act requires drug manufacturers to notify the State of Florida of reportable drug price increases on the effective date of the increase and to report annually and, in some cases, justify drug prices increases for a prescription drug with a wholesale acquisition cost of at least \$100 for a course of therapy. The reporting threshold is either any increase of 15 percent of the wholesale acquisition cost during the preceding 12 months or any 30 percent cumulative increase during the preceding three years. Florida's agencies will post the reports online (excluding trade secrets) and compile information for the governor and the legislature.

Florida Licensing of PBMs

The Florida law regulates PBMs by requiring application to and authorization from the state to act as administrator. PBMs will be required to disclose affiliated organizations, complaints and settlement agreements, and be subject to biennial investigations. The required terms for PBM contracts with

pharmacies and group health plans include significant substantive provisions that reform how PBMs may conduct business within Florida.

PBMs acting as an administrator for plan participants who are residents of Florida are subject to these rules, except to the extent not allowed by law. If a PBM is licensed out-of-state, and acts as administrator for less than 100 lives under the applicable plans, the administrator requirements do not apply.

Enforcement

Penalties for a PBM failing to obtain or maintain authorization as an administrator may be \$10,000 per violation per day. Violations of other requirements may result in an administrative fine of \$5,000 for each violation. Among the other enforcement mechanisms available to the Florida Office of Insurance Regulation, the Act specifies penalties for certain violations. Penalties for a PBM failing to obtain or maintain authorization as an administrator may be \$10,000 per violation per day. Failure to comply with the Act's consumer complaint procedures may result in penalties of up to \$2,500 per violation upon an any entity and increasing penalties up to \$1,000 on an individual. Violations of other Act requirements may result in an administrative fine of \$5,000 for each violation.



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