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Practice Update

Florida's Prescription Drug Reform Act: What's in it for Florida Pharmacies?

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The Florida legislature took aim at pharmacy benefit managers (PBMs) during the 2023 legislative session by enacting the Prescription Drug Reform Act, Chapter 2023-29, Laws of Florida (https://laws.flrules.org/2023/29) (the Act), which went into effect July 1, 2023. The Act regulates PBMs and pharmaceutical manufacturers operating in Florida with a focus on transparency, accountability, and the relationships among participants in the outpatient pharmaceutical system. It is also focused on reining in the PBMs to protect pharmacies from what have been described as abusive business practices. An earlier firm blog addressed PBM licensing issues (HealthRx blog here); this blog focuses on how the Act impacts Florida pharmacies. Provisions addressing pharmacy benefit plans and drug manufacturers are not addressed in detail.

The Act includes several provisions meant to curtail questionable PBM practices against pharmacies. This article highlights what the Prescription Drug Reform Act means for pharmacies operating in Florida with a focus on new requirements for contracts between PBMs and participating pharmacies as well as prohibited acts for PBMs as they relate to their relationships with pharmacies.

Contracts between PBMs and Pharmacy Benefit Plans or Programs

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The Act addresses contracts between PBMs and a pharmacy benefits plan or program. In some instances, these changes impact pharmacies. For instance, some of these changes benefit pharmacies by prohibiting the PBM from favoring its affiliate pharmacies over those pharmacies which are not the PBM's affiliates. Such contracts need to be updated to reflect the new requirements under Section 626.8825(2).

One of these requirements is the use of a pass-through pricing model (Section 626.8825(2)(a)). The contract must also ensure that funds received in relation to providing services for a pharmacy benefits plan or program or for a pharmacy are used or distributed only pursuant to the PBM's contract with the pharmacy benefits plan or program or the pharmacy.

Another requirement is that contracts between PBMs and a pharmacy benefits plan or program must (1) include network adequacy requirements that meet or exceed Medicare Part D program standards for convenient access to the network pharmacies as set forth in 24 C.F.R. § 423.120(a)(1) and (2) not limit a pharmacy network to solely include affiliated pharmacies (Section 626.8825(2)(e)(1)). The subsection also requires a PBM to offer a provider contract to licensed pharmacies physically located on the physical site of providers that are within the pharmacy benefits plan's or program's geographic service area and designated as (a) cancer centers of excellence, (b) organ transplant hospitals, (c) hospitals licensed as specialty children's hospitals, or (d) regional perinatal intensive care centers (Section 626.8825(2)(e)(2)(a)-(e)). The network adequacy requirements also cannot require a covered person to receive a prescription drug by mail unless the prescription is unavailable at retail (Section 626.8825(2)(e)(3)).

For the in-person administration of covered prescription drugs, the PBM cannot require a covered person to receive pharmacist services from

an affiliated pharmacy or an affiliated health care provider (white bagging from affiliate pharmacies or providers) (Section 626.8825(2)(e)(4)). The PBM also cannot offer or implement pharmacy networks that require or provide a promotional item or an incentive for a covered person to use an affiliated pharmacy or provider, nor can they market or promote an affiliated pharmacy to covered persons (Section 626.8825(2)(e)(5)). PBMs that own their own pharmacies will have to carefully craft or restrict their promotional programs so that they do not favor their own affiliated pharmacies.

Contracts between PBMs and benefit plans or programs must also comply with the requirement that a PBM cannot condition participation in one pharmacy network on participation in any other pharmacy network or penalize a pharmacy for exercising its prerogative not to participate in a specific pharmacy network (Section 626.8825(2)(f)).

These contracts also cannot allow a PBM to institute a network that requires a pharmacy to meet accreditation standards that are not the same as federal and state requirements. A PBM can, however, specify additional specialty networks that require enhanced standards related to the FDA's limited distribution requirements for drugs that require extraordinary special handling, provider coordination, or clinical care or monitoring (i.e., REMS drugs that require a special certification or special handling) (Section 626.8825(2)(g)). Also, when the PBM amends its formulary, it has to provide a 60-day continuity of care period for the drug.

Contracts between a PBM and a Pharmacy

Numerous changes benefitting pharmacies were made to participating pharmacy agreements on a going-forward basis. Many of these provisions are aimed at correcting perceived abuses by the PBM industry, presumably resulting from their long-term unequal bargaining power with the pharmacies.

Contracts between a PBM and a participating pharmacy executed, amended, adjusted, or renewed on or after July 1, 2023, for pharmacist services on or after January 1, 2024, will need to comply with new requirements, in addition to other requirements in the Florida Insurance Code. These new requirements under Section 626.8825(3) include:

- The PBM must provide the pharmacy with a remittance at either the time of adjudication of electronic claims or the time of reimbursement for non-electronic claims. That remittance must include information necessary for the pharmacy or pharmacist to identify the reimbursement schedule for the specific network applicable to the claim that is the basis the PBM used to calculate reimbursement. This information must include, but is not limited to, the applicable network reimbursement ID or plan ID as defined in the most current version of the National Council for Prescription Drug Programs (NCPDP) Telecommunication Standard Implementation Guide or its nationally recognized successor industry guide (Section 626.8825(3)(a)).
- The PBM must ensure that any basis of reimbursement information is communicated to a pharmacy in accordance with the NCPDP Telecommunication Standard Implementation Guide (or its successor industry guide) when performing reconciliation for any effective rate guarantee (likely required by HIPAA regardless). The basis of reimbursement information must be accurate and correspond with this applicable network rate, and it may be relied upon by the pharmacy (Section 626.8825(3)(b)).
- Aimed at curtailing PBM “clawbacks” and “DIR fees,” a PBM may not charge, withhold, or recoup direct or indirect remuneration fees, dispensing fees, brand name or generic effective rate adjustments through reconciliation, or any other monetary charge, withholding, or recoupments as related to discounts, multiple network reconciliation offsets, adjudication transaction

fees, and any other instance when a fee may be recouped from a pharmacy. Prohibiting PBMs from extracting uncontracted funds from the pharmacies is a significant change. However, there are exceptions. This prohibition does not apply to incentive payments provided by the PBM to a network pharmacy for meeting or exceeding predefined quality measures, such as Healthcare Effectiveness Data and Information Set (HEDIS) measures; recoupment due to an erroneous claim, fraud, waste, or abuse; a claim adjudicated in error; a maximum allowable cost appeal pricing adjustment; or an adjustment made as part of a pharmacy audit pursuant to Section 624.491. The prohibition also does not apply to any recoupment that is returned to the state for Medicaid programs or the state group insurance program in Section 110.123 (Section 626.8825(3)(c)).

- A PBM cannot unilaterally change the terms of any participation contract- another requirement addressing the historically unequal bargaining power between PBMs and pharmacies (Section 626.8825(3)(d)).
- A PBM cannot prohibit a pharmacy or pharmacist from (1) offering mail or delivery services on an opt-in basis at the sole discretion of the covered person, (2) mailing or delivering a prescription drug to a covered person upon his or her request, or (3) charging a shipping or handling fee to a covered person requesting a prescription drug be mailed or delivered if the pharmacy or pharmacist discloses to the covered person before the mailing or delivery the amount of the fee that will be charged and that the fee may not be reimbursable by the covered person's pharmacy benefits plan or program (Section 626.8825(3)(e)).
- Upon request, the PBM must provide a pharmacy a list of pharmacy benefits plans or programs in which the pharmacy is a network provider. Updates to the list must be communicated to the pharmacy within seven days, and the PBM may not restrict the pharmacy or pharmacist from

disclosing this information to the public (Section 626.8825(3)(f)).

- The PBM must ensure that the Electronic Remittance Advice contains claim-level payment adjustments in accordance with the American National Standards Institute Accredited Standards Committee, X12 format, and includes or is accompanied by the appropriate level of detail for the pharmacy to reconcile any debits or credits, including, but not limited to, pharmacy NCPDP or NPI identifier, date of service, prescription number, refill number, adjustment code (if applicable), and transaction amount (Section 626.8825(3)(g)).
- The PBM is required to provide a reasonable administrative appeal procedure to allow a pharmacy or pharmacist to challenge the maximum allowable cost (MAC) pricing information and the reimbursement made under the MAC as defined in Section 627.64741 for a specific drug as being below the acquisition cost available to the challenging pharmacy or pharmacist (Section 626.8825(3)(h)).

1. The administrative appeal procedure must include a telephone number and email address, or a website, for the purpose of submitting the administrative appeal. The appeal may be submitted by the pharmacy or an agent of the pharmacy directly to the pharmacy benefit manger or through a pharmacy service administration organization. The pharmacy or pharmacist must be given at least 30 business days after a MAC update or after an adjudication for an electronic claim or reimbursement for a nonelectronic claim to file the administrative appeal.

2. The PBM must respond to the administrative appeal within 30 business days after receipt of the appeal.

3. If the appeal is upheld, the PBM must:

a. Update the MAC pricing information to at least the acquisition cost available to the pharmacy;

b. Permit the pharmacy or pharmacist to reverse and rebill the claim in question;

c. Provide to the pharmacy or pharmacist the national drug code on which the increase or change is based; and

d. Make the increase or change effective for each similarly situated pharmacy or pharmacist who is subject to the applicable MAC pricing information.

4. If the appeal is denied, the pharmacy benefit manager must provide to the pharmacy or pharmacist the national drug code and the name of the national or regional pharmaceutical wholesalers operating in this state that have the drug currently in stock at a price below the MAC pricing information.

5. Every 90 days, a PBM shall report to the Office of Insurance Regulation the total number of appeals received and denied in the preceding 90-day period, with an explanation or reason for each denial, for each specific drug for which an appeal was submitted pursuant to this paragraph.

Prohibited Acts by PBMs in their Relationships with Pharmacies

The Act also proscribes conduct by a PBM in their relationships with pharmacies. These prohibitions include that:

- PBMs cannot prohibit, restrict, or penalize a pharmacy from disclosing to any person any information that the pharmacy or pharmacist deems appropriate (Section 626.8827(1)). This includes information regarding the nature of treatment risks or alternatives, as well as the availability of alternate treatment, consultations,

or tests. It also includes disclosing the decision of utilization reviewers or a similar person to authorize or deny pharmacist services, information on financial incentives and structures used by the PBM or program, information that may reduce the costs of pharmacist services, and whether the cost-sharing obligation exceeds the retail price for a covered prescription drug and the availability of a more affordable alternative drug, pursuant to Section 465.0244.

- PBMs cannot prohibit, restrict, or penalize a pharmacy or pharmacist from disclosing information to the Office of Insurance Regulation, the Agency for Health Care Administration, Department of Management Services, law enforcement, or state and federal government officials, provided that (1) the recipient of the information represents it has the authority, to the extent provided by state or federal law, to maintain proprietary information as confidential and, (2) before disclosure of information designated as confidential, the pharmacist or pharmacy marks as confidential any document in which the information appears or requests confidential treatment for any oral communication of the information (Section 626.8827(2)).
- PBMs cannot communicate at the point-of-sale, or otherwise require, a cost-sharing obligation for the covered person in an amount that exceeds the lesser of (a) the applicable cost-sharing amount under the applicable pharmacy benefits plan or program or (b) the usual and customary price, as defined in Section 626.8825, of the pharmacist services (Section 626.8827(3)).
- PBMs cannot transfer or share records related to prescription information containing patient-identifiable or prescriber-identifiable data to an affiliated pharmacy for any commercial purpose other than the limited purposes of facilitating pharmacy reimbursement, formulary compliance, or utilization review on behalf of the

applicable pharmacy benefits plan or program (Section 626.8827(4)).

- PBMs cannot fail to make any payment due to a pharmacy for an adjudicated claim with a date of service before the effective date of a pharmacy's termination from a pharmacy benefit network unless payments are withheld because of fraud on the part of the pharmacy or except as otherwise required by law (Section 626.8827(5)).
- PBMs cannot terminate the contract of, penalize, or disadvantage a pharmacist or pharmacy due to a pharmacist or pharmacy's disclosing information about PBM practice in accordance with the Act, exercising any of its prerogatives under this part of the Act, or sharing any portion, or all, of the PBM contract with the Office of Insurance Regulation pursuant to a complaint or a query regarding whether the contract is in compliance with the Act (Section 626.8827(6)).

Practical Considerations

The Office of Insurance Regulation (OIR) is appointed to regulate the PBMs' conduct and is required to have an employee that handles issues related PBMs. Some of the PBMs are gigantic companies, but the OIR is used to regulating very large insurance companies, so we suspect regulation will not be an issue. Perhaps the PBMs will self-regulate their conduct as other health care players do. The next few years should be interesting.

The contractual changes only appear to kick in if the contracts are "executed, amended, adjusted or renewed" after July 1, 2023, and apply to pharmacy benefits or pharmacy services, as applicable, after January 1, 2024. Most of these participating pharmacy contracts are year to year agreements, so the new terms should be effective after January 1, 2024, upon renewal or amendment. The PBMs may wish to amend them all at once to avoid having some agreements with the new provisions and some without.

PBMs will need to revisit their relationships with participating pharmacies to avoid violating the numerous provisions in the law governing their conduct and their contracts. The elimination of PBM clawbacks and DIR fees, unilateral contract amendments, and driving business to their own pharmacies; prohibitions on limiting pharmacy mail order operations; limits on MAC pricing; and other changes should greatly benefit the pharmacy industry and allow it to provide needed services from a more equitable position. Mail-order participating pharmacy agreements would seem to be a thing of the past. Each of these provisions should be carefully read with a lawyer familiar with pharmacy issues.
