



INFORMATIONAL MEMORANDUM

OIR-23-04M

ISSUED

July 19, 2023

Florida Office of Insurance Regulation

Michael Yaworsky, Commissioner

NOTIFICATION TO ALL PHARMACY BENEFIT MANAGERS TO BE REGULATED AS INSURANCE ADMINISTRATORS

~ Implementing Florida's Prescription Drug Reform Act ~

The purpose of this informational memorandum is to notify all Pharmacy Benefit Managers (PBMs) and Pharmacy Benefits Plans or Programs of recent changes to Florida Law included within the Prescription Drug Reform Act (SB 1550). [As signed by Governor DeSantis in May](#), the Prescription Drug Reform Act institutes new regulatory requirements for all PBMs, including a requirement to become fully regulated as Insurance Administrators. As the 2023 Florida Statutes have not yet been published, all citations included in this memorandum and attachments are to the Florida Statutes reflected in Chapter 2023-029, Laws of Florida, a copy can be found [here](#).

In addition to noticing the formal commencement of rulemaking in the Florida Administrative Register, the Florida Office of Insurance Regulation (OIR) is providing this informational memorandum to educate stakeholders on the implementation related activities.

Application for Certificate of Authority

As stated above, the OIR has formally initiated the rulemaking process to promulgate application forms for PBMs seeking to operate in Florida. Pursuant to the legislation, beginning on January 1, 2024, PBMs operating in Florida must continue to be registered with the OIR, using the form linked [here](#) (s. 624.490, Florida Statutes), **and** hold a valid certificate of authority (COA) as an administrator (ss. 626.88 and 626.8805, Florida Statutes).

Given that the new requirements for PBMs exceed both the current registration requirement and the application requirements of administrators not considered PBMs, all PBMs currently registered with the OIR, including those that currently hold a COA as an administrator, and any new PBM seeking to operate in Florida, will be required to complete an application to obtain a COA. The application form is available [here](#). Upon receipt and review of a complete application by a PBM that meets the requirements of Florida Law, the OIR will issue a COA.

Any PBM operating in Florida without a valid COA beginning on January 1, 2024, will be subject to a fine of \$10,000 per violation per day. The OIR urges all PBMs to make their application filing as soon as possible to avoid delays, including obtaining background reports required in the Florida Insurance Code.

Transparent Reporting Requirements

In addition to the referenced application requirements, PBMs will also be subject to a series of transparent reporting requirements including disclosures related to relationships with affiliated entities and ownership

affiliations, contracts with affiliates, pharmacies, and pharmacy benefits plans or programs, and several requirements for specified contractual terms and conditions.

The method in which PBMs and Pharmacy Benefit Plans or Programs shall report the requirements is provided below:

Financial Condition and Audited Financial Statements: The PBM's financial condition (subsection 626.89(1), Florida Statutes) and the PBM's audited annual financial statements (subsection 626.89(2), Florida Statutes) should be submitted electronically within three months after the end of the administrator's fiscal year, through <http://www.floir.com/iportal>. [Form OIR-A3-975](#) should be used to submit financial information.

Notification of Violations: The notification of any administrative, civil, or criminal complaints, settlements, or discipline of the pharmacy benefit manager or any of its affiliates which relate to a violation of the insurance laws, including pharmacy benefit laws in any state should be submitted electronically to <http://www.floir.com/iportal>, as a periodic filing, within 30 days of the complaint, settlement, or discipline (subsection 626.89(5), Florida Statutes).

Network Adequacy Attestation: Beginning January 1, 2024, the requirement for an annual attestation of compliance with network requirements (subsection 626.89(6), Florida Statutes) should be submitted electronically to <http://www.floir.com/iportal>, and included in the annual filings thereafter. PBMs are encouraged to provide additional documentation (i.e. Network Files, Analyses, etc.) to support this attestation annually, as it will also be requested during the biennial examination cycle.

Ownership Changes: Material changes of ownership (subsection 626.89(4), Florida Statutes) should immediately be submitted electronically to <http://www.floir.com/iportal>, as a periodic filing. A change of ownership affiliation of any kind with any pharmacy, which meets the requirements of section 626.8814(2) Florida Statutes, must be reported to the OIR in writing, and may be submitted electronically to <http://www.floir.com/iportal>, within 60 days of the change in ownership interest.

Appeals and Denials of Pharmacies and Pharmacists: A report of the total number of appeals and denials by pharmacies or pharmacists of the PBM's decisions regarding a drug's maximum allowable cost and reimbursement (section 626.8825, Florida Statutes) is required to be filed with the OIR every 90 days. This report may be filed at the following email address: PBMreporting@floir.com. OIR is creating a suggested template to use for reporting. Once completed, the suggested template will be posted on OIR's website [here](#). Use of this template will ensure that the information submitted is complete and the filing can be timely processed.

Agreements with Pharmacy Benefit Plans or Programs: PBMs are also directed to notify any pharmacy benefits plans or programs they are contracted with of the requirement (subsection 626.8825(2)(h)2., Florida Statutes) to annually submit a statement of attestation of compliance with the requirements of subsection 626.8825(2), Florida Statutes, governing contracts between the PBM and the pharmacy benefits plans or programs. This requirement applies to all pharmacy benefits plans or programs as defined in subsection 626.8825(1)(u), Florida Statutes. The attestations may be submitted to: PBMreporting@floir.com. If the plan or program is directed by a licensed insurer or HMO, the attestation may be submitted electronically as a periodic filing to <http://www.floir.com/iportal>.

Contract Provisions to Protect Consumers and Pharmacies

Contracts between a PBM and a Pharmacy Benefit Plan or Program: The bill institutes a series of protections for both consumers and pharmacies through contracting provisions between PBMs and Pharmacy

Benefit Plans or Programs. Of note, the bill requires that in addition to any other requirements of the Florida Insurance Code, all contractual arrangements executed, amended, adjusted, or renewed on or after July 1, 2023, which are applicable to pharmacy benefits covered on or after January 1, 2024, between a PBM and a Pharmacy Benefits Plan or Program must include, in substantial form, standard terms, except to the extent not allowed by law, shall supersede any contractual terms to the contrary. A complete listing of terms can be found in the bill (s. 626.8825(2), Florida Statutes).

Contracts between a PBM and a Participating Pharmacy: In addition to the above referenced requirements, the bill institutes a series of protections for both consumers and pharmacies through contracting provisions between PBMs and Participating Pharmacies. Of note, the bill requires that in addition to any other requirements of the Florida Insurance Code, a participation contract executed, amended, adjusted, or renewed on or after July 1, 2023, which are applicable to pharmacy services on or after January 1, 2024, between a PBM and one or more pharmacies or pharmacists must include, in substantial form, standard terms, except to the extent not allowed by law, shall supersede any contractual terms to the contrary. A complete listing of terms can be found in the bill (s. 626.8825(3), Florida Statutes).

Additionally, as published in the Florida Administrative Register, draft rules have been published detailing the method in which PBMs provide remittance to participating pharmacies.

Patient Data Privacy

The bill also prohibits PBMs from transferring or sharing records relative 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.

Additional Prohibited PBM Practices

In addition to the requirements set forth in the bill, the legislation includes additional prohibitions against PBM practices including: restricting or penalizing a pharmacy or pharmacist from disclosing relevant information to a patient, government officials, or law enforcement; communicating at the point-of-sale, or otherwise requiring, a cost-sharing obligation for a covered person that exceeds the lesser of the applicable amount in the covered person's plan or the usual and customary price. Additionally, the bill clarifies that Florida's prohibition against "fail twice" step therapy protocols apply to both plans and PBMs.

The bill also provides additional protections against PBMs exerting retaliatory action against pharmacists or pharmacies that provide information to the OIR pursuant to a compliant or a query regarding compliance with this act. A complete listing of prohibitions can be found in the bill.

Investigations & Examinations

The bill subjects PBMs to biennial exams beginning on January 1, 2025, to ensure compliance with Florida law. This requirement is in addition to any investigation or examination conducted because of a referral or complaint driven investigation or examination conducted at any time.

Any PBM found to exhibit a pattern or practice of knowing and willful violations with section 626.8825 (Pharmacy Benefit Manager Transparency & Accountability), or 626.8827 (Pharmacy Benefit Manager Prohibited Practices), may be subject to additional penalties per section 626.8828, Florida Statutes.

Additionally, as published in the Florida Administrative Register, draft rules have been published detailing the method in which PBMs provide remittance to participating pharmacies and the types of independent professional examiners who may conduct examinations.

The OIR is also directed to regularly report violations of this act to the Governor, President of the Senate, and Speaker of the House of Representatives.

This memorandum contains a significant portion of changes in Florida Law but is not intended, nor shall be considered as, an exhaustive list of all changes in Florida law. The OIR directs PBMs to review the law in its entirety and to make regulatory changes as necessary to ensure compliance with the law.

For questions regarding this memorandum, please contact InformationalMemoranda@flor.com.