

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL: CS/SB 1550

INTRODUCER: Health Policy Committee and Senator Brodeur, and others.

SUBJECT: Prescription Drugs

DATE: March 29, 2023

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Brown	HP	Fav/CS
2.			FP	
3.				

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1550 addresses the transparency of a manufacturer's prescription drug price increases above certain thresholds and the relationships between pharmacy benefit managers, pharmacy benefits plans and programs, and pharmacy providers for delivering pharmacy services to covered persons.

The bill requires prescription drug manufacturers and nonresident prescription drug manufacturers to disclose reportable prescription drug price increases. This information will be published on the Florida Health Finder website. A reportable prescription drug price increase refers to a prescription drug with a wholesale acquisition cost of at least \$100 for a course of therapy before the effective date of the increase, and the bill requires the following to be reported:

- Any increase of 15 percent or more of the wholesale acquisition cost during the preceding 12-month period; or
- Any increase of 40 percent or more of the wholesale acquisition cost during the preceding three calendar years.

The bill requires pharmacy benefit managers (PBMs) to obtain a certificate of authority for an administrator under the Florida Insurance Code (FIC) and makes them subject to existing and enhanced requirements as set forth in the bill under the FIC. The bill proscribes and prescribes certain disclosures and actions governing contractual relationships between PBMs and pharmacy benefits plans and programs and also between PBMs and pharmacy providers.

The bill provides a \$1 million appropriation to the Office of Insurance Regulation.

The bill provides an effective date of July 1, 2023.

II. Present Situation:

Prescription drugs can dramatically improve a person’s quality of life, with some therapies being the only thing separating a person from death – but the price can be steep.¹ In 2021, the U.S. health care system spent \$421 billion on retail prescription drugs. As reflected in the chart below, spending growth on drugs was largely due to growth in spending per prescription, and to a lesser extent by increased utilization (i.e., more prescriptions). The following chart depicts prescription drug expenditures (in inflation-adjusted dollars) and the number of retail prescriptions from 2016-2021.²

	Retail Expenditures, Billions (\$)	Retail Prescriptions, Millions (#)
2016	374	4,816
2017	369	4,923
2018	377	5,118
2019	389	5,243
2020	406	4,970
2021	421	5,089
% Change, 2016-2021	12.5%	5.7%

Source: ASPE analysis of IQVIA National Sales Perspective (NSP) Data

Four locations of sale for retail drug expenditures are reported in the chart above – chain store pharmacy, mail-order pharmacy, independent pharmacy, and food store pharmacy. Three of the four locations experienced an increase in sales between 2016 and 2021. Expenditures increased by 4 percent in chain store pharmacies, 35 percent for mail order pharmacies, and 1 percent for food store pharmacies, but decreased 5 percent for independent pharmacies.³

Pharmacy Benefit Managers

PBMs are companies that manage prescription drug benefits on behalf of pharmacy benefit plans or programs (health insurers, Medicare Part D drug plans, large employers, state health plans, and other payers).⁴ Key PBM functions may include administration and management of prescription drug benefits; developing and maintaining formularies; negotiating discounts and

¹ See NCSL State Policy Options and Pharmacy Benefit Managers (PBMs) updated March 23, 2022, available at: <https://www.ncsl.org/health/state-policy-options-and-pharmacy-benefit-managers> (last visited Mar. 23, 2023).

² Parasrampur, S. and Murphy, S. Trends in Prescription Drug Spending, 2016-202. Washing, DC: Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. September 2022, available at: <https://aspe.hhs.gov/sites/default/files/documents/88c547c976e915fc31fe2c6903ac0bc9/sdp-trends-prescription-drug-spending.pdf> (last visited Mar. 23, 2023).

³ *Id.*

⁴The Commonwealth Fund, Pharmacy Benefit Managers and Their Role in Drug Spending, (April 22, 2019) available at: https://www.commonwealthfund.org/sites/default/files/2019-04/Explainer_PBMs_1.pdf (last visited Mar. 23, 2023).

rebates between payers and pharmaceutical manufacturers; providing access to a contracted pharmacy network; real-time pharmacy claims processing; and performing utilization management, retroactive claims review, prior authorization, and other medication management programs.⁵

The three largest PBMs control about 80 percent of the total PBM market. In 2021, CVS Caremark led the industry, controlling 34 percent of total adjusted claims, followed by Express Scripts (25%) and Optum Rx (21%). The next group includes Humana's in-house PBM (8%), Prime Therapeutics LLC (6%) and MedImpact (4%). Approximately 60 smaller PBMs also participate in the marketplace.⁶

The FTC announced on June 7, 2022, that it would launch an investigation into contracting and other business practices in the PBM industry, requiring CVS Caremark, Express Scripts, Inc., OptumRx, Inc., Humana Inc., Prime Therapeutics LLC, and MedImpact Healthcare Systems, Inc., to provide information and records regarding their business practices.⁷ The announcement frames the inquiry as follows:

The Commission's inquiry will examine PBMs' role at the center of the U.S. pharmaceutical system. PBMs are the middlemen who are hired to negotiate rebates and fees with drug manufacturers, create drug formularies and surrounding policies, and reimburse pharmacies for patients' prescriptions. The largest PBMs are now vertically integrated with the largest health insurance companies and wholly owned mail order and specialty pharmacies.

In these roles, pharmacy benefits managers often have enormous influence on which drugs are prescribed to patients, which pharmacies patients can use, and how much patients ultimately pay at the pharmacy counter. Many of these functions depend on highly complicated, opaque contractual relationships that are difficult or impossible to understand for patients and independent businesses across the prescription drug system.

The inquiry is aimed at shedding light on several practices that have drawn scrutiny in recent years including:

- Fees and clawbacks charged to unaffiliated pharmacies;
- Methods to steer patients towards PBM-owned pharmacies;
- Potentially unfair audits of independent pharmacies;
- Complicated and opaque methods to determine pharmacy reimbursement;

⁵ U.S. Pharmacist, State PBM Regulations Protecting Community Pharmacies, (August 16, 2022) *US Pharm.* 2022;47(8):21-25 available at: <https://www.uspharmacist.com/article/state-pbm-regulations-protecting-community-pharmacies> (last visited Mar. 23, 2023).

⁶ Managed Healthcare Executive: Beyond the Big Three PBMs, (December 14, 2022), *MHE December 2022, Vol 32, Issue 12*, available at: <https://www.managedhealthcareexecutive.com/view/beyond-the-big-three-pbms> (last visited Mar. 23, 2023).

⁷ Federal Trade Commission: FTC Launches Inquiry Into Prescription Drug Middlemen Industry, Agency to Scrutinize the Impact of Vertically Integrated Pharmacy Benefit Managers on the Access and Affordability of Medicine (June 7, 2022) available at: <https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry> (last visited Mar. 23, 2023).

- The prevalence of prior authorizations and other administrative restrictions;
- The use of specialty drug lists and surrounding specialty drug policies; and
- The impact of rebates and fees from drug manufacturers on formulary design and costs of prescription drugs to payers and patients.

Minnesota Attorney General Keith Ellison is participating in a bipartisan coalition of at least 35 attorneys general⁸ from across the country in an amicus brief to the Tenth Circuit Court of Appeals supporting Oklahoma's laws that regulate abusive behavior of PBMs. In his press release announcing his participation in the coalition, he states:⁹

... PBMs profit from fees charged to market participants and by reimbursing pharmacies less than the PBM is paid by plans for dispensing medications. PBMs have imposed self-serving protections that reduce competition, limit prescription medication access, and impose various confidentiality requirements. For example, PBMs have tried to force consumers to use PBM-affiliated pharmacies at the expense of independent, often more convenient, pharmacies, by giving consumers preferential rates if they use a PBM-affiliated pharmacy, or by denying coverage at non-affiliated pharmacies altogether.

Regulation and Registration of PBMs in Florida

PBMs that contract to administer prescription drug benefits on behalf of a health insurer or health maintenance organization to residents of Florida have been required to register with the Office of Insurance Regulation (OIR) pursuant to s. 624.490, F.S., since 2019. To initially register, a PBM must submit incorporation of similar documents, identifying information pertaining to officers and directors, and non-refundable fee of \$5.00.¹⁰ The statute authorizes a fee not to exceed \$500, but it restricts fees from exceeding the cost of administering the registration process.

The registration certificate is valid for two years after its date of issue. Renewal requires submission of organizational documents if any changes have occurred, a completed registration application form, and a renewal fee of \$5.00. Similarly, the statute authorizes a renewal fee not to exceed \$500, but the same restriction applies to the amount of the renewal fee as it does to the initial fee.

⁸ The jurisdictions participating include: Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Hawaii, Idaho, Illinois, Indiana, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, Texas, Utah, Virginia, Washington, and the District of Columbia. See Pharmaceutical Care Management Association vs. Glen Mulready et. al., Brief of Amici Curiae; in the US Court of Appeals for the Tenth Circuit (No. 22-6074) available at:

https://www.ag.state.mn.us/Office/Communications/2022/docs/PCMA_AmicusBrief.pdf (last visited Mar 22, 2023).

⁹ See The Office of Minnesota Attorney General Keith Ellison, Attorney General Ellison leads bipartisan coalition to regulate abusive practices of pharmacy benefit manager (October 18, 2022); available at:

https://www.ag.state.mn.us/Office/Communications/2022/10/18_PCMA.asp (last visited Mar 22, 2023).

¹⁰ See Florida Office of Insurance Regulation Pharmacy Benefit Managers Registration and Renewal, https://www.floir.com/Sections/AppCoord/is_ac_PBM.aspx (last visited Mar 22, 2023).

A person who fails to register with the office while operating as a PBM is subject to a fine of \$10,000 for each violation. The OIR does not have explicit authority to conduct examinations of a PBM, suspend or revoke a PBM's registration, or impose a fine or civil penalty if a registered PBM violates Florida Statutes.¹¹

Currently, there are 71 PBMs registered in Florida.¹²

Other States' PBM Laws

All 50 states have enacted some form of licensure, registration, and regulation pertaining to PBMs.¹³ Common themes, some or all of which may be included in a state's law are:

- Prohibiting spread pricing. Spread pricing is typically demonstrated by a PBM reimbursing a pharmacy a lower amount than the amount the pharmacy benefits plan or program (plan or program) paid the PBM, with the PBM retaining the difference.
- Ensuring adequate pharmacy networks that are based on reasonably available retail pharmacies for patients without basing adequacy on mail-order pharmacies.
- Prohibiting PBMs from implementing arbitrary or excessive accreditation or credentialing requirements.
- Prohibiting patient steering. Patient steering can include, but is not limited to, requiring or incentivizing a patient to use a pharmacy, specialty pharmacy, or mail-order pharmacy that is affiliated (through some form of ownership interest) with the PBM or by using certain advertising practices.
- Requiring PBMs that negotiate rebates from manufacturers on behalf of the plan or program to pass all or most of the rebate amount to the plan or program to reduce premiums or to be used to reduce the cost-sharing amount the patient pays for the drug at the pharmacy.
- Banning gag clauses that restrict or penalize pharmacists for disclosing certain information to patients such as lower cost options or other alternatives, or for disclosing information to regulatory authorities.
- Prohibiting retroactive claim adjustments, such as certain clawbacks or other recoupments that reduce the amount paid by the PBM to the pharmacy but are not based on error or similar conditions.
- Requiring fair auditing procedures and appeal opportunities.
- Requiring reasonable reimbursement rates and appeal opportunities to reimbursements.
- Limiting the fees a PBM charges to a pharmacy for such things as network participation or claim adjudication.
- Providing regulatory enforcement authority for state agencies.

¹¹ The Office of Insurance Regulation 2023 Agency Legislative Bill Analysis for SB 1550, dated March 23, 2023.

¹² See The Senate Health Policy Committee recording for February 6, 2023, presentation by Kevin Jacobs from OIR at or about the 3:38 minute mark, recording available at: https://flsenate.gov/media/videoplayer?EventID=1_ky7xx6qg-202302061530&Redirect=true.

¹³ See: National Conference of State Legislatures: State Policy Options and Pharmacy Benefit Managers, (updated March 23, 2022) available at: [State Policy Options and Pharmacy Benefit Managers \(ncsl.org\)](https://www.ncsl.org/state-policy/state-policy-options-and-pharmacy-benefit-managers) (last visited Mar 22, 2023) and National Community Pharmacists Association's Excel spreadsheet entitled PBM laws by state with cites available at: <https://ncpa.org/how-states-protect-pharmacy-and-patients-pbm-abuses> (last visited Mar 22, 2023).

Several states have enacted comprehensive laws regulating pharmacy benefit plans or programs and PBMs. Two such states are Arkansas and Oklahoma. A summary of their laws are presented below.

Arkansas

Arkansas' law¹⁴ became effective September 1, 2018. It requires PBMs to be licensed by the Insurance Commissioner (commissioner) who has enforcement authority for a PBM's compliance with the law. Among other provisions, it addresses:

- Network adequacy. PBMs must provide a reasonably adequate and accessible network and a mail-order pharmacy may not be included in the calculations for determining network adequacy.
- Prohibits a PBM from conducting spread pricing.
- Requires PBMs to report quarterly to the commissioner for each health care payer [plan or program]:
 - The individual and aggregate amount paid by the healthcare payer to the PBM for pharmacist services and the individual and aggregate amount the PBM paid for pharmacist services, both itemized by pharmacy, by product, and by goods and services. The commissioner may review and approve the compensation program of a PBM with a health benefit plan to ensure that the reimbursement for pharmacist services paid to a pharmacist or pharmacy is fair and reasonable to provide an adequate network for a health benefit plan.
 - The aggregate amount of rebates received and distributed to the healthcare payer.
 - The aggregate amount of rebates passed on to the enrollees of the healthcare payer at the point of sale that reduced the enrollees' applicable cost-sharing amount.
 - The information in these quarterly reports, the information in the compensation program review, and the data acquired in an examination are not subject to the Freedom of Information Act under Arkansas law.
- Prohibiting a PBM from:
 - Using any advertisements, promotion, solicitation, representation, proposal, or offer that is untrue, deceptive, or misleading;
 - Charging a pharmacist or pharmacy a fee related to adjudication of a claim or participation in a network, unless reviewed and approved by the commissioner;
 - Requiring pharmacy accreditation standards or certification requirements inconsistent with, more stringent than, or in addition to requirements of the State Board of Pharmacy (board), unless approved by the commission and board;
 - Reimbursing a pharmacy or pharmacist less than the amount reimbursed to an affiliate of the PBM for the same pharmacist services;
 - Reimbursing for the ingredient drug product component of pharmacist services less than the national average drug acquisition cost, or if that information is unavailable, the wholesale acquisition cost, with certain exceptions;
 - Reducing the payment for pharmacist services under a reconciliation process to an effective rate of reimbursement, including generic effective rates, brand effective rates, direct and indirect remuneration fees, or any other reduction or aggregate reduction of payment; retroactively denying or reducing after adjudication of a claim or aggregate of

¹⁴ Arkansas Pharmacy Benefits Manager Licensure Act, A.C.A. Title 23, Subtitle 3, Chapter 92.

- claims unless the claim was submitted fraudulently, the claim was a duplicate claim already reimbursed, or the pharmacist services were not properly rendered; and
- Failing to pay a pharmacy or pharmacist that is terminated from the network any payment due for pharmacist services properly rendered.
 - Imposing gag clauses such as: (1) prohibiting, restricting, or penalizing a pharmacy or pharmacist from disclosing to any covered person any healthcare information that the participating provider deems appropriate regarding the nature of treatment, risks, or alternatives thereto; the availability of alternate therapies, consultations, or tests; the decision of utilization reviewers or similar persons to authorize or deny services; the process that is used to authorize or deny healthcare services or benefits, or information on financial incentives and structures used by the insurer; (2) restricting a pharmacy or pharmacist from providing to an insured information regarding the insured's total cost for pharmacist services for a prescription drug or from selling a more affordable alternative to the insured if one is available; and (3) prohibiting, restricting, or limiting disclosure of information to the commissioner, law enforcement, or state and federal governmental officials investigating or examining a complaint or conducting a review of a PBM's compliance with the law.

Oklahoma

Oklahoma's Patient's Right to Pharmacy Choice Act, (Act) was enacted and effective in 2019.¹⁵ The stated purpose of the Act is to establish minimum and uniform access to a provider and standards and prohibitions on restrictions of a patient's right to choose a pharmacy provider.¹⁶ Under the Act, a PBM may not, among other things:

- Use mail-order pharmacies to meet access standards for retail pharmacy networks.
- Require patients to use affiliated pharmacies.
- Include the name of any pharmacy unless it specifically lists all pharmacies participating in the network, in advertising or other materials, or provide information that is untrue, deceptive, or misleading.
- Charge a pharmacy or pharmacist a fee for claim submission, adjudications, or for participation in a network.
- Reimburse a pharmacy or pharmacist less than the amount the PBM reimburses to an affiliated pharmacy.
- Deny a pharmacy the opportunity to participate in a network at preferred participation status if the pharmacy is willing to accept the terms and conditions for such providers.
- Retroactively deny or reduce reimbursement for a covered service claim previously paid, with certain exceptions.
- Fail to make a payment due for a properly rendered covered service upon termination of the pharmacy from the network.
- Use spread pricing.
- Restrict a pharmacy from informing a person about lower cost alternatives, such as paying a cash price without using the plan or program's coverage.

¹⁵ See H.B. 2632, Enrolled; Laws 2019, c. 426, effective November 1, 2019, available at: <http://www.oklegislature.gov/BillInfo.aspx?Bill=hb2632&Session=1900> (last visited Mar. 22, 2023).

¹⁶ Codified at s. 36-6959

- Restrict a pharmacy from informing governmental officials or law enforcement about the PBM's compliance with the Act.
- Fail to maintain an electronic claim inquiry processing system in accordance with national standards.

Additional provisions relate to imposing responsibility on the health insurer for ensuring that requirements of the Act are met, including but not limited to ensuring an individual may choose any in-network provider which may include a retail pharmacy or a mail-order pharmacy without incentivizing through discounts that choice.

The Oklahoma Insurance Commissioner is responsible for enforcing the Act and as a part of that function must establish an Advisory Committee to assist with this responsibility. The Commissioner must provide for the receiving and processing of individual complaints alleging violations of the Act. The Advisory Committee is responsible for reviewing the individual complaints, holding hearings and taking disciplinary action for any violations, as appropriate. If the Commissioner determines, based on an investigation of complaints, that a PBM has engaged in violations of the Act with such frequency that it indicates a general business practice that warrants closer supervision, the Commissioner may impose more stringent oversight of the PBM.

Legal Discussion

Over the past ten years, states have been more active in regulating PBMs. Several challenges to certain provisions in these laws have been brought by the Pharmaceutical Care Management Association (PCMA). PCMA is the national association representing America's PBMs.¹⁷ Typically two theories support the challenges: the provisions are preempted by one or both federal laws relating to ERISA and Medicare Part D.

ERISA Preemption

The Employee Retirement Income Security Act of 1974 (ERISA) is a federal law designed to govern how employers provide benefit plans to employees. It regulates all employer-sponsored benefit plans, including group health plans. In enacting ERISA in 1974, Congress sought to provide national standards for employee benefit plans, including reporting, disclosures, fiduciary responsibilities, claims/appeals and remedies for noncompliance with the goal of making the benefits promised by an employer more secure.

To minimize the administrative and financial burden of complying with the potential patchwork effect of each state enacting their own laws regulating employee benefits, Congress included a preemption of state laws that would interfere with the uniform administration of ERISA plans. That preemption states, ERISA "supersede[s] any and all State laws insofar as they may now or hereafter relate to any employee benefit plan" covered by ERISA.¹⁸ Determining whether ERISA preempts a particular state law has not always been straightforward and until recently federal

¹⁷ PCMA, About PCMA available at: <https://www.pcmnet.org/about/> (last visited Mar. 23, 2023).

¹⁸ 29 U.S.C. s. 1144(a).

court decisions considering whether state laws regulating pharmacy benefits were preempted by ERISA were inconsistent.¹⁹

In 2020, the U.S. Supreme Court took up a challenge by the Pharmaceutical Care Management Association (PCMA) to the Arkansas statute regulating PBMs' reimbursement to pharmacies on grounds that the statute was preempted by ERISA. The court in *Rutledge v. Pharmaceutical Care Management Association*,²⁰ opined that the statute in dispute was not preempted by ERISA and provided a roadmap for determining whether a state law would be preempted by ERISA.

In *Rutledge*, the court considered whether the state law had an “impermissible connection” with an ERISA plan by requiring providers to structure benefit plans in particular ways, such as by requiring payment of specific benefits or by binding plan administrators to specific rules for determining beneficiary status.²¹ The court ruled that the statute at issue did not “relate to” an ERISA plan because the requirement that PBMs reimburse pharmacies at a rate equal to or higher than the pharmacy's acquisition cost was merely a form of cost regulation which did not dictate plan choices or design. The court stated that ERISA preempts laws that require providers to structure benefit plans in particular ways, such as requiring the payment of specific benefits or by binding plan administrators to specific rules for determining beneficiary status. The court further opined that the statute did not “refer to” ERISA, as the state did not act immediately and exclusively upon ERISA plans and the existence of such plans was not essential to the law's operation, since it regulated PBMs whether or not the plans they service fell within ERISA's coverage.²² The Arkansas law defined a plan or program as “any plan or program that pays for, reimburses, covers the cost of, or otherwise provides for pharmacist services to individuals who reside in or are employed in [Arkansas].”

Medicare Part D Preemption

Medicare Part D is an optional coverage for prescription drugs under the federal Medicare program. The preemption under Medicare Part D incorporates the express preemption provision contained in Medicare Part C.²³ Applying the Medicare Part C exemption to Medicare Part D, the preemption provides: “The standards established under this part shall supersede any State law or regulation (other than state licensing laws or state laws relating to plan solvency) with respect to prescription drug plans.²⁴ The Supreme Court has not ruled on this preemption as it relates to state regulation of PBMs and similar to the ERISA preemption challenges, lower courts have approached the analysis differently with differing outcomes.

¹⁹ See for example, *Pharmaceutical Care Management Association v. Gerhart*, 852 F.3d 722 (8th Cir. 2017), concluding the Iowa statute was pre-empted due to an “implicit reference” to ERISA and it was impermissibly connected with an ERISA plan because the law limited a plan administrator's ability to control the calculation of drug benefits; *Pharmaceutical Care Management Association v. Rowe*, 429 F.3d 294 (1st Cir. 2005), concluding Maine's Unfair Prescription Drug Practices Act was not pre-empted by ERISA; and *Pharmaceutical Care Management Association v. District of Columbia*, 613 F.3d 179 (D.C. Cir. 2010), holding the Access Rx Act, referred to at 186 as a substantially identical law to Maine's provisions addressed in *Rowe*, was pre-empted by ERISA.

²⁰ *Rutledge v. Pharmaceutical Care Management Association* 141 S. Ct. 474 (2020).

²¹ *Rutledge*, at 480, citing *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85 (1983) and *Engelhoff v. Engelhoff*, 532 U.S. 141 (2001).

²² *Rutledge*, at 481.

²³ Medicare Part C is Medicare Advantage.

²⁴ See 42 U.S.C. c. 1395w-26(b)(3), which contains Medicare Part C's preemption and 42 U.S.C. s. 1395w-112(g) (Medicare Part D's adoption of Medicare Part C's preemption).

Currently a case challenging Oklahoma's Act is in the United States Court of Appeals for the Tenth Circuit, *Pharmaceutical Care Management Association v. Mulready*.²⁵ As discussed previously in this analysis, at least 35 attorneys general²⁶ from across the country have joined in an amicus brief to the Tenth Circuit Court supporting Oklahoma's laws that regulate PBMs. Other stakeholders have also submitted briefs as amici curiae to the court. Both ERISA and Medicare Part D preemption are part of this challenge. Oral arguments before the Court are scheduled for mid-May of 2023.²⁷

Insurance Administrators in Florida

An insurance administrator is any person who directly or indirectly solicits or effects coverage of, collects charges or premiums from, or adjusts or settles claims on residents of this state in connection with an insurance policy... or provides billing and collection services to health insurers and health maintenance organizations on behalf of health care providers.²⁸

A person must obtain a certificate of authority to act as an administrator from the Office of Insurance Regulation (OIR).²⁹ The certificate of authority remains valid, unless suspended or revoked by the OIR, so long as the certificate holder continues in business in the state.³⁰ The failure to hold this certificate while acting as an administrator subjects the person to a fine ranging from \$5,000 to \$10,000 for each violation.³¹

An application for a certificate of authority for an insurance administrator requires submitting:³²

- Basic organizational documents;
- By-laws;
- The names, addresses, official positions, and professional qualifications of the individuals employed by or retained by the administrator who are responsible for the conduct of the affairs of the administrator, including all members of the board of directors, board of trustees, executive committee or other governing bodies, and the principal officers or partners;
- A complete list of officers, directors, and shareholders (holding 10% or more of voting shares) having direct or indirect control of the organization, along with a biographical affidavit, background investigative report, and fingerprint card for each person listed;
- Audited annual financial statements for the two most recent fiscal years or other specified documents if the applicant has been in existence for less than two years;

²⁵ The appeal is to *Pharmaceutical Care Management Association v. Mulready*, 598 F. Supp. 3d 1200(2022), the United States District Court, W.D. Oklahoma.

²⁶ The jurisdictions participating include: Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Hawaii, Idaho, Illinois, Indiana, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, Texas, Utah, Virginia, Washington, and the District of Columbia. See *Pharmaceutical Care Management Association vs. Glen Mulready et. al.*, Brief of Amici Curiae; in the US Court of Appeals for the Tenth Circuit (No. 22-6074) available at: https://www.ag.state.mn.us/Office/Communications/2022/docs/PCMA_AmicusBrief.pdf (last visited Mar. 23, 2023).

²⁷ *Pharmaceutical Care v. Mulready et. al.*, Court Docket updated 3/17/2023.

²⁸ See s. 626.88, F.S. Numerous exceptions of are provided in the Statute.

²⁹ See s. 626.8805, F.S.

³⁰ See s. 626.8805(5), F.S.

³¹ See s. 626.8805(1), F.S.

³² See ss. 626.8805(2), 624.34, and 624.501, F.S., and the Application for Certificate of Authority Insurance administrator available at <https://www.flair.com/siteDocuments/Applications/TPA.pdf> (last visited Mar. 23, 2023).

- A statement describing the business plan;
- Evidence of the sources of funds to demonstrate financial viability if the applicant is not currently acting as an administrator; and
- A \$100 filing fee.

On an ongoing basis, an administrator must:

- Maintain a fidelity bond.³³
- Have a written agreement between itself and each insurer for which it performs administrative functions that addresses the services to be provided and maintain books and records related thereto. These documents must be made available to the OIR for inspection and retained for 5 years after the contract ends.³⁴
- Disclose any ownership interest or affiliation of any kind with any insurance company responsible for providing benefits directly or through reinsurance to any plan for which the administrator provides administrative services.³⁵
- Immediately notify the OIR of any material change in its ownership.
- File an annual financial statement with the OIR containing the administrator's financial condition, transactions, and affairs as well as submit an audited financial statement and a filing fee.³⁶

With respect to insurance administrators, the term “affiliate” or “affiliated” means an entity or person who directly or indirectly through one or more intermediaries controls, is controlled by, or is under common control with a specified entity or person.³⁷ The term “control,” including the terms “controlling,” “controlled by,” and “under common control with,” means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a person, whether through the ownership or voting securities, by contract other than a commercial contract for goods or non-management services, or otherwise, unless the power is the result of an official position with or corporate office held by the person. Control shall be presumed to exist if any person directly or indirectly owns, controls, holds with the power to vote, or holds proxies representing 10 percent or more of the voting securities of any other person.³⁸

An insurer who uses an insurance administrator that administers more than 100 certificate-holders of that insurer must conduct, at least semiannually, a review of the administrator's operations³⁹

The OIR may suspend or revoke the certificate of administration for an administrator. Conditions are set forth in statute for mandatory and discretionary revocation or suspension, as well as discretionary suspension, without notice.⁴⁰ In lieu of discretionary suspension or revocation, the OIR may impose administrative fines on administrators. Non-willful violations arising from the

³³ See s. 626.8809, F.S.

³⁴ See ss. 626.8805(3), 626.882, and 626.884, F.S.

³⁵ See s. 626.8814, F.S.

³⁶ See s. 626.89, F.S.

³⁷ Section 626.88(2), F.S.

³⁸ Section 626.88(3), F.S.

³⁹ See s. 626.8817, F.S.

⁴⁰ See generally ss. 626.891 – 626.893, F.S.

same action are subject to: up to \$1,000 fine per violation, but not to exceed an aggregate fine of \$5,000. Willful violations arising from the same action are subject to: up to \$5,000 per violation but not to exceed an aggregate fine of \$25,000.⁴¹

The OIR has authority under s. 624.307, F.S., to conduct investigations of insurance matters that it deems necessary to determine whether a person has violated the insurance code. With regard to administrators specifically, the OIR, under s. 624.317, F.S., has authority to investigate accounts, records, documents, and transactions pertaining to the insurance affairs of any administrator. The decision whether to investigate an administrator is at the discretion of the OIR. The OIR may examine, audit, and inspect the books and records of an administrator, which must be maintained for at least five years after the duration of its written agreement with an insurer.⁴² Insurers are subject to heavier examination oversight than administrators.⁴³

Pharmacies and Pharmacy Audits

Pharmacies and pharmacists are regulated under the Florida Pharmacy Act (act) in ch. 465, F.S. The Board of Pharmacy (board), created under the Department of Health (DOH), adopts rules to implement provisions of the act and takes other actions according to duties conferred on it by the act.⁴⁴ Each pharmacy is subject to inspection by the DOH and disciplined for violations of applicable laws relating to a pharmacy.⁴⁵

Section 624.491, F.S., establishes procedures that must be followed when a pharmacy licensed in Florida is audited by a managed care plan, insurer, third-party payer, PBM, or an entity that represents companies or groups that provides pharmacy benefits. The person or entity conducting the audit must:

- Provide at least seven days prior notice of each initial on-site audit, except for a pharmacy located within a designated Health Care Fraud Prevention and Enforcement Act Team (HEAT) Task Force area that has been a member of a credentialed provider network for less than 12 months;
- Schedule the on-site audit after the first three days of the month, unless the pharmacist consents otherwise;
- Limit the audit period to 24 months after the date a claim is submitted to or adjudicated by the entity;
- Have a pharmacist conduct the audit or conduct it in consultation with a pharmacist if the audit requires clinical or professional judgment;
- Allow the pharmacy to use the written and verifiable records of a hospital, physician, or other authorized practitioner to validate the pharmacy records in accordance with state and federal law;
- Reimbursed the pharmacy for a claim that was retroactively denied for a clerical, typographical, scrivener's, or computer error, if the prescription was properly dispensed,

⁴¹ See s. 626.894, F.S.

⁴² See generally ss. 624.307(3), 624.317, and 626.884, F.S.

⁴³ See s. 624.316 and 624.3161, F.S.

⁴⁴ Sections 465.005 and 465.022, F.S.

⁴⁵ Sections 465.015 and 465.016, F.S.

unless the pharmacy has a pattern of such errors, fraudulent billing is alleged, or the error results in actual financial loss to the entity;

- Provide the pharmacy with the preliminary audit report within 120 days after the audit is concluded and the final audit report within 6 months after receiving the preliminary report;
- Allow the pharmacy 10 business days after the preliminary audit report is delivered to produce documentation to address a discrepancy or audit finding; and
- Calculate any recoupment or penalties based on actual overpayments, not extrapolation.

These required procedures do not apply to audits that are based on a suspected fraud or other willful misrepresentation evidenced by reviews or other investigative methods; audits of claims paid for by federally-funded programs; or concurrent reviews or desk audits that occur within three business days after transmission where no chargeback or recoupment is demanded.

A pharmacy may appeal the findings of the final audit report as to whether a claim payment is due and the amount of a claim payment in accordance with s. 408.7057, F.S. This law establishes a claim dispute resolution program using an independent resolution organization under contract with the Agency for Health Care Administration (AHCA). A health insurer or health maintenance organization that uses a PBM for paying pharmacies for pharmacy benefit claims for covered persons remain responsible for compliance with the pharmacy audit procedures set forth above.

Prescription Drug Manufacturers

The Department of Business and Professional Regulation (DBPR) is responsible for licensing and regulating prescription drug manufacturers under the Florida Drug and Cosmetic Act, Chapter 499, F.S. (FDCA).

A prescription drug manufacturer permit is required for any person that is a manufacturer of a prescription drug and that manufacturers or distributes those prescription drugs in this state.⁴⁶ A nonresident prescription drug manufacturer permit is required for any person that is a manufacturer of prescription drugs located outside of this state or outside the United States and that engages in the distribution in this state of such prescription drugs.⁴⁷ Prescription drug manufacturers and nonresident prescription drug manufacturers are required to comply with all provisions required of such permit holder under part I of the FDCA.

The failure to comply with requirements under part I of the FDCA include the imposition of an administrative fine of up to \$5,000 per violation per day and each day a violation continues constitutes a separate violation. Additional enforcement authority exists under the FDCA, including but not limited to denial, suspension, or revocation of a permit.

⁴⁶ Section 499.01(2)(a), F.S.

⁴⁷ Section 499.01(2)(c), F.S. An exemption exists from holding a permit as a nonresident prescription drug manufacturer for a person that is permitted as a third party logistics provider under s. 499.01(2)(q), F.S. A third party logistics provider does not take title to prescription drugs or have responsibility to direct the sale or distribution of the prescription drug, but merely warehouses and distributes a manufacturer's prescription drug into the state.

III. Effect of Proposed Changes:

This part of the document is presented by topic and may not follow the section order of the bill.

Section 1. Titles the act the “Prescription Drug Reform Act.”

Drug Price Increase Transparency

The bill requires manufacturers of prescription drugs to report to the state certain drug price increases as defined in the bill. This information will be made publicly available on the Florida Health Finder website.⁴⁸

Section 2. Amends s. 499.005, F.S., to create a new prohibited act for a Florida permitted prescription drug manufacturer or nonresident prescription drug manufacturer to fail to submit required drug price increase forms and reports as required under Section 4 of the bill.

Section 3. Amends s. 499.012, F.S., which requires, among other things, a permit for a prescription drug manufacturer located in Florida and a nonresident prescription drug manufacturer permit for a drug manufacturer that is not located in Florida but distributes its prescription drugs into the state. The bill establishes requirements for a prescription drug manufacturer or a nonresident prescription drug manufacturer permitted in Florida to notify the DBPR of reportable drug price increases as required in s. 499.026, F.S.

Section 4. Creates s. 499.026, F.S., to establish transparency parameters for Florida permitted manufacturers of prescription drugs intended for human use to submit information to the state regarding certain prescription drug price increases that will be publicly disclosed on a website maintained by the AHCA.

The bill defines:

- “Course of therapy” to mean the recommended daily dose units of a prescription drug pursuant to its prescribing label for 30 days or the recommended daily dose units pursuant to its prescribing label for a normal course of treatment that is less than 30 days.
- “Manufacturer” to mean a person holding a prescription drug manufacturer permit or a nonresident prescription drug manufacturer permit under s. 499.01, F.S.
- “Prescription drug” to have the same meaning as in s. 499.003, F.S.,⁴⁹ and includes biological products but is limited to those prescription drugs and biological products intended for human use.
- “Reportable drug price increase” to mean, for a prescription drug with a wholesale acquisition cost of at least \$100 for a course of therapy before the effective date of an increase:

⁴⁸ Available at: https://ahca.myflorida.com/medicaid/quality_mc/health_finder.shtml.

⁴⁹ Section 499.003, F.S., defines a prescription drug to mean a prescription, medicinal, or legend drug, including, but not limited to, finished dosage forms or active pharmaceutical ingredients subject to, defined by, or described by s. 503(b) of the federal act or s. 465.003, s. 499.007(13), subsection (31), or subsection (47), except that an active pharmaceutical ingredient is a prescription drug only if substantially all finished dosage forms in which it may be lawfully dispensed or administered in this state are also prescription drugs.

- Any increase of 15 percent or more of the wholesale acquisition cost during the preceding 12-month period; or
- Any increase of 40 percent or more of the wholesale acquisition cost during the preceding three calendar years.
- “Wholesale acquisition cost” to mean, with respect to a prescription drug or biological, the manufacturer’s list price for the prescription drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates, or reduction in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

Under the bill, Florida-licensed manufacturers of prescription drugs must submit two sets of information to the DBPR, portions of which may be claimed as trade secret under s. 119.0715, F.S., and therefore exempt from the public records provisions of ch. 119, F.S. The bill protects DBPR employees from release of the information in the forms and reports. The submissions are as follows:

- On the effective date of a reportable drug price increase, the manufacturer must submit on a form adopted by the DBPR all of the following information for each reportable drug price increase:⁵⁰
 - The proprietary and nonproprietary names of the prescription drug, as applicable.
 - The wholesale acquisition cost before the reportable drug price increase.
 - The dollar amount of the reportable drug price increase.
 - The percentage amount of the reportable drug increase from the wholesale acquisition cost before the reportable drug price increase.
 - A statement regarding whether a change or improvement in the prescription drug necessitates the reportable drug price increase and a description of the change or improvements if it does. The manufacturer may designate this information as trade secret, if applicable.
 - The intended uses of the prescription drug.
- By April 1 of each year, the manufacturer must submit a report to the DBPR. The report is not deemed submitted until it is approved by the department. The report must include all of the following:
 - A list of all prescription drugs identified by proprietary and nonproprietary names, as applicable, affected by a reportable drug price increase during the previous calendar year, along with the dollar amount and the percentage increase of each reportable drug price increase relative to the previous wholesale acquisition cost.
 - If more than one form was filed for reportable drug price increases for a prescription drug, the percentage increase of the prescription drug from the earliest form filed to the most recent form filed.
 - The intended uses of each prescription drug listed and whether the manufacturer benefits from market exclusivity for the prescription drug.
 - The length of time the prescription drug has been available for purchase.
 - A complete description of the factors contributing to each reportable drug price increase, provided with such specificity as to explain the need or justification for each reportable drug price increase. The DBPR may request additional information from a manufacturer

⁵⁰ The bill provides that this disclosure requirement to the DBPR does not prohibit a manufacturer from notifying other parties before the effective date of the increase.

- relating to the need or justification for any reportable drug price increase before it accepts and approves the manufacturer's report. The manufacturer may designate this information as trade secret, if applicable.
- Any action that the manufacturer has filed to extend a patent report after the first extension has been granted. The manufacturer may designate this information as trade secret, if applicable.

The DBPR is responsible for submitting all forms and reports to the AHCA for posting on the MyFloridaRX website maintained pursuant to s. 408.062, F.S. The AHCA must compile all information on the forms and reports submitted by manufacturers and make it available upon request to the Governor, The President of the Senate, and the Speaker of the House of Representatives.

The DBPR, in consultation with the AHCA, must adopt rules to implement these provisions. The DBPR is tasked with adopting an emergency rule initially. The bill provides a statutory process to follow if the initial emergency rule is held to be unconstitutional or an invalid exercise of delegated legislative authority and becomes void. In that case, the DBPR may adopt another emergency rule to replace the first one that became void. If the second emergency rule is also held to be unconstitutional or an invalid exercise of delegated legislative authority and becomes void, the DBPR must then proceed with nonemergency rulemaking under the Administrative Procedure Act (APA). If an emergency rule is challenged, within seven days after the Division of Administrative Hearings receives a sufficient petition challenging the validity of the emergency rule, an administrative law judge must be assigned who shall conduct a hearing within 14 days, unless the petition is withdrawn.

The bill exempts the emergency rulemaking from finding that an immediate danger to the public health, safety, or welfare requires emergency rulemaking under s. 120.54(4)(a), F.S., and preparing a statement of estimated regulatory costs under s. 120.54(3)(b), and s. 120.541, F.S. The bill also exempts the emergency rule from the 90-day timeframes that an emergency rule may be effective in s. 120.54(4)(c), F.S., and allows a valid emergency rule to remain in effect until replaced by rules adopted under the nonemergency rulemaking procedures of the APA.

PBMs as Administrators

Section 6. Amends s. 624.490, F.S., retaining the registration requirement for PBMs and conforming the definition of a PBM to the new definition in s. 626.88, F.S.

Section 8. Amends s. 626.88, F.S., to include PBMs in the definition of an administrator under the Florida Insurance Code and to define a PBM. Under the bill, a "PBM" means a person or entity doing business in this state which contracts to administer prescription drug benefits on behalf of a plan or program, as defined in s. 626.8825, F.S. The term includes, but is not limited to, a person or entity that performs one or more of the following services:

- Pharmacy claims processing.
- Administration or management of pharmacy discount card programs.
- Managing pharmacy networks or pharmacy reimbursement.
- Paying or managing claims for pharmacist services provided to covered persons.

- Developing or managing a clinical formulary, including utilization management or quality assurance programs.
- Pharmacy rebate administration.
- Managing patient compliance, therapeutic intervention, or generic substitution programs.
- Administration or management of a mail-order pharmacy program.

Section 9. Amends s. 626.8805, F.S., to establish the process for PBMs to obtain a certificate of authority to act as an administrator.

In order to allow time for PBMs that are currently operating in Florida to obtain a certificate of authority to act as an administrator, the bill authorizes a PBM that is registered under s. 624.490, F.S., as of June 30, 2023, to continue to operate as a PBM under that authority until January 1, 2024. By that date, a PBM must have obtained a certificate of authority to act as an administrator. A person who, on or after January 1, 2024, does not hold a certificate of authority to act as an administrator while operating as a PBM, is subject to a fine of \$10,000 per violation, per day.

The bill requires a PBM applying for a certificate of authority to act as an administrator to submit an application that includes:

- Basic organizational documents;
- By-laws;
- The names, addresses, official positions, and professional qualifications of the individuals employed by or retained by the administrator who are responsible for the conduct of the affairs of the administrator, including all members of the board of directors, board of trustees, executive committee or other governing bodies, and the principal officers or partners;
- A complete list of officers, directors, and shareholders (holding 10% or more of voting shares) having direct or indirect control of the organization, along with a biographical affidavit, background investigative report, and fingerprint card for each person listed;
- Audited annual financial statements for the two most recent fiscal years or other specified documents if the applicant has been in existence for less than two years;
- A statement describing the business plan;
- Evidence of the sources of funds to demonstrate financial viability if the applicant is not currently acting as an administrator; and
- A self-disclosure of any administrative, civil, or criminal complaints, settlements or discipline of the applicant or any of the applicant's affiliates, which relate to a violation of the insurance laws, including PBM laws, in any state.
- A statement attesting to compliance with the network requirements in s. 626.8825, F.S., beginning January 1, 2024.

A PBM applicant is required by the bill to make available for inspection by the OIR copies of all contract templates with any pharmacy and copies of all subcontracts to support its operations.

A PBM is exempt under the bill from fees associated with the initial application and the annual filing fees.

Section 14. Amends s. 626.89, F.S., to require PBMs annually to submit:

- A statement of financial condition.
- Audited financial statement prepared by an independent certified public accountant.
- A statement attesting to its compliance with the network requirements of s. 626.8825, F.S.

PBMs must also notify the OIR immediately of any material change in its ownership and within 30 days after any administrative, civil, or criminal complaints, settlements, or discipline of the PBM or any of its affiliates which relate to a violation of the insurance laws, including pharmacy benefit laws in any state.

Section 10. Amends s. 626.8814, F.S., to require PBMs to disclose to the OIR:

- Any ownership interest or affiliation with any insurance company responsible for providing benefits for which the PBM acts as an administrator, and
- Any ownership affiliation of any kind with any pharmacy that:
 - Has an investment or ownership interest in a PBM in Florida;
 - Shares common ownership with a PBM in Florida; or
 - Has an investor or a holder of an ownership interest which is a PBM in Florida.

Any change in this information must be reported in writing to the OIR within 60 days after the change occurs.

PBM Transparency and Accountability

Section 11. Creates s. 626.8825, F.S., to provide definitions, and regulate contractual agreements between PBMs and pharmacy benefits plans and programs and between PBMs and pharmacies.

Definitions

The follow definitions apply to s. 626.8825, F.S.:

- “Adjudication transaction fee” means a fee charged by the PBM to the pharmacy for electronic claim submissions.
- “Affiliated pharmacy” means a pharmacy that, either directly or indirectly through one or more intermediaries:
 - Has an investment or ownership interest in a PBM holding a certificate of authority issued under this part;
 - Shares common ownership with a PBM holding a certificate of authority issued under this part; or
 - Has an investor or a holder of an ownership interest which is a PBM holding a certificate of authority issued under this part.
- “Brand name or generic effective rate” means the contractual rate set forth by a PBM for the reimbursement of covered brand name or generic drugs, calculated using the total payments in the aggregate, by drug type, during the performance period. The effective rates are typically calculated as a discount from industry benchmarks, such as average wholesale price or wholesale acquisition cost.
- “Covered person” means a person covered by, participating in, or receiving the benefit of a plan or program.

- “Direct and indirect remuneration fees” means price concessions that are paid to the PBM by the pharmacy retrospectively and that cannot be calculated at the point of sale. The term may also include discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, upfront payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits from manufacturers, pharmacies, or similar entities.
- “Dispensing fee” means a fee intended to cover reasonable costs associated with providing the drug to a covered person. This cost includes the pharmacist’s services and the overhead associated with maintaining the facility and equipment necessary to operate the pharmacy.
- “Effective rate guarantee” means the minimum ingredient cost reimbursement a PBM guarantees it will pay for pharmacist services during the applicable measurement period.
- “Erroneous claims” means pharmacy claims submitted in error, including, but not limited to, unintended, incorrect, fraudulent, or test claims.
- “Incentive payment” means a retrospective monetary payment made as a reward or recognition by the plan or program or PBM to a pharmacy for meeting or exceeding predefined pharmacy performance metrics as related to quality measure, such as Healthcare Effectiveness Data and Information Set measures.
- “Maximum allowable cost appeal pricing adjustment” means a retrospective positive payment adjustment made to a pharmacy by the plan or program or by the PBM pursuant to an approved maximum allowable cost appeal request submitted by the same pharmacy to dispute the amount reimbursed for a drug based on the PBM’s listed maximum allowable cost price.
- “Monetary recoupments” means rescinded or recouped payments from a pharmacy or provider by the plan or program or by the PBM.
- “Network” means a group of pharmacies that agree to provide pharmacist services to covered persons on behalf of a plan or program or a group of pharmacy benefits plans or programs in exchange for payment for such services. The term includes a pharmacy that generally dispenses outpatient prescription drugs to covered persons.
- “Network reconciliation offsets” means a process during annual payment reconciliation between a PBM and a pharmacy which allows the PBM to offset an amount for over-performance or under-performance of contractual guarantees across guaranteed line items, channels, networks, or payers, as applicable.
- “Participation contract” means any agreement between a PBM and pharmacy for the provision and reimbursement of pharmacist services and any exhibits, attachments, amendments, or addendums to such agreement.
- “Pass-through pricing model” means a payment model used by a PBM in which the payments made by the plan or program to the PBM for the covered outpatient drugs are:
 - Equivalent to the payments the PBM makes to a dispensing pharmacy or provider for such drugs, including any contracted professional dispensing fee between the PBM and its network of pharmacies. Such dispensing fee would be paid if the plan or program was making the payments directly.
 - Passed through in their entirety by the plan or program or by the PBM to the pharmacy or provider that dispenses the drugs, and the payments are made in a manner that is not offset by any reconciliation.
- “Pharmacist” means a pharmacist as defined in s. 465.003, F.S.

- “Pharmacist services” means products, goods, and services or any combination of products, goods, and services provided as part of the practice of the profession of pharmacy as defined in s. 465.003, F.S., or otherwise covered by a plan or program.
- “Pharmacy benefit manager” has the same meaning as in s. 626.88, F.S.
- “Pharmacy benefits plan or program” means 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, are employed by, or receive pharmacist services from this state. The term includes, but is not limited to, health maintenance organizations, health insurers, self-insured employer health plans, discount card programs, and government-funded health plans, including the Statewide Medicaid Managed Care program established pursuant to part IV, ch. 409, F.S., and the state group insurance program pursuant to part I, ch. 110, F.S.
- “Rebate” means all payments that accrue to a PBM or its plan or program client, directly or indirectly, from a pharmaceutical manufacturer, including, but not limited to, discounts, administration fees, credits, incentives, or penalties associated directly or indirectly in any way with claims administered on behalf of a plan or program client.
- “Spread pricing” is the practice in which a PBM charges a plan or program a different amount for pharmacist services than the amount the PBM reimburses a pharmacy for such pharmacist services.
- “Usual and customary price” means the amount charged to cash customers for a pharmacist service exclusive of sales tax or other amounts claimed.

Contracts between a PBM and pharmacy benefits plan or program – Subsection (2)

The following provisions apply to 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 plan or program. These requirements are in addition to any other requirements in the FIC. The contract must:

- Use a pass-through pricing model, consistent with the next requirement.
- Excludes terms that allow for the direct or indirect practice of spread pricing unless the PBM passes along the entire amount of any difference to the plan or program.
- Ensure that funds received in relation to providing services for a plan or program or a pharmacy are received by the PBM in trust for the plan or program or pharmacy, as applicable and are used or distributed only in accordance with the PBM’s contract with the plan or program or pharmacy or as otherwise required by law.
- Require the PBM to pass 100 percent of all manufacturer rebates received to the plan or program, if the contractual arrangement delegates the negotiation of rebates to the PBM, for the sole purpose of offsetting defined cost sharing and reducing premiums of covered persons. If any excess rebate revenue remains, it must be used for the sole purpose of offsetting copayments and deductibles of covered persons. Medicaid managed care plans are excluded from this rebate provision.
- Include network adequacy requirements that meet or exceed the Medicare Part D program standards for convenient access to network pharmacies and that:
 - Do not limit a network to solely include affiliated pharmacies.
 - Require the PBM to offer a provider network contract to a pharmacy physically located onsite with essential providers as determined by the AHCA that are located within the plan’s geographic service area solely for the administration or dispensing of covered

- prescription drugs, including biologics, that are administered through infusions, intravenously injected, inhaled during a surgical procedures, or a covered parenteral drug, as part of onsite outpatient care.
- Require the PBM to offer a provider network contract to a pharmacy physically located onsite with Designated Cancer Centers of Excellence, organ transplant hospitals, specialty children's hospitals, or regional perinatal intensive care centers, regardless of the plan's geographic service area solely for the administration or dispensing of covered prescription drugs, including biologics, that are administered through infusions, intravenously injected, inhaled during a surgical procedures, or a covered parenteral drug, as part of onsite outpatient care.
 - Do not require a covered person to receive a prescription drug by mail, or some type of delivery service. However, this provision does not prohibit a PBM from operating mail-order or delivery programs on an opt-in basis at the sole discretion of a covered person.
 - Do not require a covered person, through network development; incentives, which does not include a reduced copay or premium of a covered drug; marketing; or otherwise, to receive pharmacist services from an affiliated pharmacy or affiliated health care provider for the inpatient administration of covered prescription drugs. Subject to the preceding sentence, a PBM may include an affiliated pharmacy in communications to covered persons regarding network pharmacies and prices, provided that information, such as links to all nonaffiliated network pharmacies, is included in the communications. The information for all network pharmacies must be accurate and of equal prominence. This provision does not prohibit a PBM from entering into an agreement with an affiliated pharmacy to provide pharmacist services to covered persons.
 - Prohibit the ability of a PBM to 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.
 - Prohibit a PBM from instituting a network that requires a pharmacy to meet accreditation standards that are inconsistent with or exceed state pharmacy licensure requirements.

Contracts between a PBM and a participating pharmacy – Subsection (3)

In addition to any other requirements in the FIC, all participation contracts between a PBM and one or more pharmacies or pharmacists that are executed, amended, adjusted, or renewed on or after July 1, 2023, and which are applicable to pharmacist services on or after January 1, 2024, must include, in substantial form, terms that ensure compliance with all the following requirements and which, except to the extent not allowed by law, shall superseded any contractual terms in the participation contract to the contrary:

- At the time of adjudication or reimbursement of claims, the PBM must provide the pharmacy with detailed information in accordance with national standards that is sufficient for the pharmacy to identify and validate the payment. The OIR is required to adopt rules to implement this requirement.
- The PBM must ensure that reimbursement information relating to reconciliation transactions are accurate and reliable and are communicated to the pharmacy in accordance with national standards.
- A prohibition of financial clawbacks, reconciliation offsets, or retroactive recoupments, with limited exceptions related to performance measures; erroneous claims, fraud, waste, or abuse;

claims adjudicated in error, adjustments made as part of a pharmacy audit, or recoupments returned to the state for certain programs.

- A PBM may not unilaterally change the terms of a participation contract.
- A PBM may not prevent a pharmacy or pharmacist from offering and providing mail or delivery services on an opt-in basis at the sole discretion of the covered person or charging a shipping or handling fee to the covered person if the pharmacy or pharmacist disclosed before the service the amount of the fee that will be charged and that the fee may not be reimbursable by the covered person's plan or program.
- If a pharmacy requests, a PBM must provide a list of plans or programs in which that pharmacy is a part of the network, with applicable updates. The pharmacy may disclose this information to the public.
- A PBM must ensure that the electronic remittance advice contains claim level payment adjustments in accordance with national standards with the appropriate level of detail to reconcile debits and credits.
- A PBM must provide a reasonable administrative appeal procedure for a pharmacy to challenge the maximum allowable cost (MAC) reimbursement or price update. Timeframes of 30 business days are provided for the pharmacy to appeal the MAC rate and for the PBM to respond after receipt of the appeal. If the appeal is upheld, the PBM must update the MAC information, allow the pharmacy to rebill the claim, provide the pharmacy with information on which the increase or change is based, and make the change effective for each similarly situated pharmacy that is subject to the applicable MAC pricing information. If the appeal is denied, the PBM must provide the pharmacy with the national drug code (NDC) and the name of a national or regional wholesaler operating in Florida with that drug in stock at a price below the MAC pricing information. PBMs are required to report to the OIR every 90 days the total number of appeals received and denied in the preceding 90-day period for each specific drug for which an appeal was submitted.

Section 12. Creates s. 626.8827, F.S., to specify prohibited practices of PBMs. In addition to other prohibitions related to practices of administrators, a PBM may not:

- Prohibit, restrict, or penalize a pharmacy or pharmacist from:
 - Disclosing to any person information that the pharmacy or pharmacist deems appropriate, including, but not limited to:
 - The nature of treatment, risks, or alternatives thereto.
 - The availability of alternate treatment, consultations, or tests.
 - The decision of utilization reviewers to authorize or deny pharmacist services.
 - The process used to authorize or deny pharmacist services or benefits.
 - Information on financial incentives and structures used by the plan or program.
 - Information that may reduce the costs of pharmacist services.
 - Whether the cost-sharing obligation exceeds the retail price for a covered prescription drug and the availability of a more affordable alternative drug.
 - Disclosing information to the OIR, the AHCA, the Department of Management Services, law enforcement, or state and federal government officials provided the recipient represents it has the authority to maintain proprietary information as confidential and the pharmacy or pharmacist marks documents with such proprietary information as confidential or requests confidential treatment for any oral communication of the information.

- Communicate at the point-of-sale, or otherwise require, a cost-sharing obligation for a covered person in an amount that exceeds the lesser of the cost-sharing amount under the applicable plan or program or the usual and customary price of the pharmacist services.
- Transfer or share patient-identifiable or prescriber-identifiable prescription data to an affiliated pharmacy for any commercial purpose other than the limited purposes of the PBM's responsibilities of the applicable plan or program.
- Fail to pay a pharmacy for an adjudicated claim with a date of service before any termination of the pharmacy in the network, unless payment is withheld due to actual fraud on the pharmacy's part or as otherwise required by law.
- Terminate the contract of, penalize, or disadvantage a pharmacist or pharmacy that:
 - Discloses information about the PBM's practices in accordance with the act.
 - Exercises any of its prerogatives under the sections of law relating to administrators.
 - Shares any portion of the PBM contract with the OIR pursuant to a complaint or query regarding whether the contract is in compliance with the act.
- Fail to comply with the requirements in s. 626.8825, F.S., which contains the contracting provisions created in this bill or s. 624.491, F.S., relating to pharmacy audit requirements.

Investigations and Examinations of PBMs

Section 5. Amends s. 624.307, F.S., to require the Division of Consumer Services (Division) within the Department of Financial Services to designate an employee as the primary contact for consumers and pharmacies on issues relating to PBMs. All complaints that allege conduct that may constitute a violation of part VII, ch. 626, F.S., relating to Insurance administrators, or if a PBM does not respond to a written request for documents and information pertaining to a consumer complaint, must be referred to the Office of Insurance Regulation for further action.

Section 13. Creates s. 626.8828, F.S., to provide specific parameters for conducting investigations and examinations of PBMs, paying the expenses associated with these investigations and examinations, and assessing penalties, as appropriate.

The bill confers upon the OIR the authority to investigate administrators who are PBMs and an applicant for authorization to act as an administrator who is a PBM. The OIR is required to:

- Review referrals from the Division relating to PBMs and investigate any referral that the Commissioner of Insurance Regulation, or designee, has determined reasonably indicates a possible violation of the statutes regulating administrators.
- Examine the business and affairs of each PBM at least every two years, beginning July 1, 2023. This biennial examination must be a systematic review to determine the PBM's compliance with the laws and rules applicable to PBMs, and include a detailed review of the PBM's compliance with ss. 626.8825 and 626.8827, F.S.
- Deliver a report by January 1 of the year following a 2-year cycle, to the Governor, President of the Senate, and Speaker of the House of Representatives summarizing the results of the biennial examination, including a detailed description of any violations committed by each PBM and detailed actions taken by the OIR related to the violations.
- Begin an examination of a PBM or include findings within an ongoing examination if a referral is made from the Division pursuant to s. 624.307, F.S., which reasonably indicates a pattern or practice of violations by a PBM.

Based on the findings of an examination that a PBM or applicant for authorization has exhibited a pattern or practice of knowing and willful violations of s. 626.8825, F.S., or s. 626.8827, F.S., the office may, pursuant to ch. 120, F.S., order a PBM to file all contracts between the PBM and pharmacies or the PBM and plans or programs to which s. 626.8825, F.S., applies, and any policies, guidelines, rules, protocols, standard operating procedures, instructions, or directives that govern or guide the manner in which the PBM or applicant conducts business related to such knowing and willful violations for review and inspection for the following 36-month period. These documents are public records and are not trade secrets or otherwise exempt from s. 119.07(1), F.S. “Knowing and willful” means any act or commission or omission which is committed intentionally, as opposed to accidentally, and which is committed with knowledge of the act’s unlawfulness or with reckless disregard as to the unlawfulness of the act.

The OIR also may conduct additional examinations of PBMs and applicants for authorization as often as it deems advisable or necessary to ascertain compliance with the laws and rules applicable to PBMs.

The bill cross-references other sections of the FIC that are also applicable to the investigations and examinations of PBMs relating to: the conduct of examinations; examination and investigation report; witnesses and evidence; compelled testimony; hearings; fingerprinting; and any other provision of ch. 624, F.S., applicable to the investigation or examination of an administrator.

The bill requires PBMs to maintain an accurate record of all contracts and records with all pharmacies and plans or programs for five years after the contract ends. These contracts must be made available and kept in a form accessible to the OIR. In addition, the PBM must produce any records, book, files, contracts, advertising and solicitation materials, or other information to the OIR. The OIR may take statements under oath to determine whether the PBM or applicant is in violation of the law or is acting contrary to the public interest.

Examinations may be conducted by an independent professional examiner under contract with the OIR. In this case, the PBM must pay the contracted examiner directly in accordance with the rates and terms agreed to by the OIR and the examiner. Otherwise, the PBM or applicant for authorization must pay to the OIR the expenses of the examination or investigation in accordance with the detailed statement submitted by the examiner. The bill provides that all moneys collected from the PBMs relating to the expenses of examinations or investigations must be deposited into the Insurance Regulatory Trust Fund. The bill requires the Commission to adopt rules for the qualifications of the examiners, that rates charged to the PBM are consistent and comparable with rates charged by other firms in a similar profession for comparable examinations, and that a firm selected to perform the examination must have no conflicts of interest that might affect its ability to independently perform its responsibilities for the examination.

The bill requires the OIR to impose an administrative fine of \$5,000 for each violation of s. 626.8825, F.S., or s. 626.8827, F.S. Each instance of a PBM’s violation of these sections against each individual pharmacy or plan or program is a separate violation and there is no limitation on aggregate fines assessed under this statute. These fines are in addition to any other enforcement

authority available to the OIR. A PBM that fails to pay expenses incurred for investigations and examinations or imposed administrative fines may have its certificate of authority denied, suspended, or revoked.

Other Provisions

Section 7. Amends s. 624.491, F.S., to extend the pharmacy audit requirements in this section to pharmacy benefits plans or programs. The exemptions pertaining to claims paid for by federally funded programs currently in that section remains unchanged.

Section 15 and Section 18. Amend ss. 627.42393, F.S., and s. 641.31, F.S., respectively, relating to step-therapy protocols to extend the application of these provisions to PBMs acting on behalf of a health insurer or health maintenance organization (HMO). These sections currently forbid an insurer or HMO from requiring an insured to complete a step therapy protocol for a covered prescription drug if the insured recently completed a step therapy protocol under a previous health coverage plan and otherwise meets the criteria set forth in the statute. These statutes also set forth a process for requesting a protocol exception and appealing a denial of the protocol exception.

Section 16, Section 17, and Section 19. Amend ss. 627.64741, 627.6572, and 641.314, F.S., relating to PBM contracts with individual health plans, group health plans, and HMOs, respectively, to specify these plans must also comply with the contractual requirements between PBMs and plans and programs in Part VII, ch. 626, F.S. Additional provisions that are in these statutory sections have been moved into s. 626.8825, F.S., created in this bill.

Section 19. Conforms the cross-reference for the definition of a PBM in s. 624.491, F.S., relating to pharmacy audits to the definition of a PBM as an administrator.

Section 20. Creates a non-statutory section of the Laws of Florida addressing three subjects:

- Expresses Legislative intent that the act establishes requirements for PBMs acting for or otherwise on behalf of a plan or program, as defined in s. 626.8825, Florida Statutes, which includes providing coverage for, including but not limited to, governmental programs. The specific governmental programs enumerated include Titles XVIII, XIX, or XXI of the Social Security Act, 42 U.S.C. ss. 1395 et. seq., 1396 et seq., and 1397aa et seq., known as Medicare, Medicaid, or any other similar coverage under a state or Federal government funded health plan, including the Statewide Medicaid Managed Care program established pursuant to part IV, ch. 409, F.S., and the state group insurance program pursuant to part I, ch. 110, F.S. This provision is not intended to be a limiting statement of applicability.
- The act is not intended, nor may it be construed, to conflict with existing, relevant federal law.
- A severability clause: If any provision of this act or its application to any person or circumstances is held invalid, the invalidity does not affect other provisions or applications of this act which can be given effect without the invalid provision or application, and to this end the provisions of this act are severable.

Section 21. Creates a non-statutory section of the Laws of Florida providing a \$1,127,525-appropriation (\$980,705 recurring and \$146,820 nonrecurring) from the Insurance Regulatory Trust Fund to the Office of Insurance Regulation, along with salary rate for 10 full-time equivalent positions to implement the bill.

The bill provides an effective date of July 1, 2023.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

A separate bill, CS/SB 1552, addresses extending the current exemptions from s. 119.07(1), F.S., the public record law and s. 24(a), Art. I of the State Constitution that are applicable to Administrators under the FIC to PBMs, which are a new class of Administrator. Section 119.0715, F.S., provides that a trade secret held by an agency is confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

Similar legislation in other states has been challenged on the grounds that certain provisions are preempted by ERISA or Medicare Part D.

In 2020, the U.S. Supreme Court took up a challenge by the Pharmaceutical Care Management Association (PCMA) to an Arkansas statute regulating PBMs' reimbursement to pharmacies on grounds that the statute was preempted by ERISA. The court in *Rutledge v. Pharmaceutical Care Management Association*,⁵¹ opined that the statute in dispute was not preempted by ERISA and provided a roadmap for determining whether a state law would be preempted by ERISA.

In *Rutledge*, the court considered whether the state law had an “impermissible connection” with an ERISA plan by requiring providers to structure benefit plans in particular ways, such as by requiring payment of specific benefits or by binding plan administrators to specific rules for determining beneficiary status.⁵² The court ruled that the statute at issue did not “relate to” an ERISA plan because the requirement that PBMs

⁵¹ *Supra* 20. *Rutledge*.

⁵² *Supra* 21.

reimburse pharmacies at a rate equal to or higher than the pharmacy's acquisition cost was merely a form of cost regulation which did not dictate plan choices or design. The court stated that ERISA preempts laws that require providers to structure benefit plans in particular ways, such as requiring the payment of specific benefits or by binding plan administrators to specific rules for determining beneficiary status. The court further opined that the statute did not "refer to" ERISA, as the state did not act immediately and exclusively upon ERISA plans and the existence of such plans was not essential to the law's operation, since it regulated PBMs whether or not the plans they service fell within ERISA's coverage.⁵³

The preemption under Medicare Part D incorporates the express preemption provision contained in Medicare Part C. Applying the Medicare Part C exemption to Medicare Part D, the preemption provides: "The standards established under this part shall supersede any State law or regulation (other than state licensing laws or state laws relating to plan solvency) with respect to prescription drug plans."⁵⁴ The Supreme Court has not ruled on this preemption as it relates to state regulation of PBMs and lower courts have approached the analysis differently. Currently a case challenging Oklahoma's Act is in the United States Court of Appeals for the Tenth Circuit, *Pharmaceutical Care Management Association v. Mulready*.⁵⁵ Although this decision would not be dispositive of the provisions in CS/SB 1550, or similar legislation, if enacted, it is of interest to the majority of states that have taken an active role in enacting laws to regulate PBMs.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Violation of the provisions in the bill might result in significant fines and penalties to PBMs. The actual fiscal impact is indeterminate.

Some of the bill's provisions may prohibit PBMs from employing mechanisms designed to reduce costs of prescription drugs for insurers, HMOs, and other pharmacy benefits plans and programs, which could have the effect of increasing premiums and/or other costs for such payers or for persons with individual coverage. The extent of such effect is indeterminate.

Retail pharmacies may be able to negotiate with PBMs on a more even status under the bill; however, the fiscal impact is indeterminate.

⁵³ *Supra* 22.

⁵⁴ *Supra* 24.

⁵⁵ *Supra* 25.

C. Government Sector Impact:

The Department of Financial Services Division of Consumer Services will need to designate an employee as the primary contact to receive complaints on issues relating to PBMs and to process preliminary reviews of the complaints.

The State Group Health Insurance program utilizes a PBM to manage its pharmacy benefit. The Department of Management Services, which operates state group health insurance, has submitted an analysis estimating a recurring cost to general revenue of approximately \$2.2 million, attributed to the bill's requirement that state group health insurance must discontinue its use of an exclusive specialty pharmacy arrangement with its PBM and the inability to utilize a cost accumulator program under the bill.

The OIR will require additional staff to regulate PBMs as administrators. The OIR indicates additional staff in the Life and Health Market Regulation Unit and the Life and Health Financial Oversight Unit will be needed to process applications, respond to and investigate complaints, and conduct examinations and investigations. In addition, legal resources to pursue enforcement or administrative discipline as applicable will be needed. The OIR estimates salary and benefits at \$1,127,525.

The DBPR indicates a position and information technology resources will be needed to process manufacturer reportable drug price increase submissions but indicates this may be accomplished within existing resources.

The AHCA will incur costs to receive and publish on its website manufacturer reportable drug price increase information.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 499.005, 499.012, 624.307, 624.490, 624.491, 626.88, 626.8805, 626.8814, 626.89, 627.42393, 627.64741, 627.6572, 641.31, and 641.314.

This bill creates the following sections of the Florida Statutes: 499.026, 626.8825, 626.8827, and 626.8828.

This bill creates two non-statutory sections of the Laws of Florida.

IX. Additional Information:

- A. **Committee Substitute – Statement of Substantial Changes:**
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Policy on March 27, 2023:

The substantive changes in the CS compared to the underlying bill include:

- Allowing manufacturers to claim certain information as trade secret in the submissions of reportable drug price increases.
- Providing a designated point of contact for pharmacies to complain about PBM practices.
- Extending the pharmacy audit requirements in s. 624.491 to pharmacy benefits plans or programs, while retaining the exemptions pertaining to claims paid for by federally funded programs currently in that section and including the failure to comply with these requirements as a prohibited act in s. 626.6627.
- Revising definitions of PBM and network.
- Requiring PBMs to pass 100 percent of all rebates received to the plan or program, if the contractual arrangement delegates the negotiation of rebates to the PBM, for the sole purpose of offsetting defined cost sharing and reducing premiums of covered persons. If any excess remains, the rebate revenue must be used for the sole purpose of offsetting copayments and deductibles of covered persons. The Medicaid managed care plans are exempted from this requirement.
- Expanding the pharmacies to which a PBM must offer a network contract to those co-located in designated Cancer Centers of Excellence, organ transplant hospitals, specialty children’s hospitals, and Regional Perinatal Intensive Care Centers.
- Clarifying that a reduced copay or premium of a covered drug is not a prohibited promotional item or an incentive.
- Prohibiting PBMs from preventing pharmacies from providing mail-order or delivery services.
- Streamlining the MAC appeal process when an appeal has been denied to providing a pharmacy with an NDC (national drug code) and identification of wholesalers that have the drug in stock at a price below the MAC pricing information, and authorizing appeals to be submitted by a pharmacy’s agent.
- Authorizing the Commission to adopt rules for the qualifications of professional examiners and the requirement for comparable rates and independence with no conflicts of interest.
- Extending a 15-day reporting timeframe to 30 days for notifying OIR of administrative, civil, or criminal events.
- Providing a more detailed appropriation.

- B. **Amendments:**

None.