

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 Banking and Insurance

BILL: CS/SB 1338

INTRODUCER: Banking and Insurance Committee and Senators Wright and Harrell

SUBJECT: Prescription Drug Coverage

DATE: January 29, 2020

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Johnson	Knudson	BI	Fav/CS
2.			AHS	
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Technical Changes

I. Summary:

CS/SB 1338 revises provisions of the Florida Insurance Code (code) relating to the transparency and oversight of pharmacy benefit managers (PBM) by the Office of Insurance Regulation (OIR). Many public and private employers and health plans contract with PBMs to administer their prescription drug benefits and to help control drug costs. The PBMs may negotiate drug prices with retail pharmacies and drug manufacturers on behalf of health plans or employers and, in addition to other administrative, clinical, and cost containment services, process drug claims for the plans or employers.

In recent years, the price of prescription drugs has gained attention at the state and federal level. Access to affordable prescription drugs is a significant issue for a number of consumers, particularly those without insurance; those prescribed expensive specialty drugs for treating serious or rare diseases; or those enrolled in private insurance with high cost-sharing requirements. The PBMs and drug manufacturers have come under scrutiny as policymakers have attempted to understand their role in the drug supply chain. Due to a lack of transparency in the marketplace, it is difficult to determine how much various payers and supply chain intermediaries pay for prescription drugs. Stakeholders have raised concerns regarding the regulatory oversight of the pharmacy benefit managers.

The bill provides the following changes to the code to increase oversight of PBMs and provide greater drug price transparency:

- Clarifies that the OIR has the authority to conduct market conduct examinations of PBMs to determine compliance with the provisions of the code.
- Requires insurers or HMOs, and their PBMs to comply with the pharmacy audit provisions, and provides authority for the OIR to enforce these provisions.
- Provides that a pharmacy may appeal audit findings, relating to the payment of a claim or the amount of a claim payment, through the Statewide Provider and Health Plan Claim dispute Resolution Program under the Agency for Health Care Administration.
- Clarifies that an insurer or HMO remains responsible for any violations of the pharmacy audit requirements and the prompt pay law by a PBM acting on its behalf.
- Clarifies the OIR's authority to review an insurer's contract with a PBM; authorizes OIR to review reasonableness of PBM fees; and allows the OIR to order the cancellation of such contracts under certain conditions. Currently, the OIR has the authority to review the reasonableness of fees within an HMO contract, and cancel such contracts if the fees are not reasonable.
- Revises the definition of the term, "maximum allowable cost;" and creates definitions of the terms, "brand drug," and "generic drug."
- Requires a PBM to pass through generic rebates to an insurer or HMO.
- Increases PBM transparency by requiring the submission of an annual report to the OIR regarding rebates and other information.

According to the PBM for the State Group Insurance program, the fiscal impact of the bill will result in an increase in plan cost of \$8.82 million, which is \$24.57 per member per year. There would be an increase in total members cost of \$1.7 million.

II. Present Situation:

In 2019, private health insurance spending is expected to increase by 3.3 percent.¹ This trend is the net effect of faster spending growth in many services such as physician and clinical services and prescription drugs. In 2019, prescription drug spending growth is projected to increase by 4.6 percent, due to faster utilization growth from both existing and new drugs, as well as a modest increase in drug price growth. For the remainder of the projection, 2020-2027, prescription drug spending is expected to grow by 6.1 percent per year on average, influenced by higher use anticipated from new drugs and efforts by employers and insurers that encourage patients with chronic conditions to treat their disease.²

The Drug Supply Chain

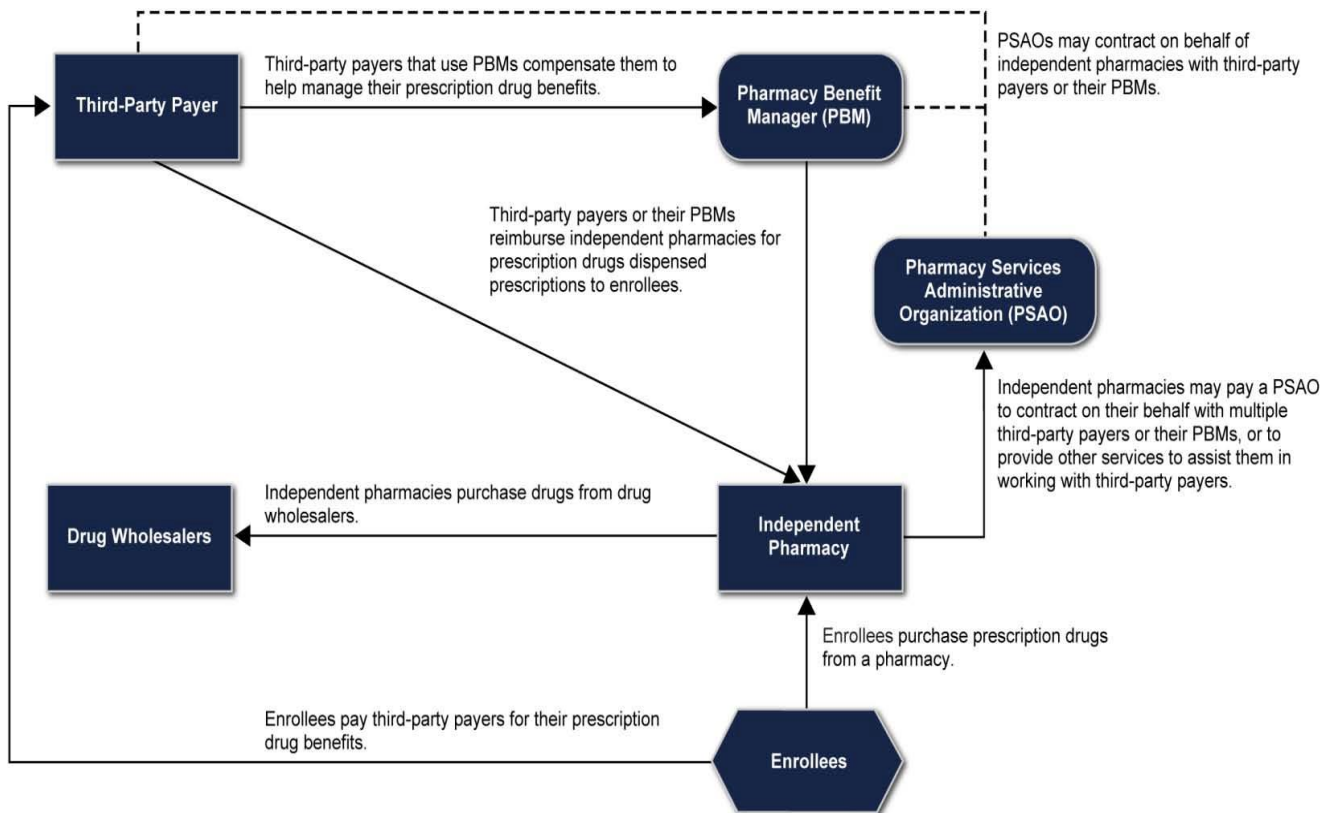
The affordability of prescription drugs has gained attention at the state and federal level. In recent years, PBMs and drug manufacturers have come under scrutiny as policymakers have attempted to understand their role in the drug supply chain. Many stakeholders (drug manufacturers, drug wholesalers, pharmacy services administrative organizations, pharmacy

¹ See National Health Expenditure Projections 2018-2027, Forecast Summary, The Office of the Actuary in the Centers for Medicare & Medicaid Services, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ForecastSummary.pdf> (last viewed Nov. 20, 2019).

² *Id.*

benefit managers, health plans, employers, and consumers) are involved with, and pay different prices for, prescription drugs as they move from the drug manufacturer to the insured.

In general, manufacturers develop and sell their drugs to wholesalers, and wholesalers then sell the drugs to pharmacies. With limited time and resources, some independent pharmacies may need assistance in interacting with these entities, particularly with third-party payers that include large private and public health plans. Many use a pharmacy services administrative organization (PSAO) to interact on their behalf. The PSAOs develop networks of pharmacies by signing contractual agreements with each pharmacy that authorizes them to negotiate with third-party payers on the pharmacy's behalf. Drug wholesalers and independent pharmacy cooperatives owned the majority of PSAOs in operation in 2011 or 2012.³ Health insurers, HMOs, or employers may contract with PBMs to manage their prescription drug benefits.. The interaction among key entities involved in the distribution and payment of prescription drugs is depicted below:⁴



Source: GAO analysis based on interviews and industry reports.

³ General Accounting Office, *The Number, Role, and Ownership of Pharmacy Services Administrative Organizations* (GAO-13-176) (Feb 28, 2013) at <https://www.gao.gov/products/GAO-13-176> (last viewed Jan. 20, 2020).

⁴ *Id.*

A Study of 15 Large Employer Plans⁵

In response to concerns about rising drug costs, a recent study evaluated drug utilization from plan sponsors to estimate savings from reducing the use of high cost, low-value drugs and described some of the cost concerns and challenges relating to the drug supply chain, as follows:

PBMs negotiate with pharmaceutical manufacturers for price discounts, which are typically paid as rebates based on sales volumes driven by formulary placement. Rebates can reduce the final net price to the plan sponsor and may be passed on to patients. However, in exchange for low administration fees, plan sponsors allow PBMs to keep a portion of the negotiated rebates and other fees. Contracts between PBMs and plan sponsors contain rebate guarantees, perpetuating the demand for high-rebate drugs by encouraging PBMs to maximize rebate revenue, giving preference to some drugs over others on formularies based on rebate revenue rather than their value and final cost to the patient or plan sponsor. Additionally, PBMs earn revenue from “spread” pricing, which is the difference between what PBMs pay pharmacies on behalf of plan sponsors and what PBMs are reimbursed by the plan sponsor. This also encourages PBMs to prioritize higher-cost drugs to allow for a larger spread.

The report⁶ further describes additional factors, which may increase costs for employers and insureds:

...plan sponsors often allow broad formularies that include wasteful drugs because they are concerned that employees will be disappointed if their prescribed drugs are not covered. Doctors prescribe these drugs because they are often unaware of drug costs. Pharmaceutical manufacturers contribute to these patterns by promoting their products through “detailers” — pharmaceutical salespeople calling on doctors — when less costly alternatives may be clinically appropriate for patients. Plan sponsors have addressed the resulting high spending by increasing patient cost-sharing on lower-value drugs. Manufacturers counteract cost-sharing and formulary management tools by flooding the market with copayment coupons that undermine the benefit structure put in place by plan sponsors.

Pharmacy Benefit Managers

Many public and private employers and health plans contract with PBMs to help control drug costs. While PBMs provide pharmacy claims processing and mail-order pharmacy services to their customers, many provide additional services, including rebate negotiations with drug manufacturers, development of pharmacy networks, drug formulary management, prospective and retrospective drug utilization reviews, generic drug substitutions, and disease management. A recent report found that PBMs passed through 78 percent of manufacturer rebates to health

⁵ Vela, Lauren, *Reducing Wasteful Spending in Employers’ Pharmacy Benefit Plans* (Aug. 2019) the Commonwealth Fund at <https://www.commonwealthfund.org/publications/issue-briefs/2019/aug/reducing-wasteful-spending-employers-pharmacy-benefit-plans> (last viewed Jan. 3, 2020).

⁶ *Id.*

plans in 2012 and 91 percent in 2016.⁷ For the same period, the report noted that manufacturer rebates grew from \$39.7 billion to \$89.5 billion, and played a growing role in partially offsetting increases in list prices, which the study noted have risen more quickly than overall retail prescription drug spending.⁸

In 2018, three companies processed about 75 percent of all equivalent prescription claims: CVS Health (including Caremark and Aetna), Express Scripts, and the OptumRx business of UnitedHealth. The top six PBMs handled more than 95 percent of the total U.S. equivalent prescription claims managed.⁹ The top six PBMs were:

- CVS Health (Caremark)/Aetna, 30 percent
- Express Scripts, 23 percent
- OptumRx (UnitedHealth), 23 percent
- Humana Pharmacy Solutions, 7 percent
- Medimpact Healthcare Systems, 6 percent
- Prime Therapeutics, 6 percent

Reimbursement of Pharmacies by PBMs

Generally, a contract between a PBM and a health plan sponsor or employer specify the amount a plan or employer will pay a PBM for brand name and generic drugs. These prices are typically set as a discount off the average wholesale price for brand-name drugs and at a maximum allowable cost (MAC) for generic drugs (and sometimes brand drugs that have generic versions), plus a dispensing fee. The MAC represents the upper limit price that a plan will pay or reimburse for generic drugs and sometimes brand drugs that have generic versions available (multisource brands). A MAC pricing list creates a standard reimbursement amount for identical products.

A MAC pricing list is a common cost management tool that is developed from a proprietary survey of wholesale prices existing in the marketplace, taking into account market share, inventory, reasonable profit margins, and other factors. One of the purposes of the MAC pricing list is to ensure that the pharmacy or their buying groups are motivated to seek and purchase generic drugs at the lowest price in the marketplace. If a pharmacy procures a higher-priced product, the pharmacy may not make as much profit or in some instances may lose money on that specific purchase. If a pharmacy purchases generic drugs at a more favorable price, they will be more likely to make a profit.

Retail Pharmacies

Independent pharmacies¹⁰ are a type of retail pharmacy with a store-based location—often in rural and underserved areas—that dispense medications to consumers, including both prescription and over-the-counter drugs. Nationwide, the number of independent pharmacies in

⁷ Reynolds, Ian, et. al., *The Prescription Drug Landscape, Explored* (Mar. 2019). The Pew Charitable Trusts.

⁸ *Id.* There were 123 survey responses comprised of 114 individuals from commercial, managed Medicaid, and Medicare Part D health plans and 9 from PBMs.

⁹ Drug Channels, CVS, Express Scripts, and the Evolution of the PBM Business Model (May 29, 2019) at <https://www.drugchannels.net/2019/05/cvs-express-scripts-and-evolution-of.html> (last viewed Jan. 10, 2020).

¹⁰ One definition of an independent provides that a pharmacy is considered independent if the total store count is fewer than four stores. See https://www.pharmacist.com/sites/default/files/files/Profile_16_Independent_SDS_FINAL_090307.pdf (last viewed Jan. 20, 2020).

the United States continues to decline. In 2010, there were 23,106 independent pharmacies; by 2017, that number had dropped to 21,909.¹¹ Another report¹² noted that the number of independent retail pharmacies in Florida increased 32.4 percent from 2010 to 2019. During that same period, the number of independent retail pharmacists peaked in 2017 at 1,735, and declined to 1,541 in 2019.¹³

The decision of employers, HMOs, or insurers to contract with PBMs may shift business away from smaller retail pharmacies that are also known as independent pharmacies. Historically, independent pharmacies were important health care providers in their communities and their pharmacists had long-term relationships with their patients.¹⁴ However, many independent pharmacies have closed in recent years because of the competition resulting from the proliferation of large, chain retail pharmacies¹⁵ that can negotiate with PBMs at deeply discounted reimbursement levels based on large volume sales. In 2018, further innovation and competition in the marketplace occurred with Amazon acquiring PillPack, a mail-order pharmacy, which has pharmacy licenses in all 50 states.¹⁶ One report noted that Amazon has begun the process of undercutting prices of over the counter medications.¹⁷ Further, some Amazon prices are 20 percent lower than brand medications sold at Walgreens and CVS.¹⁸

Regulation of Health Insurance in Florida

The OIR licenses and regulates insurers, HMOs, and other risk-bearing entities.¹⁹ To operate in Florida, an insurer or HMO must obtain a certificate of authority from the OIR.²⁰ The Agency for Health Care Administration (AHCA) regulates the quality of care provided by HMOs under part III of ch. 641, F.S. Prior to receiving a certificate of authority from the OIR, an HMO must receive a Health Care Provider Certificate from the AHCA.²¹ As part of the certification process used by the AHCA, an HMO must provide information to demonstrate that the HMO has the ability to provide quality of care consistent with the prevailing standards of care.²²

Section 641.234, F.S., authorizes the OIR to require a HMO to submit any contract for administrative services, contract with a provider other than an individual physician, contract for management services, and contract with an affiliated entity to the OIR. After review of a

¹¹ Arnold, Karen, *Independent Pharmacies: Not Dead Yet*, (Jan. 12, 2019, vol. 163, issue 1) Drug Topics, Voice of the Pharmacist.

¹² Quest Analytics analysis of NCPDP Pharmacy Count Data, 2019. Provided by PCMA. On file with Banking and Insurance Committee.

¹³ *Id.*

¹⁴ Independent pharmacies are a type of retail pharmacy with a store-based location—often in rural and underserved areas—that dispense medications to consumers, including both prescription and over-the-counter drugs. See <http://www.gao.gov/assets/660/651631.pdf> (last viewed Jan. 19, 2020).

¹⁵ Such as Walmart, CVS, Walgreens, Publix or Kroger.

¹⁶ Garcia, Ahiz, *Amazon rolls out “Amazon Pharmacy” branding to PillPack*, CNN Business (Nov. 15, 2019) at <https://www.cnn.com/2019/11/15/tech/amazon-pharmacy-pillpack/index.html> (last viewed Jan. 22, 2020).

¹⁷ Cauley, Michael, *Amazon: What Will be its Impact on Community Pharmacy?*

<https://www.managedhealthcareconnect.com/blog/amazon-what-will-be-its-impact-community-pharmacy>

¹⁸ *Id.*

¹⁹ Section 20.121(3)(a)1., F.S.

²⁰ Sections 624.401 and 641.21(1), F.S.

²¹ Section 641.49, F.S.

²² Section 641.495, F.S.

contract, the OIR may order the HMO to cancel the contract in accordance with the terms of the contract and applicable law if it determines:

- That the fees to be paid by the health maintenance organization under the contract are so unreasonably high as compared with similar contracts entered into by the HMO or as compared with similar contracts entered into by other HMOs in similar circumstances that the contract is detrimental to the subscribers, stockholders, investors, or creditors of the HMO; or
- That the contract is with an entity that is not licensed under state statutes, if such license is required, or is not in good standing with the applicable regulatory agency.

Oversight of PBMs

In 2018, legislation was enacted to require PBMs to register with the OIR, effective January 1, 2019, and impose contractual provisions on insurers or HMOs and their PBMs.²³ The law defined a PBM as a person or entity doing business in Florida, which contracts to administer prescription drug benefits on behalf of a health insurer or a HMO to residents of Florida.²⁴

Registration. The registration process requires an applicant to remit a nonrefundable fee not to exceed \$500, a copy of certain corporate documents, and a completed registration form. Registration and registration renewal certificates are valid for 2 years and are nontransferable.²⁵ Registrants must report any change in the registration information within 60 days of the change to the OIR.

Contract Provisions. The 2018 law also repealed provisions in the Florida Pharmacy Act, s. 465.1862; F.S., relating to PBM contracts, and transferred them to the insurance code.²⁶ These provisions require contracts between health insurers or HMOs and PBMs to:

- Require the PBM to update the maximum allowable cost (MAC) pricing information at least once every 7 calendar days;
- Require the PBM to maintain a process that will eliminate drugs from the MAC lists or modify drug prices in a timely manner to remain consistent with changes in pricing data;
- Prohibit the PBM from limiting a pharmacist's ability to disclose whether the cost-sharing obligation exceeds the retail price for a covered prescription drug, and the availability of a more affordable alternative drug, pursuant to s. 465.0244, F.S.
- Prohibit the PBM from requiring an insured to pay for a prescription drug at the point of sale in an amount that exceeds the lesser of:
 - The applicable cost sharing amount; or
 - The retail price of the drug in the absence of prescription drug coverage.

Maximum Allowable Cost. The 2018 law also creates the definition of the term, "maximum allowable cost" (MAC) to mean the per-unit amount that a PBM reimburses a pharmacist for a prescription drug, excluding dispensing fees, prior to the application of copayments, coinsurance, and other cost-sharing charges, if any.

²³ Ch. 2018-91, s. 3, L.O.F.

²⁴ Section 624.490, F.S.

²⁵ *Id.*

²⁶ See ss. 627.64741, 627.6572, and 641.314, F.S.

However, the legislation did not provide the OIR with enforcement authority over PBMs to ensure compliance with these contractual provisions, such as being able to revoke or suspend a PBM's registration or fine the PBM. Therefore, when the OIR addresses any statutory violations by a PBM, the OIR looks to the insurer or HMO, which contracts with the PBM to fulfill its obligations under the insurance code to resolve the situation.²⁷

Payment of claims. Sections 627.6131 and 641.3155, F.S., requires a PBM, acting on behalf of an insurer or HMO, to pay a provider's claim within a prescribed time. Further, the Department of Financial Services reviews alleged violations, relating to claims of providers not paid or denied by the insurer or HMO, pursuant to these provisions.²⁸

Florida Pharmacy Act

Pursuant to the Florida Pharmacy Act, a "pharmacy" includes a community pharmacy, an institutional pharmacy, a nuclear pharmacy, a special pharmacy, and an Internet pharmacy. The term "community pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.²⁹ The term, "independent pharmacy," is not defined.

Section 465.1885, F.S., prescribes the rights of a pharmacy in connection with an audit by a PBM, Medicaid managed care plan, or insurance company. These rights include:

- To be notified at least 7 calendar days before the initial onsite audit.
- To have the onsite audit scheduled after the first 3 calendar days of a month unless the pharmacist consents otherwise.
- To have the audit period limited to 24 months after the date a claim is submitted to or adjudicated by the entity.
- To have an audit that requires clinical or professional judgment conducted by or in consultation with a pharmacist.
- To use the written and verifiable records of a hospital, physician, or other authorized practitioner, which are transmitted by any means of communication, to validate the pharmacy records in accordance with state and federal law.
- To be reimbursed for a claim that was retroactively denied for a clerical error, typographical error, scrivener's error, or computer error if the prescription was properly and correctly dispensed, unless a pattern of such errors exists, fraudulent billing is alleged, or the error results in actual financial loss to the entity.
- To receive the preliminary audit report within 120 days after the conclusion of the audit.
- To produce documentation to address a discrepancy or audit finding within 10 business days after the preliminary audit report is delivered to the pharmacy.
- To receive the final audit report within 6 months after receiving the preliminary audit report.
- To have recoupment or penalties based on actual overpayments and not according to the accounting practice of extrapolation.

²⁷ Office of Insurance Regulation, *2020 Legislative Analysis of SB 1338* (Jan. 2, 2020).

²⁸ Department of Financial Services, *Medical Providers, find out who to contact about your claim payment concerns* at <https://apps.fldfs.com/eservice/MedicalProvider.aspx> (last viewed Jan. 22, 2020).

²⁹ Section 465.003(11), F.S.

However, the Department of Health nor the Board of Pharmacy has authority under ch. 465, F.S., the Florida Pharmacy Act, to enforce these provisions against any entity not complying with these requirements.

State Group Insurance Program

Under the authority of s. 110.123, F.S., the Department of Management Services (department), through the Division of State Group Insurance (DSGI), administers the State Group Insurance program under a cafeteria plan consistent with s. 125, Internal Revenue Code. To administer the program, the department contracts with third-party administrators for self-insured health plans, fully insured HMOs, and a Pharmacy Benefits Manager (PBM) for the self-insured State Employees' Prescription Drug Program (program) pursuant to s. 110.12315, F.S.

The program has four dispensing avenues: participating 30-day retail pharmacies, participating 90-day retail pharmacies, the PBM's mail order pharmacies, and the PBM's specialty pharmacies. The retail network provides 3,961 pharmacies within the state of Florida and 59,520 nationally. The only chain pharmacy not included in the program's retail network is Walgreens.

During the invitation to negotiate process, the department determined that using a slightly less broad network provided significant savings to the program while having zero access disruption to members.³⁰ While the program does offer a mail order pharmacy network in the contract with the current PBM, members are not required to use mail order and may fill their prescriptions for up to a 90-day supply at network retail pharmacies that agree to the same pricing as the mail order. Contractually, and as stated in the benefit documents, specialty drugs, as defined by the PBM, must be dispensed by the PBM's specialty pharmacies. However, the first fill of oncology specialty drugs may be covered when dispensed by a network retail pharmacy. This process allows the patient to obtain the medication as soon as possible while providing time for the prescriber to get the patient set up at the PBM's specialty pharmacy. To assist members and prescribers, the PBM's specialty pharmacies have clinicians trained in each of the clinical disciplines, conditions, and specialties corresponding to the specialty drugs being dispensed.

The program covers all federal legend drugs unless specifically excluded or if prescribed to treat a non-covered medical condition. The program does not have fail first requirements or step therapy. The contract between the PBM and the state requires that 100 percent of all manufacturer payments including rebates must be passed through to the state; and that spread pricing at retail pharmacies is prohibited.

The health plans (PPO and HMOs) and the PBM on behalf of the program each apply their respective medical policy guidelines to determine medical necessity for drugs; none of the plans (medical and Rx) cover experimental and/or investigational drugs and treatments.

Copayments (and coinsurance for high deductible plans) for each drug tier are the same for all members, as follows:

³⁰ See Department of Management Services, *2020 Legislative Analysis of SB 1338 (Jan. 16, 2020)*.

Drug Tier	Retail – Up to 30-Day Supply	Retail and Mail – Up to 90-Day Supply and Specialty Medications
Generic	\$7	\$14
Preferred Brand	\$30	\$60
Non-Preferred Brand	\$50	\$100

The State Group Insurance Program typically makes benefit changes on a plan year basis, which is January 1 through December 31. Benefit changes are subject to approval by the Legislature. The current PBM for the State Group Insurance Program is CaremarkPCS Health, LLC (CVS Caremark).

Statewide Provider and Health Plan Claim Dispute Resolution Program

The intent of this program, administered by the Agency for Health Care Administration (agency), is to assist contracted and noncontracted providers and health plans for resolution of claim disputes that are not resolved by the provider and the health plan.³¹ The agency contracts with an independent dispute resolution organization to assist health care providers and health plans in order to resolve claim disputes. These services are available to Medicaid managed care providers and health plans. Claims submitted to managed care plans that have been denied in full or in part, or allegedly underpaid or overpaid may be eligible for dispute under the arbitration process.³²

Federal Regulations Relating to Medical Loss Ratios, Rebates, and Spread Pricing

Insurers, HMOs, and PBMs

Health insurers and HMOs are required to report how much they spend on health care and how much they spend on administrative costs, such as salaries and marketing. If an insurer or HMO spends less than 80 percent (85 percent in the large group market) of premium on medical care and efforts to improve the quality of care, they must refund the portion of premium that exceeds this limit. The 80 percent (or 85 percent) is the medical loss ratio. The PBMs must report rebate information to the health insurers and HMOs, and the insurer or HMO includes this information as a deduction from the amount of incurred claims in the MLR reporting to the Department of Health and Human Services (HHS).³³ The Medicaid plans must also calculate and report medical loss ratios, which must account for rebates and spread pricing, as described below.

Medicaid

According to the Centers for Medicare and Medicaid Services (CMS), states are increasingly reporting instances of spread pricing in Medicaid, including cases in Ohio and Texas, and CMS is concerned that spread pricing is inflating prescription drug costs that are borne by beneficiaries

³¹ Section 408.7057, F.S.

³² *Id.*

³³ Section 2718 of the Public Health Service Act. The HHS has the authority to examine insurers and HMOs and their vendors, such as PBMs.

and by taxpayers.³⁴ Further, if spread pricing is not monitored, a PBM can profit from charging health plans an excess amount above the amount paid to the pharmacy dispensing a drug, which increases Medicaid costs for taxpayers.

According to CMS, spread pricing has been reported predominantly for generic prescriptions. States have raised concerns that PBMs can reimburse pharmacies for generic prescriptions based on lower pricing benchmarks than the benchmarks used for charging Medicaid and CHIP managed care plans for the same prescriptions.

In response to these concerns, the CMS released guidance that prohibits PBMs using spread pricing to upcharge health plans and increase costs for states.³⁵ For purposes of the medical loss ratio³⁶ (MLR) regulation, “prescription drug rebates” means any price concession or discount received by the managed care plan or by its PBM, regardless of who pays the rebate or discount.³⁷ Some possible examples include payments from pharmaceutical manufacturers, wholesalers, and retail pharmacies. Therefore, the amount retained by a PBM under spread pricing would have to be excluded from the amount of claims costs used for calculating the Medicaid managed care plan’s MLR. The policy underlying this guidance is that spread pricing should not be used to artificially inflate a Medicaid or CHIP managed care plan’s MLR. For purposes of calculating the medical loss ratio, the Medicaid managed care regulations³⁸ require that prescription drug rebates received and accrued must be deducted from incurred claims. The CMS also interprets this requirement to apply equally regardless of whether the prescription drug rebate is received by the managed care plan (i.e., directly) or by a subcontractor (i.e., indirectly) administering the covered outpatient drug benefit on behalf of the managed care plan.

When a managed care plan subcontracts with a third-party vendor to administer, and potentially provide, a portion of Medicaid covered services to enrollees, the subcontractor must report to the managed care plan all of the underlying data needed for the Medicaid managed care plan to calculate and report the managed care plan’s MLR.³⁹ The regulations at 42 CFR 438.8(k) also require states, through their contracts with managed care plans, to require each managed care plan to submit an annual MLR report.

Drug Pricing Transparency

Due to a lack of transparency in the marketplace, it can be difficult to determine the final price of a prescription drug. Drug companies price discriminate, meaning they sell the same drug to different buyers (wholesalers, health plans, pharmacies, hospitals, government purchasers, and other providers) at different prices. The final price of a drug may include rebates and discounts to

³⁴ Centers for Medicare and Medicaid Services, *CMS Issues New Guidance Addressing Spread Pricing in Medicaid, Ensures Pharmacy Benefit Managers are not Up-Charging Taxpayers* (May 15, 2019) at <https://www.cms.gov/newsroom/press-releases/cms-issues-new-guidance-addressing-spread-pricing-medicaid-ensures-pharmacy-benefit-managers-are-not> (last viewed Jan. 3, 2020).

³⁵ Centers for Medicare and Medicaid Services, *Medical Loss Ratio (MLR) Requirements Related to Third-Party Vendors* (May 15, 2019) <https://www.medicaid.gov/federal-policy-guidance/downloads/cib051519.pdf> (last viewed Jan. 3, 2020).

³⁶ CMS regulations require Medicaid and CHIP managed care plans to report an MLR and use an MLR target of 85 percent in developing rates. The 85 percent target means that only 15 percent of the revenue for the managed care plan can be used for administrative costs and profits.

³⁷ 42 CFR 438.8(e)(2)(ii)(B).

³⁸ *Id.*

³⁹ 42 CFR 438.230(c)(1) and 42 CFR 438.8(k)(3).

health plans and pharmacy benefit managers that are not disclosed. Market participants, such as wholesalers, add their own markups and fees. Drug manufacturers may offer direct consumer discounts, such as prescription drug coupons that can be redeemed when filling a prescription at a pharmacy.

Drug pricing transparency requires manufacturers, PBMs, and others to expand public disclosures and report more information on drug pricing to the state or federal government. Strategies may be aimed at various parties:

- Manufacturers – price increases, list prices, pricing policies.
- Pharmacy Benefit Managers (PBMs) – rebates, other roles.
- Insurers – formularies, cost sharing for brand and generic drugs, and utilization management techniques.
- Providers – price markups.
- State agencies – drug expenditures and usage trends.

Federal Reporting

Medicare Part D plans and qualified health plan issuers who have their own PBM or contract with a PBM are required to report to the U.S. Department of Health and Human Services (HHS) aggregate information about rebates, discounts, or price concessions that are passed through to the plan sponsor or retained by the PBM. In addition, the plans must report the difference between the amount the plan pays the PBM and the amount that the PBM pays its suppliers (spread pricing). The reported information is confidential, subject to certain limited exceptions.⁴⁰

State Reporting

In 2016, Vermont approved the first law requiring manufacturer disclosure for drugs that underwent large percentage price increases.⁴¹ Each year, this law requires state regulators to compile a list of 15 drugs used by Vermont residents that experience the largest annual price increases. Manufacturers are required to justify the price increase to the Attorney General. The act requires the Attorney General to provide an annual report to the General Assembly based on the information the Office receives from manufacturers and to post the report on the Office's website.

Oregon established a legislative task force in 2018 (HB 4005) that has developed more than a dozen recommendations for further work, including state agency reporting on the 10 most expensive drugs and the 10 with the highest price increases; manufacturer justification of high prices; insurer explanation of formulary practices; provider disclosure of markups; and evaluation of PBM rebates. Maine also enacted a law in 2018 (LD 1406) requiring the state's APCD to annually report on the price of the state's most frequently prescribed and costliest prescription drugs, and to develop a plan for the collection of cost and pricing information from drug manufacturers.⁴²

⁴⁰ 42 U.S.C. s. 1320b-23.

⁴¹ See <https://legislature.vermont.gov/Documents/2016/Docs/ACTS/ACT165/ACT165%20Act%20Summary.pdf> (last viewed Jan. 11, 2020).

⁴² Ario, Joel, *Strategies to Expand Transparency, Enhance Competition and Control Costs: A Toolkit for Insurance Regulators* Manatt Health Strategies (Jul. 2019) at

The California Drug Pricing Reporting Law (the law)⁴³ is designed to provide greater information about trends and factors relating to drug cost and pricing for policymakers and the public. The law imposes price justification, notification, and reporting requirements on pharmaceutical manufacturers for price increases on their drugs sold to state purchasers, insurers, and pharmacy benefit managers in California. The law requires manufacturers to notify state regulators regarding price increases, too. Further, the law requires insurers and health maintenance organizations to report specified cost information regarding covered prescription drugs and the impact of such cost on premiums. The state is required to compile such information and post the annual report on its website. The state may impose civil penalties against entities failing to comply with the reporting requirements. The law requires manufacturers to provide written notification to:

- Purchasers (insurers, HMOs, pharmacy benefit managers, and state agencies) of a drug price increase that exceeds 16 percent over a 2-year period for any drugs with a wholesale acquisition cost (WAC)⁴⁴ of greater than \$40. The notice must include a statement regarding whether a change or improvement in the drug necessitates the price increase, and if applicable, a description of such change or improvement. This notification must be provided at least 60 days prior to the effective date of the increase.
- The state for each drug for which an increase in WAC, as described above, occurs, or other specified drug price increases. Manufacturers must provide information regarding such drug's indication and dosage, factors used to increase the WAC, and marketing materials.

In the notice to purchasers, as described above, the manufacturer may limit the disclosure to information that it is in the public domain. The state is required to publish on the internet information submitted by manufacturers to the state, as described above, in a manner that identifies the information on a per-drug basis.

III. Effect of Proposed Changes:

Section 1 amends s. 624.3161, F.S., to authorize the OIR to conduct market conduct examinations of PBMs.

Section 2 transfers s. 465.1885, F.S., and renumbers the section as s. 624.491, F.S., and amends the section to clarify existing requirements and limitations for pharmacy audits by an insurer or HMO or an entity on behalf of the insurer or HMO, including but not limited to a PBM. The section specifies:

- Limits on when audits can be conducted;
- Audit scope;
- Use of a consulting pharmacist;
- Use of written and verifiable records of health care providers to validate pharmacy records;

https://www.naic.org/meetings1908/cmte_b_health_inn_wg_2019_summer_nm_materials_strategies.pdf (last viewed Jan. 3, 2020).

⁴³ See Cal. Health & Safety Code s. 1367.243, s. 1385.045, s. 127280, s. 127675, s. 127676, s. 127677, s. 127679, s. 127681, s. 127683, s. 127685, and s. 127686 (Senate Bill No. 17, 2017).

⁴⁴ Under federal law, the term “wholesale acquisition cost” means, with respect to a drug or biological, the manufacturer’s list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions 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. See 42 U.S. Code s. 1395w-3a.

- Retroactive reimbursement for claims denied for certain errors;
- The timeframe for the provision of preliminary audits;
- Allowance for production of preliminary documentation to rebut an audit finding;
- Time period for production of the final audit;
- How final recoupment and penalties are calculated.

The section allows a pharmacy to appeal claim payments that are due as a result of an audit with the Statewide Provider and Health Plan Claim Dispute Resolution Program at the Agency for Health Care Administration.

Section 3 creates s. 624.491, F.S., to require health insurers and HMOs, or a PBM acting on behalf of a health insurer or HMO, to report to OIR annually by March 1, the following information for the preceding policy or contract year:

- The total number of prescriptions that were dispensed.
- The number and percentage of all prescriptions that were provided through retail pharmacies compared to mail-order pharmacies.
- The general dispensing rate, which is the number and percentage of prescriptions for which a generic drug was available and dispensed.
- The aggregate amount and types of rebates, discounts, price concessions, or other earned revenues that the health insurer, HMO, or PBM negotiated for and are attributable to patient utilization under the plan, excluding bona fide service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs. If negotiated by the pharmacy benefit manager, the aggregate amount of the rebates, discounts, or price concessions, which were passed through to the health insurer or HMO. These provisions are consistent with the current federal PBM transparency reporting requirements.
- If the health insurer or HMO contracted with a PBM, the aggregate amount of the difference between the amount the health insurer or HMO paid the PBM and the amount the PBM paid retail pharmacies and mail order pharmacies.

Sections 4, 5, and 6 amend ss. 627.64741, 627.6572, and 641.14, F.S., respectively, relating to insurance policies and HMO contracts.

The bill defines “brand name drug” as a drug described by the Medi-Span Master Drug Database and has a multi-source code containing an “M” an “O” or an “N” except for a drug with a multi-source code of “O” and “Dispense as Written code” of 3, 4, 5, 6, or 9; or, the drug has an equivalent brand drug designation in the First Database FDB MedKnowledge database.

A “generic drug” is defined as a drug described by Medi-Span with a multi-source code containing a “Y” or an “O” and a “Dispense as Written code” of 3, 4, 5, 6, or 9; or the drug has an equivalent generic designation in the First Databank FDB MedKnowledge database.

The definition of the term, “maximum allowable cost” is revised to mean the per unit amount that a pharmacy benefit manager reimburses a pharmacist for prescription drugs:

- As specified at the time of claim processing and directly or indirectly reported on the initial remittance advice of an adjudicated claim for a generic drug, a brand name drug, biological product, or a specialty drug;
- Which amount must be based on the pricing published in the Medi-Span Master Drug Database or, if the pharmacy only uses the First Databank FDB Medknowledge, the pricing must be based on the price published in First Databank FDB Medknowledge; and
- Which excludes dispensing fees, prior to the application of copayments, coinsurance, and other cost-sharing charges, if any.

The bill provides that drugs identified as brand name drugs must be considered brand name drugs for all purposes under an agreement, contract, or amendment to a contract between a PBM and a pharmacy, or a pharmacy services organization on behalf of a pharmacy. A single source generic drug with only one manufacturer must be reimbursed as if it were a brand name drug. A drug identified as a generic drug must be considered a generic drug for all purposes under an agreement, contract, or amendment between a PBM and a pharmacy, or a pharmacy services organization on behalf of a pharmacy. A PBM and the pharmacy, or a pharmacy services administrative organization on behalf of the pharmacy, must agree that if any rebate or other financial benefit for a generic drug is provided to the PBM, the PBM shall only serve as a pass-through to the health insurer or HMO.

Further, the sections provide that a health insurer or HMO may only contract with a PBM that:

- Updates its maximum allowable cost pricing information at least every 7 days.
- Maintains a process that will, in a timely manner, eliminate drugs from maximum allowable cost lists or modify drug prices to remain consistent with changes in pricing data used in formulating maximum allowable cost prices and product availability.
- Does not limit a pharmacist's ability to disclose whether the cost-sharing obligation exceeds the retail price for a covered prescription drug, and the availability of a more affordable alternative drug.
- Does not require an insured to make a payment for a prescription drug at the point of sale in an amount that exceeds the lesser of the applicable cost-sharing amount or the retail price in the absence of prescription drug coverage.

The sections also provide that the OIR may require any health insurer or HMO to submit any PBM contract or amendment for the administration of pharmacy benefits to the office for review. After review of the contract, the OIR may order the health insurer or HMO to cancel the contract in accordance with the contract terms and applicable law if any of the following conditions exist:

- The PBM fees paid by the health insurer or HMO are unreasonably high compared to similar contracts entered by health insurers or HMOs, or as compared to similar contracts in similar circumstances, that the contract is detrimental to the policyholders or subscribers of the insurer or HMO.
- The contract does not comply with the code.
- The PBM is not registered with the OIR pursuant to s. 624.490, F.S.

Section 7 provides that this bill takes effect July 1, 2020.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The bill provides pharmacies with a process to appeal PBM audit filings relating to claim payments with the Statewide Provider and Health Plan Claim Dispute Resolution Program. The bill also provides statutory requirements for audits of pharmacies by PBMs.

The bill provides greater PBM transparency by requiring PBMs to submit an annual report to the OIR, which is consistent with a current federal reporting requirement.

C. Government Sector Impact:

Office of Insurance Regulation

The OIR will need pharmacy-related training and/or a contract with a pharmacist in order to provide effective oversight of PBM market conduct examinations and respond to any complaints involving pharmacy audits. The minimum estimated cost to contract with a pharmacist would be \$100,000 - \$200,000 (contracted services).⁴⁵

⁴⁵ Office of Insurance Regulation, *2020 Agency Legislative Bill Analysis of SB 1338* (Jan. 2, 2020).

Division of State Group Insurance/Department of Management Services (DSGI)⁴⁶

According to CVS/Caremark, the fiscal impact of these definition changes to DSGI would be an increase in plan cost of \$8.82M, which is \$2.05 per member per month or \$24.57 per member per year. There would be an increase in total member cost of \$1.7M. The calculations used are:

- Approximately 70K claims that would change from generic to brand drugs. All these claims would now be at the brand-drug rates and members would have to pay the brand-drug copayments.
- Approximately 3,000 claims that would change from brand to generic drugs. All these claims would now be at the generic rates and members would pay the generic copayments.

VI. Technical Deficiencies:

Sections 4, 5, and 6 include terms, which are not defined, such as “pharmacy services administrative organization”, “rebate”, and “other financial benefit.”

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 624.3161, 627.64741, 627.6572, and 641.314.

This bill creates section 624.491 of the Florida Statutes.

This bill repeals section 465.1885 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

Banking and Insurance on January 28, 2020:

The CS provides a technical change to correct a scrivener’s error.

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill’s introducer or the Florida Senate.

⁴⁶ Department of Management Services, *2020 Agency Legislative Bill Analysis of SB 1338* (Jan. 16, 2020).