

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 Appropriations Subcommittee on Health and Human Services

BILL: PCS/CS/SB 1338 (599864)

INTRODUCER: Appropriations Subcommittee on Health and Human Services; Banking and Insurance Committee; and Senators Wright, Harrell, Rodriguez, and Perry

SUBJECT: Prescription Drug Coverage

DATE: February 26, 2020 **REVISED:** _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Johnson</u>	<u>Knudson</u>	<u>BI</u>	<u>Fav/CS</u>
2.	<u>Gerbrandt</u>	<u>Kidd</u>	<u>AHS</u>	<u>Recommend: Fav/CS</u>
3.	_____	_____	<u>AP</u>	_____

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Technical Changes

I. Summary:

PCS/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). Specifically, the bill:

- Authorizes the OIR to examine PBMs to determine compliance with the provisions of the code;
- Requires insurers or Health Maintenance Organizations (HMO), and entities acting on their behalf, including a PBM, to comply with the pharmacy audit provisions;
- Provides that a pharmacy may appeal certain audit findings;
- 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;
- Requires health insurers, HMOs, or pharmacy benefit managers on behalf of health insurers and HMOs to annually report to the OIR regarding rebates and other information;
- Authorizes the OIR to review an insurer's or HMOs contract with a PBM and to order the cancellation of the contract under certain conditions; and

The bill may have a significant negative fiscal impact on the OIR. See Section V.

The bill takes effect on July 1, 2020.

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 was 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 period, 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 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.

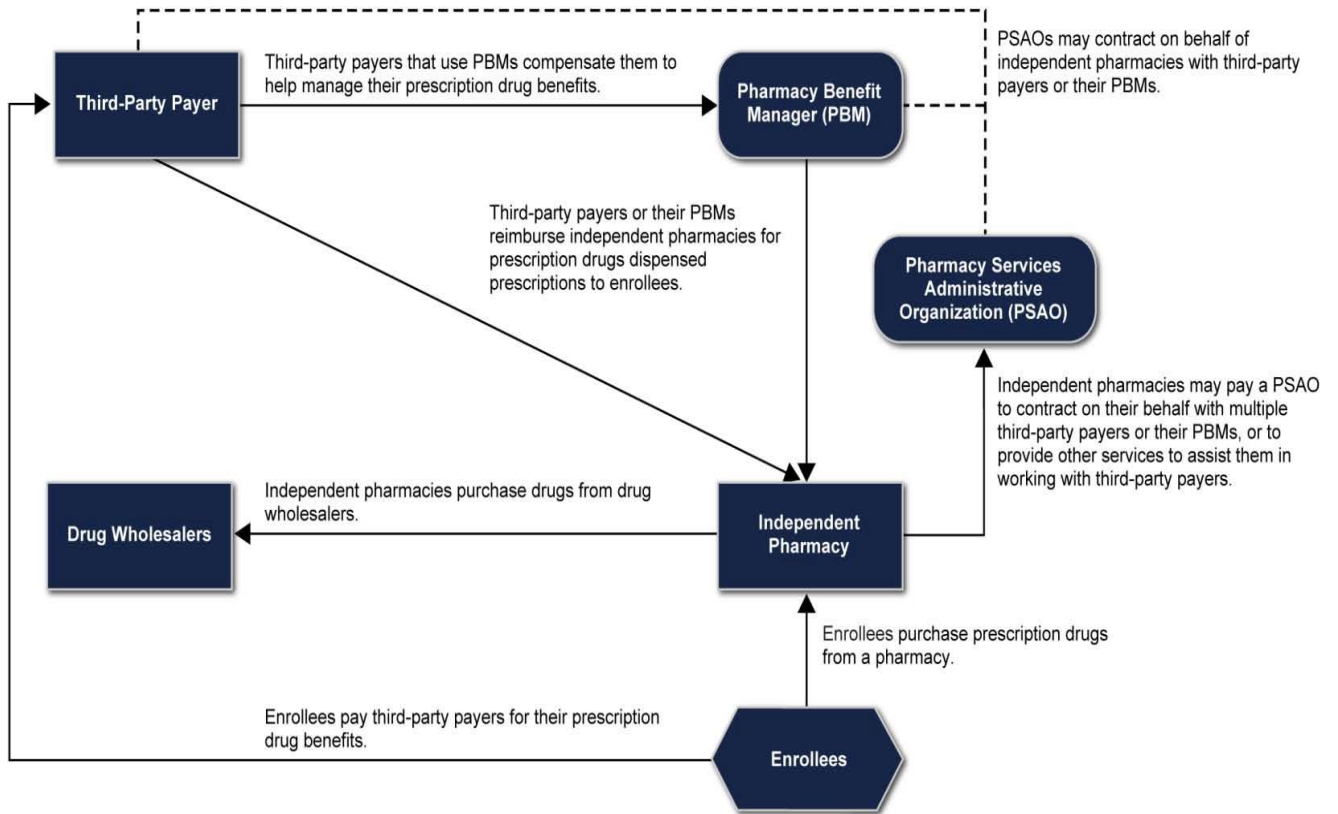
In general, manufacturers develop and sell their drugs to wholesalers, and wholesalers then sell the drugs to pharmacies. With limited time and resources, some independent pharmacies may need assistance in interacting with these entities, particularly with third-party payers that include large private 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

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.*

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.*



Source: GAO analysis based on interviews and industry reports.

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.

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 Feb. 12, 2020).

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 manage prescription drug costs. PBMs negotiate with retail pharmacies to obtain various discounts on prescription drugs. PBMs also offer the following services:

- Pharmacy claims processing;
- Mail-order pharmacy services;
- Drug formulary development and management;⁷
- Rebate negotiations with drug manufacturers;
- Pharmacy network development and management;
- Prospective and retrospective drug utilization reviews;
- Generic drug substitutions; and
- Disease management.⁸

A recent report found that PBMs passed through 78 percent of manufacturer rebates to health plans in 2012 and 91 percent in 2016.⁹ 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.¹⁰

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

⁶ *Id.*

⁷ A list of drugs that a health plan uses to make reimbursement decisions.

⁸ Office of Program Policy Analysis and Government Accountability, Florida Legislature, *Legislature Could Consider Options to Address Pharmacy Benefit Manager Business Practices*, Report No. 07-08 (Feb. 2007).

⁹ Reynolds, Ian, et. al., *The Prescription Drug Landscape, Explored* (Mar. 2019). The Pew Charitable Trusts.

¹⁰ *Id.* There were 123 survey responses comprised of 114 individuals from commercial, managed Medicaid, and Medicare Part D health plans and 9 from PBMs.

UnitedHealth. The top six PBMs handled more than 95 percent of the total U.S. equivalent prescription claims managed.¹¹ 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 specifies 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 pharmacies¹² 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 the United States continues to decline. In 2010, there were 23,106 independent pharmacies; by 2017, that number had dropped to 21,909.¹³ Another report¹⁴ 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 2019.¹⁵

¹¹ 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).

¹² 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).

¹³ Arnold, Karen, *Independent Pharmacies: Not Dead Yet*, (Jan. 12, 2019, vol. 163, issue 1) Drug Topics, Voice of the Pharmacist.

¹⁴ Quest Analytics analysis of NCPDP Pharmacy Count Data, 2019. Provided by PCMA. On file with Banking and Insurance Committee.

¹⁵ *Id.*

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.¹⁶ However, many independent pharmacies have closed in recent years because of the competition resulting from the proliferation of large, chain retail pharmacies¹⁷ 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.¹⁸ One report noted that Amazon has begun the process of undercutting prices of over the counter medications.¹⁹ Further, some Amazon prices are 20 percent lower than brand medications sold at Walgreens and CVS.²⁰

Oversight of PBMs

Current law requires PBMs to register with the OIR and requires contracts with PBMs to contain certain provisions.²¹ However, the OIR does not have enforcement authority over PBMs to ensure compliance with the required 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.²²

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.²³ Registrants must report any change in the registration information within 60 days of the change to the OIR.

Contract Provisions. Current law mandates that contracts between health insurers or HMOs and PBMs contain provisions requiring a PBM to:²⁴

- Update the maximum allowable cost (MAC) pricing information at least once every 7 calendar days;
- 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;

¹⁶ 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).

¹⁷ Such as Walmart, CVS, Walgreens, Publix or Kroger.

¹⁸ 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).

¹⁹ Cauley, Michael, *Amazon: What Will be its Impact on Community Pharmacy?*

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

²⁰ *Id.*

²¹ See section 624.490, F.S., for information on registration of pharmacy benefit managers, and s. 627.64741, F.S., for information on pharmacy benefit manager contract requirements.

²² Office of Insurance Regulation, *2020 Legislative Analysis of SB 1338* (Jan. 2, 2020).

²³ *Id.*

²⁴ Sections 627.64741, 627.6572, and 641.314, F.S.

- Refrain 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.
- Refrain 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. Current law defines the term “maximum allowable cost” (MAC), as 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.²⁵ The MAC represents the upper limit price that a plan sponsor will pay or reimburse for generic and brand-name drugs that have generic versions available.²⁶ The purpose of the MAC pricing list is to ensure that the pharmacy is motivated to seek and purchase generic drugs at the lowest price in the marketplace.

Payment of claims. Current law requires a PBM, acting on behalf of an insurer or HMO, to pay a provider’s claim within a prescribed time.²⁷ Further, the Department of Financial Services reviews alleged violations, relating to claims of providers not paid or denied by the insurer or HMO.²⁸ The Agency for Health Care Administration (AHCA) administers the Statewide Provider and Health Plan Claim Dispute Resolution Program to assist contracted and noncontracted providers and health plans in resolving claim disputes that are not resolved by the provider and the health plan.²⁹ Dispute resolution 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.³⁰

Pharmacy Audits

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.³¹ The term, “independent pharmacy,” is not defined.

The audit process is one means used by PBMs and health plan sponsors to review payments to pharmacies. The audits are designed to ensure that procedures and reimbursement mechanisms

²⁵ Section 627.64741, F.S.

²⁶ Brent J. Eberle, RPh, Alan Van Amber, *Your PBM’s MAC List Impacts Your Bottom Line*, Managed Healthcare Executive, (December 1, 2008), available at <https://www.managedhealthcareexecutive.com/drug-costs/your-pbms-mac-list-impacts-your-bottom-line> (last visited Feb. 12, 2020).

²⁷ See ss. 627.6131 and 641.3155, F.S.

²⁸ Department of Financial Services, *Medical Providers Information Memorandum, find out who to contact about your claim payment concerns* at <https://apps.fldfs.com/eservice/MedicalProvider.aspx> (last viewed Feb. 12, 2020).

²⁹ Section 408.7057, F.S.

³⁰ *Id.*

³¹ Section 465.003(11), F.S.

are consistent with contractual and regulatory requirements.³² 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.

Neither 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 provide prescription drug benefits for state employees and state university employees. 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.

³² The Florida Senate, *CS/SB 702, Pharmacy Audits, Bill Analysis* (March 13, 2014).

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.³³ 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.³⁴

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.³⁵

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.³⁶

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

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).³⁷

³³ See Department of Management Services, *2020 Legislative Analysis of SB 1338 (Jan. 16, 2020)*.

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.*

³⁷ *Id.*

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 (MLR). 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).³⁸ The Medicaid plans must also calculate and report MLRs, 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 and by taxpayers.³⁹ 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.⁴⁰

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.⁴¹ For purposes of the MLR regulation,⁴² “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.⁴³ 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

³⁸ Section 2718 of the Public Health Service Act. The HHS has the authority to examine insurers and HMOs and their vendors, such as PBMs.

³⁹ 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).

⁴⁰ *Id.*

⁴¹ Centers for Medicare and Medicaid Services, *Medical Loss Ratio (MLR) Requirements Related to Third-Party Vendors* (May 15, 2019) <https://www.medicare.gov/federal-policy-guidance/downloads/cib051519.pdf> (last viewed Jan. 3, 2020).

⁴² 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.

⁴³ 42 CFR 438.8(e)(2)(ii)(B).

MLR. For purposes of calculating the MLR, the Medicaid managed care regulations⁴⁴ 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.⁴⁵

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. 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.⁴⁶

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 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.⁴⁷

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:⁴⁸

- 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

⁴⁴ *Id.*

⁴⁵ *Supra* note 41.

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

⁴⁷ *See supra* note 3, 5 and 8.

⁴⁸ *Id.*

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.⁴⁹

State Reporting

In 2016, Vermont approved the first law requiring manufacturer disclosure for drugs that underwent large percentage price increases.⁵⁰ 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.⁵¹

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.⁵² Maine also enacted a law in 2018 (LD 1406) requiring the state's All Payer Claims Database 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.⁵³

The California Drug Pricing Reporting Law (the law)⁵⁴ 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)⁵⁵ of greater than \$40. The notice must include a statement regarding

⁴⁹ 42 U.S.C. s. 1320b-23.

⁵⁰ See <https://legislature.vermont.gov/Documents/2016/Docs/ACTS/ACT165/ACT165%20Act%20Summary.pdf> (last viewed Jan. 11, 2020).

⁵¹ *Id.*

⁵² Oregon Legislative Assembly, *HB 4005, Prescription Drug Transparency Act*, 2018.

⁵³ Ario, Joel, *Strategies to Expand Transparency, Enhance Competition and Control Costs: A Toolkit for Insurance Regulators Manatt Health Strategies* (Jul. 2019) at

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

⁵⁴ 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).

⁵⁵ 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

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.⁵⁶

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 bill transfers pharmacy audit provisions from the Florida Pharmacy Act to the Florida Insurance Code.

The bill clarifies that a health insurer or HMO remains responsible for any violations of the pharmacy auditing requirements and payment of claims violations by a PBM acting on its behalf. The bill also allows a pharmacy to appeal final audit findings related to claim payments with the Statewide Provider and Health Plan Claim Dispute Resolution Program administered by the AHCA.

Section 3 creates s. 624.492, F.S., to require health insurers and HMOs, or a PBM acting on behalf of a health insurer or HMO, to report to the OIR annually by March 1. Consistent with federal reporting requirements and to increase PBM transparency, the report must contain 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.

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.

⁵⁶ *Supra* note 53.

- If negotiated by the PBM, 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.

The bill also requires PBMs that submit the above information to the OIR must also provide the information to the health insurer and the HMO with which the PBM is under contract.

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

The bill allows the OIR to require health insurers and HMOs to submit PBM contracts to the office for review and allows the OIR to order the insurer or HMO to cancel the contract (in accordance with the contract terms and applicable law) if any of the following conditions exist:

- Unreasonably high PBM fees that are detrimental to the policyholders or subscribers of the insurer;
- Noncompliance with the Florida Insurance Code; or
- The PBM is not registered with the OIR pursuant to s. 624.490, F.S.

Section 7 provides that the 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:

PCS/CS/SB 1338 will increase the administrative costs of health insurers, HMOs, and PBMs due to the bill's requirements that:^{57,58}

- The OIR conduct market examinations of PBMs; and
- Health insurers, HMOs, and PBMs submit an annual report to the OIR.

C. Government Sector Impact:

The bill has an indeterminate negative fiscal impact on state expenditures due to the bill's impact to the administrative costs of health insurers, HMOs, and PBMs. To the extent that these administrative costs are passed down to customers, such as DSGI, there will be a fiscal impact.⁵⁹

According to the OIR, the bill will increase state expenditures. Specifically, the OIR will need pharmacy-related training and/or to contract with a pharmacist in order to provide effective oversight of PBM market conduct examinations and respond to any complaints involving pharmacy audits. According to the OIR the minimum estimated cost to contract with a pharmacist would be \$100,000 to \$200,000.⁶⁰

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 624.492 of the Florida Statutes.

This bill repeals section 465.1885 of the Florida Statutes.

⁵⁷ Department of Management Services, *2020 Agency Legislative Bill Analysis of SB 1338* (Jan. 16, 2020).

⁵⁸ Office of Insurance Regulation, *2020 Agency Legislative Bill Analysis of SB 1338* (Jan. 2, 2020).

⁵⁹ *Id.* and *supra* note 46.

⁶⁰ *Supra* note 47.

IX. Additional Information:**A. Committee Substitute – Statement of Changes:**

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

Recommended CS/CS by Appropriations Subcommittee on Health and Human Services on February 25, 2020:

The committee substitute removes the definitions of brand-name drug and generic drug and reverts to the current law definition of maximum allowable cost. The committee substitute also removes the requirement that contracts between a PBM and pharmacy or PSAO include:

- Drugs identified as brand-name drugs must be considered brand-name drugs for all purposes under an agreement, contract, or amendment to a contract.
- Single source generic drugs with only one manufacturer must be reimbursed as if they are a brand-name drug.
- Drugs identified as a generic drugs must be considered generic drugs for all purposes under an agreement, contract, or amendment to a contract.
- Rebates and other financial benefits for generic drugs provided to the PBM must be passed through to the health insurer or HMO.

Banking and Insurance on January 28, 2020:

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

B. Amendments:

None.