

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 Agriculture, Environment, and General Government

BILL: CS/SB 390

INTRODUCER: Banking and Insurance Committee and Senator Wright

SUBJECT: Prescription Drug Coverage

DATE: April 12, 2021

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Johnson</u>	<u>Knudson</u>	<u>BI</u>	<u>Fav/CS</u>
2.	<u>Sanders</u>	<u>Betta</u>	<u>AEG</u>	<u>Recommend: Favorable</u>
3.	_____	_____	<u>AP</u>	_____

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 390 revises provisions of the Florida Insurance Code (code) relating to the oversight of pharmacy benefit managers (PBMs) by the Office of Insurance Regulation (OIR). Specifically, the bill:

- Authorizes the OIR to conduct market conduct examinations of PBMs to determine compliance with applicable provisions of the code;
- Requires a health insurer or Health Maintenance Organizations (HMO), and any entity acting on their behalf, including a PBM, to comply with the pharmacy audit provisions;
- Provides that a health insurer or HMO may only contract with a PBM that complies with specified statutory requirements;
- Authorizes an audited pharmacy to appeal certain pharmacy audit findings made by health insurers or HMO; and
- 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.

The OIR estimates that it will incur a negative fiscal impact, ranging from \$100,000 to \$200,000, to contract with a pharmacist to provide oversight of PBM market conduct examinations and respond to complaints involving pharmacy audits.

The Division of State Group Insurance program may incur an indeterminate negative fiscal impact associated with the administrative costs associated with any market conduct examination

of its PBM by the OIR, to the extent such examination occurs and such costs are passed down to participants of the program.

The bill is effective July 1, 2021.

II. Present Situation:

In 2019, total U.S. health care spending increased 4.6 percent from the prior year to reach \$2.8 trillion or \$11,482 per person.¹ Over the past 20 years, U.S. drug spending has increased by 330 percent compared with a 208 percent increase in total U.S. health expenditures.²

The Prescription Drug Supply Chain

In recent years, the affordability of prescription drugs has gained attention, resulting in pharmacy benefit managers (PBMs) and drug manufacturers coming 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.

Due to a lack of transparency in the marketplace, it can be difficult to determine the final price of a prescription drug. The final price of a drug may include rebates and discounts to insurers, Health Maintenance Organizations (HMO), or pharmacy benefit managers that are not disclosed.³ Market participants, such as drug wholesalers, may add their own markups and fees, and drug manufacturers may offer direct consumer discounts, such as prescription drug coupons that can be redeemed when filling a particular prescription at a pharmacy.⁴

Some independent pharmacies may contract with pharmacy services administrative organizations (PSAO) to interact on their behalf with other stakeholders, such as drug wholesalers and third-party payers, such as large private and public health plans and their PBMs.⁵ 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 2012.⁶ Health insurers, HMOs, or self-insured employers may contract with PBMs to manage their

¹ Centers for Medicare and Medicaid Services, *National Health Expenditure 2019 Highlights*, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical> (last visited Mar. 22, 2021).

² Kirzinger, A., et. al., for the Kaiser Family Foundation. *US Public's Perspective on Prescription Drug Costs*. *JAMA*. 2019;322(15):1440. doi:10.1001/jama.2019.15547, <https://jamanetwork.com/journals/jama/fullarticle/2752910> (last visited Mar. 22, 2021).

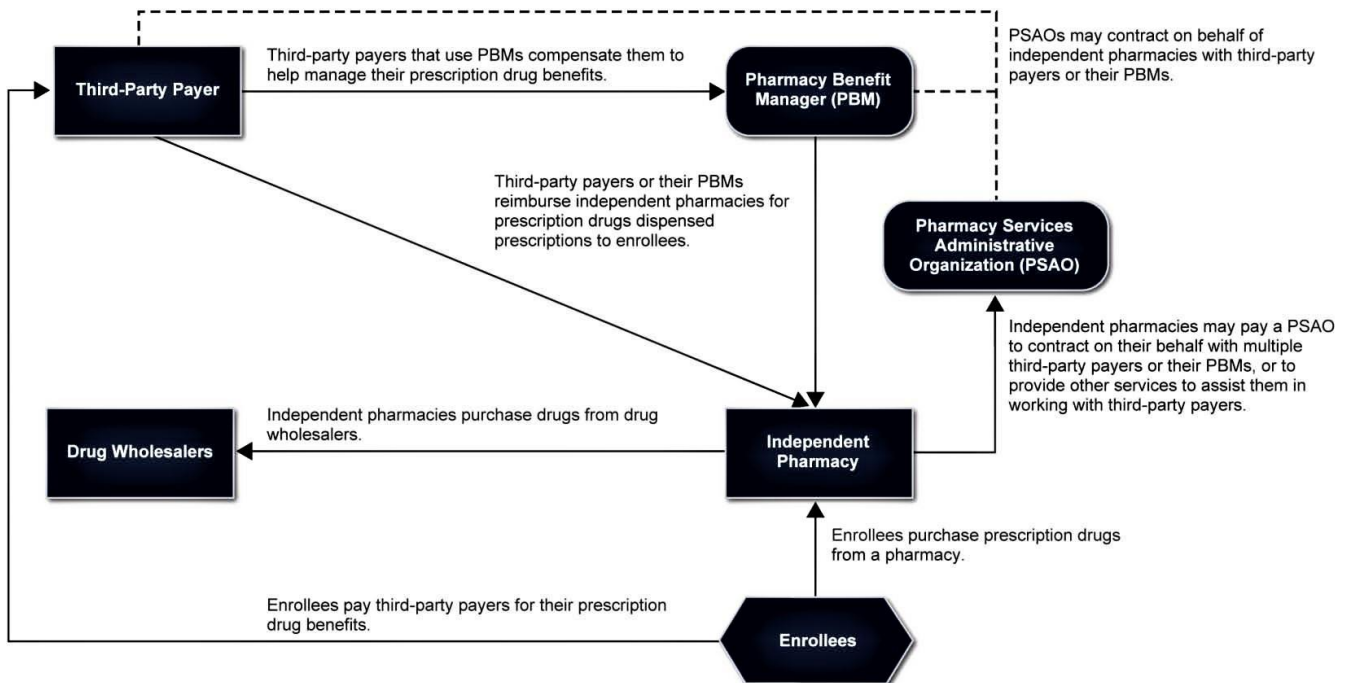
³ *Annu. Rev. Public Health*. 1999. 20:361–401.

⁴ Reynolds, Ian, et. al., *The Prescription Drug Landscape, Explored* (Mar. 2019). The Pew Charitable Trusts, <https://www.pewtrusts.org/en/research-and-analysis/reports/2019/03/08/the-prescription-drug-landscape-explored> (last visited Mar. 22, 2021).

⁵ General Accounting Office, *The Number, Role, and Ownership of Pharmacy Services Administrative Organizations* (GAO-13-176) (Feb 28, 2013), <https://www.gao.gov/assets/gao-13-176.pdf> (last visited Mar. 22, 2021).

⁶ *Id.*

prescription drug benefits. The interaction among key entities involved in the distribution and payment of prescription drugs is depicted below:⁷



Source: GAO analysis based on interviews and industry reports.

The Commonwealth Fund Study of 15 Large Employer Plans⁸

In response to concerns about rising drug costs, a recent study by The Commonwealth Fund 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

⁷ *Id* at pg. 15.

⁸ Vela, Lauren, *Reducing Wasteful Spending in Employers’ Pharmacy Benefit Plans* (Aug. 2019) the Commonwealth Fund, <https://www.commonwealthfund.org/publications/issue-briefs/2019/aug/reducing-wasteful-spending-employers-pharmacy-benefit-plans> (last visited Mar. 22, 2021).

and what PBMs are reimbursed by the plan sponsor. This also encourages PBMs to prioritize higher-cost drugs to allow for a larger spread.⁹

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

[P]lan 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.¹⁰

Pharmacy Benefit Managers

Many public and private employers and health plans contract with PBMs to help manage drug costs.¹¹ Some of the services provided by the PBMs include processing pharmacy claims; providing mail-order pharmacy services to their customers; negotiating rebates (discounts paid by a drug manufacturer to a PBM), developing pharmacy networks, creating drug formularies; reviewing drug utilization; and providing disease management.¹² Generally, a contract between a PBM and a health plan or an employer specifies the amount a plan or an employer will pay a PBM for brand name and generic drugs and specify certain savings guarantees.¹³ A recent report found that PBMs passed through 78 percent of manufacturer rebates to health plans in 2012 and 91 percent in 2016.¹⁴ 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.¹⁵

In recent years, significant consolidations in the PBM industry have occurred. Further, many health insurers are acquiring PBMs. Many entities have cited reducing drug cost as a factor for

⁹ *Id.*

¹⁰ *Id.*

¹¹ Pharmacy Benefit Managers and Their Role in Drug Spending (Apr. 22, 2019), <https://www.commonwealthfund.org/publications/explainer/2019/apr/pharmacy-benefit-managers-and-their-role-drug-spending> (last visited Mar. 22, 2021).

¹² *Supra* note 3.

¹³ *Policy Options To Help Self-Insured Employers Improve PBM Contracting Efficiency*, Health Affairs Blog, (May 29, 2019), <https://www.healthaffairs.org/doi/10.1377/hblog20190529.43197/full/> (last visited Mar. 22, 2021).

¹⁴ *Supra* note 4.

¹⁵ *Id.*

many of the acquisitions.¹⁶ In 2018, three PBMs processed about 75 percent of all equivalent prescription claims: CVS Health (including Caremark and Aetna), Express Scripts, and the OptumRx business of UnitedHealth.¹⁷ The following six PBMs handled more than 95 percent of the total U.S. equivalent prescription claims managed:

- CVS Caremark/Aetna, 30 percent;
- Express Scripts, 23 percent;
- OptumRx (UnitedHealth), 23 percent;
- Humana Pharmacy Solutions, seven percent;
- Medimpact Healthcare Systems, six percent; and
- Prime Therapeutics, six percent.¹⁸

Reimbursement of Pharmacies by PBMs

Generally, the maximum allowable cost (MAC) price 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).¹⁹ A PBM can maintain multiple MAC lists, each tied to the requirements of a particular employee benefit plan or other payer.²⁰ A MAC pricing list is a 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.²¹ One of the goals 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.²² 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.²³

Retail Pharmacies

Independent pharmacies are a type of retail pharmacy with a physical store location—often in rural and underserved areas—that dispense medications to consumers, including both prescription and over-the-counter drugs.²⁴ Nationwide, the number of independent pharmacies in the United States continues to decline. In 2010, there were 23,106 independent pharmacies; by

¹⁶ Barlas, Stephen, Vertical Integration Heats Up in Drug Industry: Will Medication Price Hikes Cool Down as a Result? *Pharmacy & Therapeutics: a peer-reviewed journal for formulary management* vol. 43,1 (2018): 31-39, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5737250/> (last visited Mar. 22, 2021).

¹⁷ Drug Channels, CVS, Express Scripts, and the Evolution of the PBM Business Model (May 29, 2019), <https://www.drugchannels.net/2019/05/cvs-express-scripts-and-evolution-of.html> (last visited Mar. 22, 2021).

¹⁸ *Id.*

¹⁹ Academy of Managed Care Pharmacy, Maximum Allowable Cost (MAC) Pricing (May 22, 2019), <https://www.amcp.org/policy-advocacy/policy-advocacy-focus-areas/where-we-stand-position-statements/maximum-allowable-cost-mac-pricing> (last visited Mar. 22, 2021).

²⁰ Hyman, David, *The Unintended Consequences of Restrictions on the Use of Maximum Allowable Cost Programs ("MACs") for Pharmacy Reimbursement* (Apr. 2015), <https://www.pcmanet.org/wp-content/uploads/2016/08/hyman-mac-white-paper-april-2015.pdf> (last visited Mar. 22, 2021)

²¹ *Id.*

²² *Supra* note 18.

²³ *Id.*

²⁴ *Supra* note 3. In the report, an independent pharmacy means a pharmacy having one to three pharmacies under common ownership.

2017, that number had dropped to 21,909.²⁵ Independent community pharmacies represented an estimated 35 percent of all community pharmacies nationwide in 2019, and comprised a \$73.7 billion marketplace.²⁶

The decision of employers, HMOs, or insurers to contract with PBMs may shift business away from smaller, local 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.²⁷ However, many independent pharmacies have closed in recent years because of the competition resulting from the proliferation of large, chain retail pharmacies²⁸ that can negotiate with PBMs at deeply discounted reimbursement levels based on large volume sales.

Further, innovations and greater competition in the pharmacy marketplace are occurring. In 2018, Amazon acquired PillPack, a mail-order pharmacy, which has pharmacy licenses in all 50 states.²⁹ Further, many digital pharmacies are entering the marketplace and focus on certain strategies, such as:

- Home delivery of individual prescriptions;
- Operating at least one brick-and mortar retail location (so that the pharmacy can remain in a PBM's network);
- Dispensing 30-day prescriptions, not 90-day maintenance prescriptions;
- Offering a mobile application so consumers can manage their account, order prescription refills, and schedule delivery; and
- Providing telehealth consultations with prescribers.³⁰

Federal Oversight of Health Insurance

On March 23, 2010, the Patient Protection and Affordable Care Act (PPACA) was signed into law.³¹ Among its significant changes to the U.S. health insurance system are requirements for health insurers to make coverage available to all individuals and employers, without exclusions for preexisting medical conditions and without basing premiums on any health-related factors.³²

²⁵ Arnold, Karen, *Independent Pharmacies: Not Dead Yet*, (Jan. 12, 2019, vol. 163, issue 1) Drug Topics, Voice of the Pharmacist, <https://www.drugtopics.com/view/independent-pharmacies-not-dead-yet> (last visited Mar. 22, 2021).

²⁶ APhA, *National Community Pharmacists Association Releases 2020 Digest Report* (Oct. 22, 2020), <https://www.pharmacist.com/article/ncpa-releases-2020-digest-report> (last visited Mar. 22, 2021).

²⁷ 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 visited Mar. 22, 2021).

²⁸ Such as Walmart, CVS, Walgreens, Publix or Kroger. See <https://www.beckershospitalreview.com/pharmacy/15-largest-pharmacies-in-the-us.html> (last visited Mar. 22, 2021).

²⁹ Garcia, Ahiz, *Amazon rolls out “Amazon Pharmacy” branding to PillPack*, CNN Business (Nov. 15, 2019), <https://www.cnn.com/2019/11/15/tech/amazon-pharmacy-pillpack/index.html> (last visited Mar. 22, 2021).

³⁰ Drug Channels, *The Promise and Limits of Digital Pharmacies* (Feb. 16, 2021), <https://www.drugchannels.net/2021/02/the-promise-and-limits-of-digital.html> (last visited Mar. 22, 2021).

³¹ Pub. L. 111–148 was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), which amended and revised several provisions of the PPACA, was enacted on March 30, 2010. The two laws are collectively referred to as the “Patient Protection and Affordable Care Act.” See <https://www.healthcare.gov/where-can-i-read-the-affordable-care-act/> (last visited Mar. 22, 2021).

³² Most of the insurance regulatory provisions in PPACA amend Title XXVII of the Public Health Service Act (PHSA), (42 U.S.C. s. 300gg et seq.).

The PPACA imposes many other requirements on qualified health plans offered by individual and group plans, including required benefits, reporting of medical loss ratios, and internal and external appeals of adverse benefit determinations.³³

Medical Loss Ratios, Rebates, and Spread Pricing

If an insurer or HMO spends less than 80 percent in the individual or small group market (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.³⁴ 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).³⁵

Insurer Reporting of Health Plan Spending on Drugs

Beginning in 2021, federal law requires a group health plan or health insurance issuer offering group or individual health insurance coverage to report to the Secretary of the Department of Labor and the Secretary of the Department of Treasury the following information with respect to the health plan or coverage in the previous plan year:

- The 50 brand prescription drugs most frequently dispensed and the total number of paid claims for each drug;
- The 50 most costly prescription drugs by total annual spending;
- The 50 prescription drugs with the greatest increase in plan expenditures over the preceding plan year;
- Total spending on health care services by such plan or coverage, categorized by type of costs, including hospital, health care provider, clinical services, prescription drugs, and other medical costs;
- Spending on prescription drugs by the plan or coverage, and the enrollees;
- Average monthly premium paid by the employer and by participants and beneficiaries; and
- Impact of rebates, fees and other remuneration paid by drug manufacturers on premiums and out-of-pocket costs.³⁶

Oversight of Health Insurers, HMOs, and PBMs in Florida

Insurers and HMOs

The Office of Insurance Regulation (OIR) licenses and regulates insurers, HMOs, and other risk-bearing entities.³⁷ To operate in Florida, an insurer or HMO must obtain a certificate of authority from the OIR.³⁸

³³ *Id.*

³⁴ 45 CFR 158.210 and 158.211.

³⁵ 42 U.S.C. s. 2718.

³⁶ Consolidated Appropriations Act, 2021, Title II (H.R. 133), Public L. No. 116-260 (Dec. 27, 2020). See <https://www.congress.gov/116/bills/hr133/BILLS-116hr133enr.pdf> (last visited Mar. 22, 2021).

³⁷ Section 20.121(3)(a)1., F.S.

³⁸ Sections 624.401 and 641.21(1), F.S.

Oversight of PBMs

A PBM is a person or entity doing business in Florida, which contracts to administer prescription drug benefits on behalf of a health insurer or an HMO to residents of Florida.³⁹ The PBMs are required to register with the OIR.⁴⁰ 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 two years and are nontransferable.⁴¹

The Insurance Code⁴² mandates that contracts between health insurers or HMOs and PBMs contain certain provisions. However, there is no statutory penalty if the PBM does not comply with these contractual provisions. These mandatory contractual provisions require the PBM to:

- Update the maximum allowable cost (MAC) pricing information at least once every seven 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;
- 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, pursuant to s. 465.0244, F.S.; and
- Not require 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.⁴³

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.⁴⁴ Further, the Department of Financial Services reviews alleged violations, relating to claims of providers not paid or denied by the insurer or HMO.⁴⁵

Florida Pharmacy Audits

Pursuant to ch. 465, F.S., 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

³⁹ Section 624.490, F.S.

⁴⁰ *Id.*

⁴¹ Office of Insurance Regulation, *Registration Form for Pharmacy Benefit Managers*, <https://www.floir.com/siteDocuments/AllFormsPBM.pdf> (last visited Mar. 22, 2021). The current registration fee is \$5.

⁴² Sections 627.64741, 627.6572, and 641.314, F.S.

⁴³ *Id.*

⁴⁴ Sections 627.6131 and 641.3155, F.S.

⁴⁵ Department of Financial Services, Division of Consumer Services, *Medical Provider Informational Memorandum* at <https://apps.fldfs.com/eservice/MedicalProvider.aspx> (last visited Mar. 22, 2021).

compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.⁴⁶ The term, “independent pharmacy,” is not defined.

Pharmacies are subject to routine audits by an insurer, HMO, or a PBM acting on behalf of an insurer or HMO. Audits of pharmacies are conducted to determine compliance with respect to billing, reimbursement, and other contractual requirements.⁴⁷ Section 465.1885, F.S., prescribes the following rights of a pharmacy in connection with an audit conducted directly or indirectly by an insurance company, a managed care company, or a PBM:

- To be notified at least seven calendar days before the initial onsite audit;
- To have the onsite audit scheduled after the first three 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; and
- To have recoupment or penalties based on actual overpayments and not according to the accounting practice of extrapolation.⁴⁸

However, 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.

Statewide Provider and Health Plan Claim Dispute Resolution Program

The Agency for Health Care Administration (AHCA), administers the Statewide Provider and Health Plan Claim Dispute Resolution Program, which assists contracted and noncontracted providers and health plans to resolve claim disputes that are not resolved by the provider and the health plan.⁴⁹ The AHCA contracts with an independent dispute resolution organization to assist health care providers and health plans in order to resolve claim disputes. These services are

⁴⁶ Section 465.003(11), F.S.

⁴⁷ JD Supra, *Pharmacy Compliance: Will Your Pharmacy’s Policies and Protocols Withstand a DEA or PBM Audit?* (Aug. 3, 2020), <https://www.jdsupra.com/legalnews/pharmacy-compliance-will-your-pharmacy-78764/> (last visited Mar. 22, 2021).

⁴⁸ Section 465.188, F.S., prescribes the rights of a pharmacy in connection with a Medicaid audit.

⁴⁹ Section 408.7057, F.S.

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.⁵⁰

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 medical and 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 PBM for the self-insured State Employees' Prescription Drug Program pursuant to s. 110.12315, F.S. The current PBM for the state employees' prescription drug plan is CaremarkPCS Health, LLC (CVS Caremark).⁵¹

Recent U.S. Supreme Court Decision

In 2015, Arkansas enacted a law, Senate Bill 688, Act 900 of the Regular Session (Act),⁵² which effectively requires PBMs to reimburse Arkansas pharmacies at a price equal to or higher than the pharmacy's acquisition cost. To accomplish this result, the law requires PBMs to update their MAC lists in a timely manner when drug prices increase, and to provide pharmacies with an administrative appeal process to challenge MAC reimbursement rates that are below the pharmacies' acquisition costs.⁵³ If a pharmacy could not have acquired the drug at a lower price from its typical wholesaler, a PBM must increase its reimbursement rate to cover the pharmacy's acquisition cost.⁵⁴ A PBM must also allow pharmacies to "reverse and rebill" each reimbursement claim affected by the pharmacy's inability to procure the drug from its typical wholesaler at a price equal to or less than the MAC reimbursement price.⁵⁵ Lastly, the Act allows a pharmacy to decline to sell a drug to a consumer if the relevant PBM will reimburse the pharmacy at less than its acquisition cost.⁵⁶

In late 2020, the U.S. Supreme Court decided that Arkansas' law regulating PBMs was not preempted by the federal Employee Retirement Income Security Act of 1974 (ERISA),⁵⁷ because the Arkansas law has neither an impermissible connection with nor reference to ERISA⁵⁸ and is, therefore, not preempted.⁵⁹

⁵⁰ *Id.*

⁵¹ Department of Management Services, Division of State Group Insurance, *2021 Benefits State Employees' Prescription Drug Plan*, https://www.mybenefits.myflorida.com/content/download/150426/1002145/2021_CVS_Caremark_Brochure.pdf (last visited Mar. 10, 2021)

⁵² AR SB 688, 2015 90th General Assembly (Apr. 2, 2015). Act 900, 2015 Session. *See* <https://www.arkleg.state.ar.us/Acts/Document?type=pdf&act=900&ddBienniumSession=2015%2F2015R> (last visited Mar. 22, 2021).

⁵³ Arkansas Code 17-92-507 (2019 Supp.).

⁵⁴ Section 17-92-507(c)(4)(C)(i)(b) (Supp. 2019).

⁵⁵ Section 17-92-507(c)(4)(C)(iii) (Supp. 2019).

⁵⁶ Section 17-92-507(e) (Supp. 2019).

⁵⁷ 88 Stat. 829, as amended, 29 U. S. C. s. 1001 *et seq.*

⁵⁸ 29 U. S. C. s. 1144(a).

⁵⁹ *Rutledge v. Pharmaceutical Care Management Assn.*, 592 U.S. ____ (2020) [No. 18-540 (Dec. 10, 2020)].

III. Effect of Proposed Changes:

Section 1 amends s. 624.3161, F.S., to authorize the Office of Insurance Regulation (OIR) to conduct market conduct examinations of pharmacy benefits managers (PBMs). This section currently authorizes the OIR to examine insurers and Health Maintenance Organizations (HMOs).

Section 2 transfers s. 465.1885, F.S., renumbers the section as s. 624.491, F.S., and amends the section to clarify the existing rights of a pharmacy, relating to a pharmacy audit, are statutory requirements for an insurer or HMO or any entity acting on behalf of the insurer or HMO, including, but not limited to, a PBM conducting a pharmacy audit. The section specifies:

- Limits on when audits can be conducted;
- Audit periods;
- Use of a consulting pharmacist;
- Use of written and verifiable records of health care providers to validate pharmacy records;
- 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; and
- Methodology for calculating final recoupment and penalties.

The section allows a pharmacy to appeal claim payments due because of an audit with the Statewide Provider and Health Plan Claim Dispute Resolution Program at the Agency for Health Care Administration pursuant to s. 408.7057, F.S.

Sections 3, 4, 5, and 6 amend s. 627.64741, 627.6572, 627.6699, and 641.314, F.S., respectively, relating to individual health insurance policies, large and small group health insurance policies, and HMO contracts.

The bill prohibits an insurer or HMO from contracting with a PBM, unless the PBM:

- Updates its maximum allowable cost (MAC) information at least every seven days;
- Maintains a process that, in a timely manner, will eliminate drugs from MAC lists or modify drug prices to remain consistent with changes in pricing data used in formulating MAC 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; and
- Does not require an insured to make a payment for a prescription drug in an amount that exceeds the lesser of the applicable cost-sharing amount or the retail price of the drug.

Under current law, an insurer or HMO must include these provisions in any contract with a PBM. However, there is no statutory penalties for a PBM's noncompliance with these provisions.

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 OIR 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 contract does not comply with the Florida Insurance Code.
- The PBM is not registered with the OIR pursuant to s. 624.490, F.S.

Under current law, s. 641.234, F.S., authorizes the OIR to require an 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 contract, the OIR may order the HMO to cancel the contract in accordance with the terms of the contract and applicable law if:

- 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
- 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.

Section 7 provides that this bill takes effect July 1, 2021.

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 clarifies statutory provisions relating to pharmacy audits to impose audit requirements rather than rights, which will provide greater transparency regarding the audit process. The bill provides pharmacies with a process to appeal pharmacy benefits managers (PBMs) audit filings related to claim payments with the Statewide Provider and Health Plan Claim Dispute Resolution Program.

Since the bill authorizes the Office of Insurance Regulation (OIR) to conduct market conduct examinations of PBMs, the bill will increase the administrative costs of health insurers, Health Maintenance Organizations (HMOs), and PBMs to the extent PBMs are examined. Entities examined by the OIR are responsible for the payment of the examination expenses.⁶⁰

C. Government Sector Impact:**Office of Insurance Regulation⁶¹**

According to the OIR, the bill will have a negative fiscal impact of \$100,000 to \$200,000 on a recurring basis. The OIR would incur costs associated with obtaining pharmacy-related training or contracting 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).

Department of Management Services/Division of State Group Insurance⁶²

The costs of a PBM market conduct examination conducted by the OIR could result in an indeterminate increase in administrative costs of the program's PBM. These costs could be recouped from individuals enrolled in the Division of State Group Insurance program.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 624.3161, 465.1885, 627.64741, 627.6572, 627.6699, and 641.314.

⁶⁰ Section 624.6131(4), F.S.

⁶¹ Office of Insurance Regulation, *2021 Legislative Session, Analysis SB 390* (Jan. 4, 2021).

⁶² Department of Management Services, *2021 Agency Legislative Bill Analysis of SB 390* (Feb. 19, 2021).

This bill transfers, renumbers to section 624.491 and amends, section 465.1885 of the Florida Statutes.

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 Banking and Insurance Committee on March 16, 2021:

The CS makes the following changes:

- Eliminates changes to the definition of maximum allowable cost.
- Revises conditions in which the Office of Insurance Regulation (OIR) may cancel contracts of insurers or Health Maintenance Organizations (HMOs) with pharmacy benefits managers (PBMs) by eliminating the ability of the OIR to cancel because the fees paid by the insurer or HMO are so unreasonably high, as compared with contracts entered into by other insurers or HMOs in similar circumstances, that the contract is detrimental to policyholders or subscribers of the insurer or HMO, respectively.

- B. **Amendments:**

None.