

**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.)

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Prepared By: The Professional Staff of the Appropriations Subcommittee on Agriculture, Environment, and General Government

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BILL: SB 1476

INTRODUCER: Senator Wright

SUBJECT: Prescription Drug Coverage

DATE: February 15, 2022      REVISED: \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Johnson</u>	<u>Knudson</u>	<u>BI</u>	<u>Favorable</u>
2.	<u>Sanders</u>	<u>Betta</u>	<u>AEG</u>	<u>Pre-meeting</u>
3.	_____	_____	<u>AP</u>	_____

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**I. Summary:**

SB 1476 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;
- Authorizes an audited pharmacy to appeal certain final audit findings made by health insurers or HMO, or PBM acting on their behalf; and
- Provides a person who fails to register with the OIR while operating as a PBM is subject to a \$10,000 fine for each violation.

The bill has an indeterminate, yet negative impact to state revenue and expenditures. The OIR estimates contracting with a pharmacist to provide oversight of PBM market conduct examinations and respond to complaints involving pharmacy audits will cost \$125,000 to \$200,000 annually.

The Division of State Group Insurance program may experience an indeterminate, yet negative fiscal impact relating to administrative costs of any market conduct examination of its PBM by the OIR. To the extent such examination occurs, such costs are passed down to participants of the program.

The bill is effective July 1, 2022.

## II. Present Situation:

### National Health Care Expenditures in 2020<sup>1</sup>

Health care spending in the United States increased 9.7 percent to reach \$4.1 trillion in 2020, a much faster rate than the 4.3 percent increase experienced in 2019. Gross Domestic Product declined 2.2 percent in 2020, leading to a sharp increase in the share of the overall economy related to health care spending—from 17.6 percent in 2019 to 19.7 percent in 2020. The acceleration in national health spending in 2020 was primarily due to a 36.0 percent increase in federal expenditures for health care that occurred largely in response to the COVID-19 pandemic.

In regards to retail prescription drugs, spending increased 3.0 percent to \$348.4 billion in 2020, a slower rate than in 2019 when spending increased 4.3 percent. The slowdown was a result of a 4.2 percent decline in out-of-pocket expenditures, which resulted from slower overall utilization and an increased use of coupons, which lowers point-of-sale expenditures for consumers.

### 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 (HMOs), or pharmacy benefit managers that are not disclosed.<sup>2</sup> 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.<sup>3</sup>

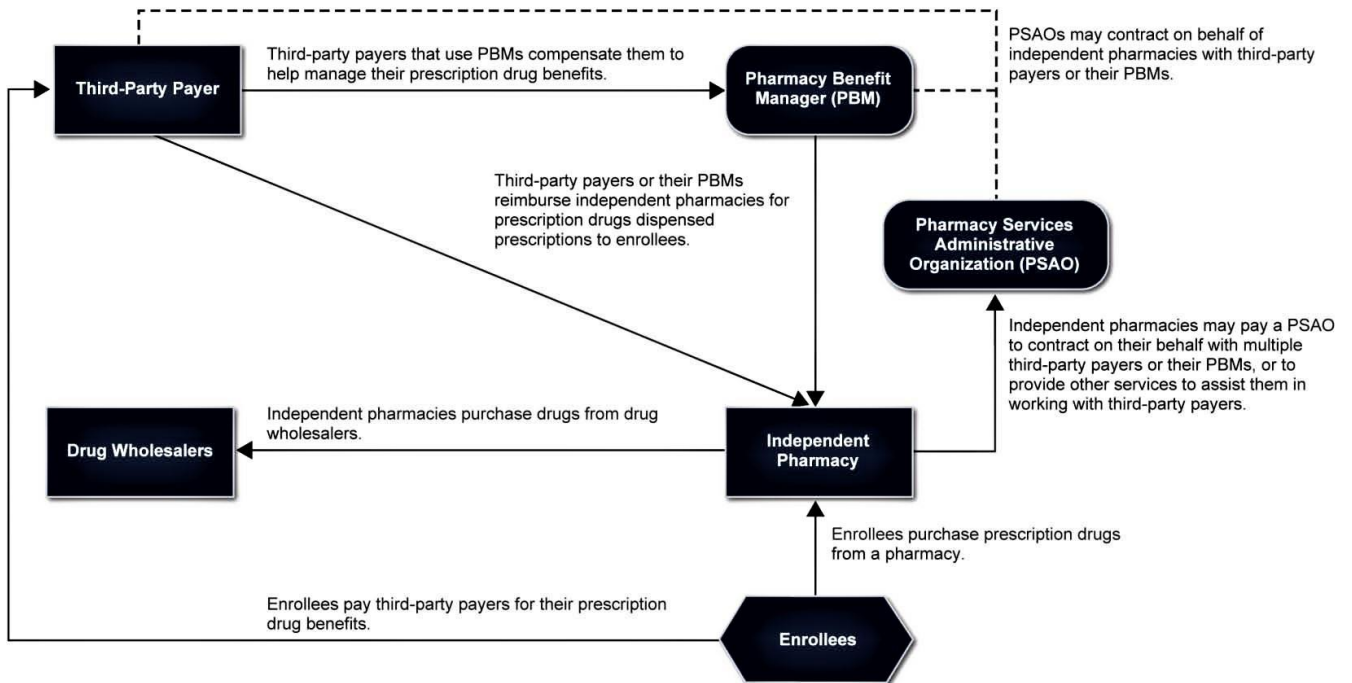
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<sup>1</sup> Centers for Medicare and Medicaid Services, *National Health Expenditure 2020 Highlights*, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical> (last visited Jan. 28, 2022).

<sup>2</sup> *Annu. Rev. Public Health*. 1999. 20:361–401.

<sup>3</sup> Reynolds, Ian, *et. al.*, *The Prescription Drug Landscape, Explored* (Mar. 2019). The Pew Charitable Trusts.

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.<sup>4</sup> 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.<sup>5</sup> Health insurers, HMOs, or self-insured 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:<sup>6</sup>



### A Study of 15 Large Employer Plans<sup>7</sup>

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

<sup>4</sup> General Accounting Office, *The Number, Role, and Ownership of Pharmacy Services Administrative Organizations* (GAO-13-176) (Feb 28, 2013), <https://www.gao.gov/products/GAO-13-176> (last visited Jan. 28, 2022).

<sup>5</sup> *Id.*

<sup>6</sup> *Id.*

<sup>7</sup> 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 viewed Jan. 28, 2022).

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 report further describes additional factors that 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.<sup>8</sup>

### Pharmacy Benefit Managers

Many public and private employers and health plans contract with PBMs to help manage drug costs.<sup>9</sup> 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.<sup>10</sup> 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.<sup>11</sup> A recent report found that PBMs passed through 78 percent of manufacturer rebates to health plans in 2012 and 91 percent in 2016.<sup>12</sup> For the same period, the report noted manufacturer rebates grew from \$39.7 billion to \$89.5 billion, and played a growing role in partially offsetting increases in list

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<sup>8</sup> *Id.*

<sup>9</sup> Commonwealth Fund, *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 Jan. 28, 2022).

<sup>10</sup> *Id.*

<sup>11</sup> *Policy Options To Help Self-Insured Employers Improve PBM Contracting Efficiency*, Health Affairs Blog, (May 29, 2019). DOI: 10.1377/hblog20190529.43197.

<sup>12</sup> *Supra* note 3.

prices, which the study noted have risen more quickly than overall retail prescription drug spending.<sup>13</sup>

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 many of the acquisitions.<sup>14</sup> In 2020, three PBMs, CVS Health (including Caremark and Aetna), the Express Scripts business of Cigna, and the OptumRx business of the UnitedHealth Group, were estimated to process about 77 percent of all equivalent prescription claims.<sup>15</sup> The remaining estimated 22 percent was processed by Humana Pharmacy Solutions (eight percent), Medimpact Healthcare Systems, (six percent), Prime Therapeutics (four percent), and all other PBMs and cash pay (four percent). In 2018, three PBMs processed about 76 percent of all equivalent prescription claims: CVS Health (including Caremark and Aetna), Express Scripts, and OptumRx (UnitedHealth).<sup>16</sup>

### ***Reimbursement of Pharmacies by PBMs***

Generally, the maximum allowable cost (MAC) price represents the upper limit price a plan will pay or reimburse for generic drugs and sometimes brand drugs that have generic versions available (multisource brands).<sup>17</sup> A PBM can maintain multiple MAC lists, each tied to the requirements of a particular employee benefit plan or other payer.<sup>18</sup> 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.<sup>19</sup> One of the goals of the MAC pricing list is to ensure the pharmacy or their buying groups are motivated to seek and purchase generic drugs at the lowest price.<sup>20</sup> 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.<sup>21</sup>

### **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.<sup>22</sup> Nationwide, the number of independent pharmacies in

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<sup>13</sup> *Id.*

<sup>14</sup> Barlas, Stephen, Vertical Integration Heats Up in Drug Industry: Will Medication Price Hikes Cool Down as a Result? *P & T: a peer-reviewed journal for formulary management* vol. 43,1 (2018): 31-39.

<sup>15</sup> Drug Channels, [Drug Channels: The Top Pharmacy Benefit Managers of 2020: Vertical Integration Drives Consolidation](#) (Apr. 6, 2021) (last visited Jan. 7, 2022).

<sup>16</sup> 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 visited Jan. 28, 2022).

<sup>17</sup> Academy of Managed Care Pharmacy, Maximum Allowable Cost (MAC) Pricing (Oct. 28, 2021), <https://www.amcp.org/policy-advocacy/policy-advocacy-focus-areas/where-we-stand-position-statements/maximum-allowable-cost-mac-pricing> (last visited Jan. 28, 2022).

<sup>18</sup> Hyman, David, *The Unintended Consequences of Restrictions on the Use of Maximum Allowable Cost Programs ("MACs") for Pharmacy Reimbursement* (Apr. 2015), at <https://www.pcmnet.org/wp-content/uploads/2016/08/hyman-mac-white-paper-april-2015.pdf> (last visited Jan. 29, 2022)

<sup>19</sup> *Id.*

<sup>20</sup> *Supra* note 17.

<sup>21</sup> *Id.*

<sup>22</sup> 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 Jan. 28, 2022).

the United States continues to decline. In 2010, there were 23,106 independent pharmacies; by 2017, that number had dropped to 21,909.<sup>23</sup> As of June 2021, there were 19,397 independent pharmacies.<sup>24</sup>

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.<sup>25</sup> However, many independent pharmacies have closed in recent years because of the competition resulting from the proliferation of large, chain retail pharmacies<sup>26</sup> 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.<sup>27</sup> 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.<sup>28</sup>

### **Federal Oversight of Health Insurance**

On March 23, 2010, the Patient Protection and Affordable Care Act (PPACA) was signed into law.<sup>29</sup> 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.<sup>30</sup> The PPACA imposes many other requirements on qualified health plans offered by individual

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<sup>23</sup> *Id.*

<sup>24</sup> Chain Drug Review, NCPA releases 2021 NCPA Digest Report (Oct. 11, 2021) [NCPA releases 2021 NCPA Digest report - CDR – Chain Drug Review](https://www.chaindrugreview.com/news/ncpa-releases-2021-ncpa-digest-report-cdr-chain-drug-review) (last visited Jan. 28, 2022). The store count in previous years' Digest reports was based on an NCPA analysis of NCPDP data and NCPA research, which most recently produced a store count of 21,683 in 2019.

<sup>25</sup> 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 supra* note 4. (last visited Feb. 1, 2022).

<sup>26</sup> Such as Walmart, CVS, Walgreens, or Publix.

<sup>27</sup> 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 Jan. 22, 2022).

<sup>28</sup> Drug Channels, *The Promise and Limits of Digital Pharmacies* (Feb. 16, 2021) at <https://www.drugchannels.net/2021/02/the-promise-and-limits-of-digital.html> (last visited Feb. 28, 2022).

<sup>29</sup> 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.”

<sup>30</sup> 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.).

and group plans, including required benefits, reporting of medical loss ratios, and internal and external appeals of adverse benefit determinations.<sup>31</sup>

### ***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 dollar on medical care and efforts to improve the quality of care, the HMO or insurer must refund the portion of premium that exceeds this limit.<sup>32</sup> The 80 percent (or 85 percent) is the medical loss ratio<sup>33</sup> (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).<sup>34</sup>

### ***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.<sup>35</sup>

### **Office of Insurance Regulation**

The OIR is responsible for the regulation of insurers, HMOs, and other risk-bearing entities.<sup>36</sup> Prior to transacting insurance in Florida or operating a HMO, an insurer or HMO, respectively must meet certain requirements to obtain a certificate of authority from the OIR.<sup>37</sup>

<sup>31</sup> *Id.*

<sup>32</sup> 45 CFR 158.210 and 158.211.

<sup>33</sup> Medical loss ratio (MLR) is defined as: A basic financial measurement used in the Affordable Care Act to encourage healthplans to provide value to enrollees. If an insurer uses 80 cents out of every premium dollar to pay its customers' medical claims and activities that improve the quality of care, the company has a medical loss ratio of 80 percent.

<https://www.healthcare.gov/glossary/medical-loss-ratio-mlr/#:~:text=A%20basic%20financial%20measurement%20used,medical%20loss%20ratio%20of%2080%25>. (last visited Feb. 10, 2022).

<sup>34</sup> 42 U.S.C. s. 2718.

<sup>35</sup> 42 USC s. 300gg-120.

<sup>36</sup> Section 20.121(3)(a)1., F.S.

<sup>37</sup> Sections 624.404 and 641.21, F.S.

Section 624.3161, F.S., authorizes the OIR to conduct market conduct examinations of insurers.<sup>38</sup> The entity subject to an examination is responsible for the payment of the examination costs, as provided in s. 624.320, 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 a HMO to insureds or subscribers of this state.<sup>39</sup> The PBMs are required to register with the Office of Insurance Regulation (OIR).<sup>40</sup> 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. The current registration fee is five dollars.<sup>41</sup> Initial registration and registration certificate renewals are valid for two years and are nontransferable.<sup>42</sup> Currently, 66 pharmacy benefit managers have a letter of registration with the OIR.<sup>43</sup>

**Mandatory Contractual Provisions.** The Insurance Code<sup>44</sup> mandates 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.<sup>45</sup>

**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.<sup>46</sup> Further, the Department of Financial Services

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<sup>38</sup> Section 624.3161, F.S.

<sup>39</sup> Section 624.490, F.S.

<sup>40</sup> *Id.*

<sup>41</sup> Office of Insurance Regulation, Registration Form for Pharmacy Benefit Manager [AllFormsPBM.pdf \(florir.com\)](https://www.florir.com/AllFormsPBM.pdf) (last visited Jan. 27, 2022).

<sup>42</sup> Rules 690-238.001 and 690-238.002, F.A.C.

<sup>43</sup> OIR, Company Directory: Search Results available at <https://www.florir.com/CompanySearch/> (last visited Jan. 28, 2022).

<sup>44</sup> Sections 627.64741, 627.6572, and 641.314, F.S.

<sup>45</sup> *Id.*

<sup>46</sup> Sections 627.6131 and 641.3155, F.S.



(DFS) reviews alleged violations, relating to claims of providers not paid or denied by the insurer or HMO.<sup>47</sup>

### ***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 compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.<sup>48</sup> 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.<sup>49</sup> 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 six 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.<sup>50</sup>

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.

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<sup>47</sup> 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. 28, 2022).

<sup>48</sup> Section 465.003(11), F.S.

<sup>49</sup> JD Supra, *Pharmacy Compliance: Will Your Pharmacy’s Policies and Protocols Withstand a DEA or PBM Audit?* (Aug. 3, 2020), at <https://www.jdsupra.com/legalnews/pharmacy-compliance-will-your-pharmacy-78764/> (last visited Jan. 28, 2022).

<sup>50</sup> Section 465.188, F.S., prescribes the rights of a pharmacy in connection with a Medicaid audit.

## Statewide Provider and Health Plan Claim Dispute Resolution Program

The Agency for Health Care Administration (agency), 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.<sup>51</sup> 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.<sup>52</sup>

## 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 pharmacy benefits manager (PBM) for the self-insured State Employees' Prescription Drug Program (program) pursuant to s. 110.12315, F.S. The current PBM for the state employees' prescription drug plan is CaremarkPCS Health, LLC (CVS Caremark).<sup>53</sup>

## 2020 U.S. Supreme Court Decision

In 2015, Arkansas enacted a law<sup>54</sup> that 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.<sup>55</sup> 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.<sup>56</sup> 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.<sup>57</sup> Lastly, the law 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.<sup>58</sup>

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<sup>51</sup> Section 408.7057, F.S.

<sup>52</sup> *Id.*

<sup>53</sup> Department of Management Services, Division of State Group Insurance, Contacts, available at [Contact Information / Health | MyBenefits / Department of Management Services \(myflorida.com\)](#) (last visited Jan. 27, 2022)

<sup>54</sup> AR SB 688, 2015 90<sup>th</sup> General Assembly (Apr. 2, 2015). Act 900, 2015 Session.

<sup>55</sup> Arkansas Code 17-92-507 (2019 Supp.)

<sup>56</sup> Section 17-92-507(c)(4)(C)(i)(b) (Supp. 2019)

<sup>57</sup> Section 17-92-507(c)(4)(C)(iii) (Supp. 2019)

<sup>58</sup> Section 17-92-507(e) (Supp. 2019)

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)<sup>59</sup> because the Arkansas law has neither an impermissible connection with nor reference to ERISA<sup>60</sup> and is therefore not preempted.<sup>61</sup>

### 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 other specified entities.

**Section 2** amends s. 624.490, F.S., to provide a person who fails to register with the OIR while operating as pharmacy benefit manager is subject to a fine of \$10,000 per violation.

**Section 3** 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 health maintenance organization (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:

- Prior notice requirements for onsite audits;
- Audit date scheduling requirements;
- Use of a consulting pharmacist;
- Limitation on the duration of the audit period;
- Use of written and verifiable records of health care providers to validate pharmacy records;
- Retroactive reimbursement for claims denied for certain errors;
- Deadline for the provision of preliminary audits;
- Allowance for production of preliminary documentation to rebut an audit finding;
- Deadline for production of the final audit; and
- Methodology for calculating final recoupment and penalties.

The section authorizes a pharmacy to appeal final audit findings as to whether a claim payment is due and the amount of a claim payment is due 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.

The section provides a health insurer or HMO that, under terms of a contract, transfers to a PBM the obligation to pay a pharmacy licensed under ch. 465, F.S., for any pharmacy claim arising from services provided to or for the benefit of an insured or subscriber remains responsible for a violation of this section.

**Section 4** provides that this bill takes effect July 1, 2022.

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<sup>59</sup> 88 Stat. 829, as amended, 29 U. S. C. s. 1001 *et seq.*

<sup>60</sup> 29 USC s. 1144(a).

<sup>61</sup> *Rutledge vs. Pharmaceutical Care Management Association* (Dec. 10, 2020) No. 18-540.

**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 manager (PBM) 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.<sup>62</sup>

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<sup>62</sup> Section 624.6131(4), F.S.

**C. Government Sector Impact:****Office of Insurance Regulation<sup>63</sup>**

The OIR estimates a recurring negative fiscal impact of \$125,000 to \$200,000 as the OIR will need to contract with a pharmacist in order to obtain pharmacy related training, provide oversight of PBM market conducted examinations, and respond to complaints involving pharmacy audits.

**Department of Management Services/Division of State Group Insurance**

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:**

**Section 3** requires a health insurer or health maintenance organizations (HMO), and any entity acting on their behalf, including a pharmacy benefit manager (PBM), to comply with the pharmacy audit provisions. However, no penalty is authorized for noncompliance.

**VIII. Statutes Affected:**

This bill substantially amends the following sections of the Florida Statutes: 624.3161 and 624.490.

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

**B. Amendments:**

None.

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

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<sup>63</sup> Office of Insurance Regulation, 2022 Legislative Session, Analysis SB 1476 (Jan. 10, 2022).