HOUSE OF REPRESENTATIVES STAFF FINAL BILL ANALYSIS

BILL #: CS/CS/CS/HB 1509 Prescription Drugs
SPONSOR(S): Health & Human Services Committee and Appropriations Committee and Healthcare Regulation Subcommittee, Chaney and others
TIED BILLS: **IDEN./SIM. BILLS:** CS/CS/SB 1550

FINAL HOUSE FLOOR ACTION: 118 **Y's** 0 **N's** **GOVERNOR'S ACTION:** Approved

SUMMARY ANALYSIS

CS/CS/CS/HB 1509 passed the House on May 2, 2023 as CS/CS/SB 1550.

Americans spend more on prescription drugs each year – about $1,300 per person – than any other country, with prescription drug prices in the U.S. more than 2.5 times as high as those in other similar high-income nations. Total spending on prescription drugs in the United States is also growing, rising to $603 billion in 2021, of which $421 billion was on retail drugs. The ever-increasing number of high-cost specialty drugs fuels the increase; specialty drugs account for 55 percent of medication spend, up from 28 percent in 2011.

Prescription drug benefit plans – health insurers, self-insured employers, union health plans, and government purchasers – contract with pharmacy benefit managers (PBMs) to manage drug costs. PBMs establish pharmacy networks, pay claims, and negotiate drug manufacturer rebates, among other things. PBMs earn profits through a combination of revenues, including administrative fees charged to health plans, retention of drug rebates paid by pharmaceutical manufacturers, and fees charged to network pharmacies. Until recently, PBMs operated largely in the absence of federal or state regulation. In the past five years, a plurality of state legislatures passed laws to prohibit specific PBM practices in response to industry and consumer complaints. In Florida, PBMs must register with the Office of Insurance Regulation (OIR), but are otherwise unregulated (except to the extent their functions are regulated through the regulated health plan).

CS/CS/CS/HB 1509 establishes a PBM regulatory program in Florida. Specifically, the bill:

- Amends the PBM regulatory structure from registration to a certificate of authority as an insurance administrator under part VI of ch. 626, F.S., regulated by OIR.
- Requires PBMs to submit to examinations and investigations, make available certain documents and records, and comply with recordkeeping requirements.
- Regulates PBM contracts with pharmacy benefit plans and programs (insurers, HMOs, self-insured employers, etc.).
- Regulates PBM contracts with pharmacies, including claims payment requirements, and prohibits many current practices.
- Imposes specific pharmacy network standards on PBMs.
- Requires drug manufacturers and nonresident drug manufacturers to notify the Department of Business and Professional Regulation and the Agency for Health Care Administration of drug price increases and submit forms and reports for public availability.

The bill provides an appropriation of $980,705 in recurring funds and $146,820 in nonrecurring funds from the Insurance Regulatory Trust Fund, and 10 full-time equivalent positions, to OIR to implement the provisions in the bill. OIR may see an increase in revenue from imposing fines established in the bill. See Fiscal Analysis and Economic Impact Statement.

The bill was approved by the Governor on May 3, 2023, ch. 2023-29, L.O.F., and will become effective on July 1, 2023.

I. SUBSTANTIVE INFORMATION

A. EFFECT OF CHANGES:

Background

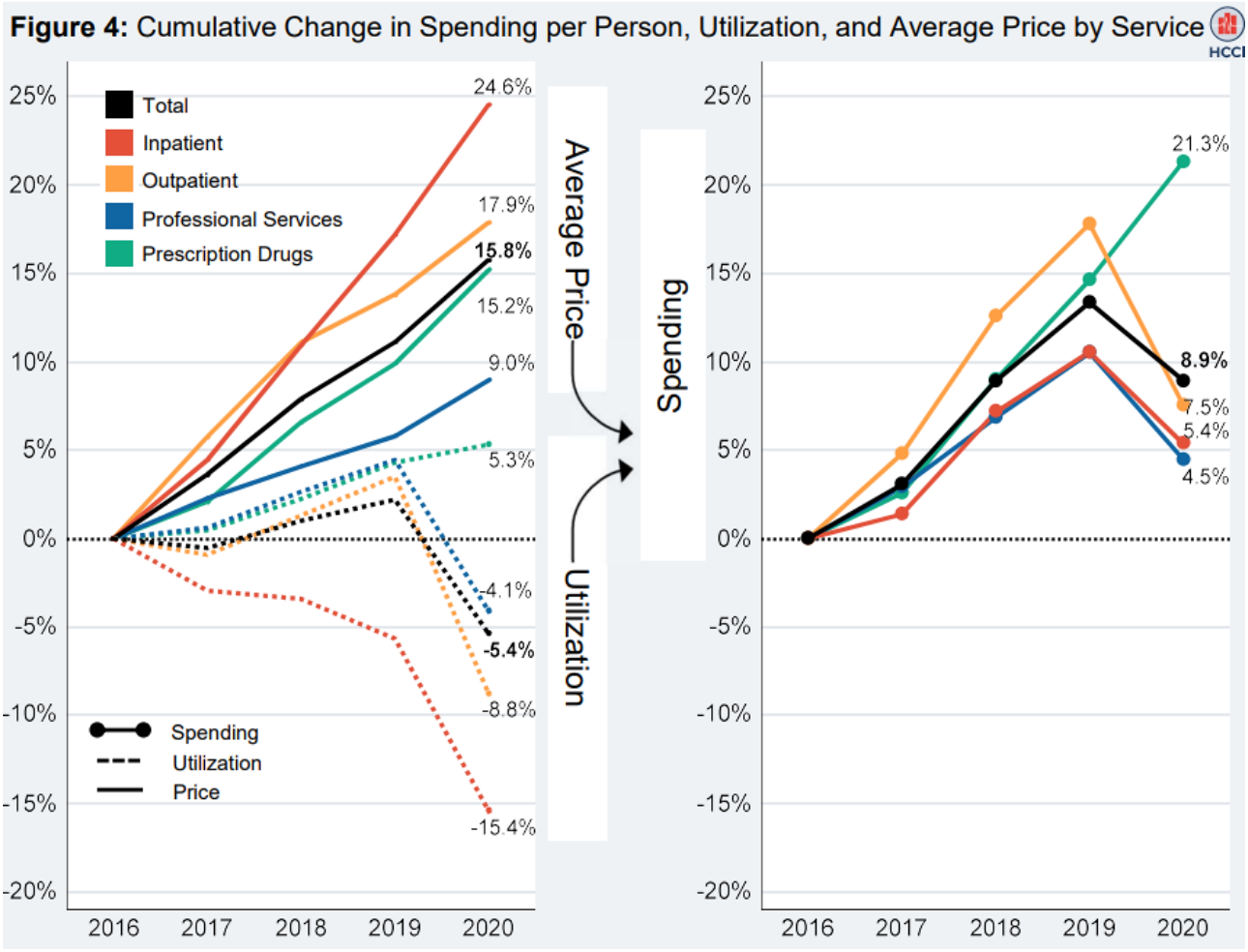
Prescription Drug Spending

Americans spend more on prescription drugs – about $1,300 per person – than any other country[1], with prescription drug prices in the U.S. more than 2.5 times as high as those in other similar high-income nations.[2] Total spending on prescription drugs in the United States is also growing, rising to $603 billion in 2021, of which $421 billion was on retail drugs.[3] The ever increasing number of specialty drugs fuels the increase; specialty drugs account for 55 percent of medication spend, up from 28 percent in 2011.[4] The federal Centers for Medicare and Medicaid Services projects national prescription drug expenditures of approximately $6.8 trillion dollars for the 10-year period of 2021-2030.[5]

Although prescription drug prices account for only roughly 10 percent of overall healthcare spending, Americans pay more out-of-pocket for prescription drugs than for hospital care or health insurance. In the past decade, drug prices have risen three times faster than inflation and patient out-of-pocket costs have risen 53 percent.

The following chart details the increase in prescription drug average price, utilization, and spending from 2016 to 2020.[6]

[1] Robert Langreth, *Why Prescription Drug Prices in the US Are So High*, Bloomberg News-Business QuickTake (July 19, 2022), available at https://www.bloomberg.com/news/articles/2022-07-19/why-prescription-drug-prices-in-the-us-are-so-high-quicktake (last viewed on March 26, 2023).
[2] U.S. Dept. of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, Office of Science & Data Policy, *Issue Brief-Trends in Prescription Drug Spending*, 2016-2021, pg. 1 (September 2022).
[3] Id.
[4] Id.
[5] Centers for Medicare and Medicaid Services, *CMS Office of the Actuary Releases 2021-2030 Projections of National Health Expenditures*, March 28, 2022, available at https://www.cms.gov/newsroom/press-releases/cms-office-actuary-releases-2021-2030-projections-national-health-expenditures (last viewed on March 26, 2023).
[6] Health Care Cost Institute, *2020 Health Care Cost and Utilization Report*, May 2022, pg. 3, figure 4, available at https://healthcostinstitute.org/images//pdfs/HCCI_2020_Health_Care_Cost_and_Utilization_Report.pdf.

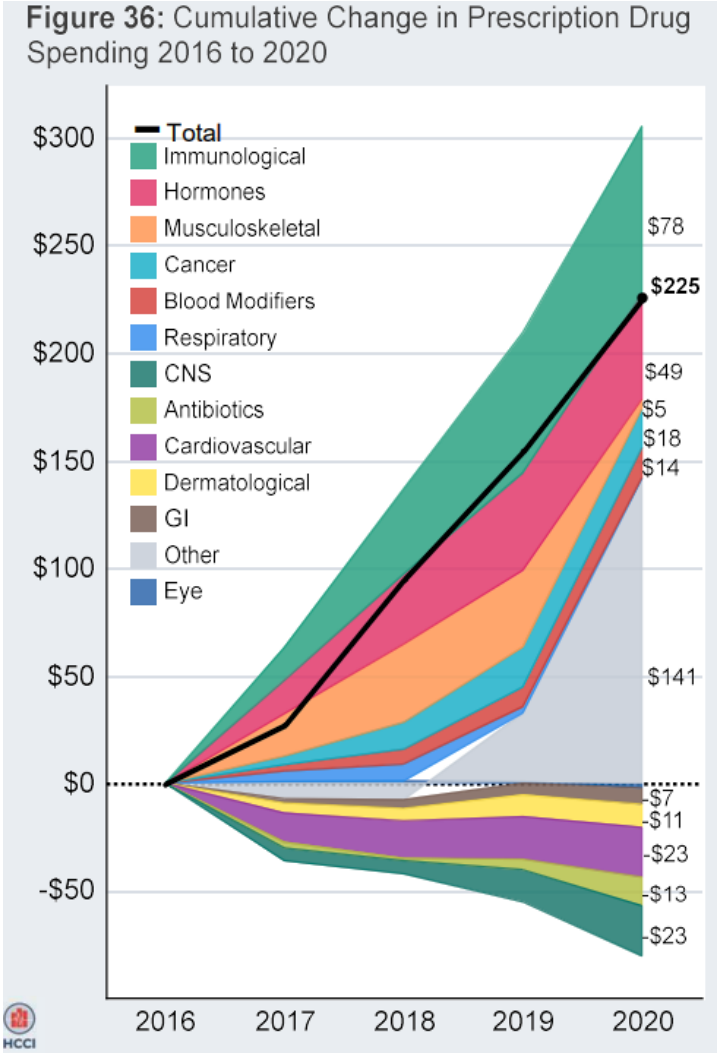


There are two competing ideas about what drives the increase in list prices. Some argue that manufacturers are solely to blame, because they unilaterally set list prices[7] and manipulate patent protection to achieve financial advantages. Others argue that insurers and pharmacy benefit managers (PBMs) share the blame for increasing drug costs because their demands for higher rebates drive manufacturers to raise list prices to maintain profit margins net of those higher rebates.[8]

Despite dramatically increasing rebates, prescription drug costs have risen three times faster than inflation over the past decade, even after the discounts provided to PBMs.[9] From 2010-2016, prescription drug list prices increased 129 percent for 14 medications with the highest drug expenditures.[10] At the same time, patient out-of-pocket costs increased 53 percent and insurance payments to PBMs for those drugs increased 64 percent after rebates and discounts.[11]

The following chart shows the cumulative change in prescription drug spending by category of drug from 2016 to 2020.[12]

[7] A. Roy, *Drug Companies, Not "Middlemen", Are Responsible for High Drug Prices*, Oct. 2018, available at https://www.forbes.com/sites/theapothecary/2018/10/22/drug-companies-are-responsible-for-high-drug-prices-not-middlemen/#1ac50c254947.
[8] J. Shepherd, *Pharmacy Benefit Managers, Rebates, and Drug Prices: Conflicts of Interest in the Market for Prescription Drugs*, Yale Law Policy Rev., January 2019 1(38).
[9] Jeff Lagasse, *Drug prices rose three times faster than inflation over the last decade, even after discounts*, Healthcare Finance (March 4, 2020), available at https://www.healthcarefinancenews.com/news/drug-prices-rose-three-times-faster-inflation-over-last-decade-even-after-discounts.
[10] Id.
[11] Id.
[12] Supra, FN 7 at pg. 20, figure 36.



Pharmacy Benefit Managers

Pharmacy benefit managers (PBMs) represent health insurers, self-insured employers, union health plans, state government employee plans, and government purchasers in the plan design, plan administration, selection, purchase, and distribution of pharmaceuticals, acting as third-party administrators of prescription drug benefits for more than 266 million people nationwide.[13]

Acting as intermediaries between insurers and other members of the health care system, PBMs are primarily responsible for negotiating prescription drug prices with pharmaceutical manufacturers, processing drug claims, managing drug formularies, and negotiating reimbursement rates.[14] PBMs earn profits through a combination of revenues, which may include administrative fees charged to health plans, retention of drug rebates paid by pharmaceutical manufacturers, and fees charged to network pharmacies, among others.

Drug pricing and benefit management involve complex and opaque industry activities. The following table contains some common terms that are used in the drug cost and benefit discussion.[15]

[13] National Conference of State Legislatures, *Summary–Pharmacy Benefit Manager Reform*, June 1, 2022, available at https://www.ncsl.org/health/pharmacy-benefit-manager-reform (last viewed on March 26, 2023).
[14] Report from the New York Senate, Committee on Investigations and Government Operations, *Final Investigative Report: Pharmacy Benefit Managers in New York*, May 31, 2019, pg. 7.
[15] U.S. Pharmacist, 2012;37(6), *Generic Drug Review Supplement*, pgs. 40-45, available at https://www.uspharmacist.com/article/understanding-drug-pricing (last viewed on March 26, 2023).

Term	Definition
Federal upper limit (FUL)	A price ceiling used by the Centers for Medicare and Medicaid Services (CMS) to control prices for certain medications paid to pharmacies
Maximum allowable cost (MAC)	A price ceiling, similar to the FUL, established at the state level
Usual and customary price (U&C)	The average cash price paid at a retail pharmacy
Average wholesale price (AWP)	An estimate of the price retail pharmacies pay for drugs from their wholesale distributor. This price is calculated and published by companies such as Medi-Span and First Databank
Wholesale acquisition cost (WAC)	An estimate of the manufacturer's list price for a drug to wholesalers or other direct purchasers, not including discounts or rebates. This price is defined by federal law
Average manufacturer price (AMP)	The price a manufacturer charges wholesalers or pharmacies that purchase directly from the manufacturer after discounts. This price is defined by federal law
Average sales price (ASP)	A calculation of the weighted average of manufacturer's sales price for a drug for all purchasers, net of price adjustments. This price is defined by federal law
Estimated acquisition cost (EAC)	An estimate of the price generally paid by providers for a drug. Formula specific for each state as defined by the state Medicaid agency
Average Actual cost (AAC)	An estimate of retail pharmacy acquisition costs for drugs through a review of actual pharmacy invoices
Dispensing fee	The amount reimbursed to the pharmacy to cover the charge for professional services and overhead costs
National Drug Code (NDC)	An 11-digit code used by Medicaid to identify a drug based on its manufacturer, strength, and package size

Until recently, PBMs operated largely in the absence of federal or state regulation; rather, they operated solely pursuant to contract terms negotiatied with employers and insurers. In the past 5 years, a plurality of state legislatures has passed laws to prohibit specific practices by PBMs. In 2018, the Legislature created a registration program for PBMs, within the Office of Insurance Regulation (OIR). Since 2019, PBMs operating in the state are required to register with OIR by submitting a completed application form and fee for registration. The Legislature also prohibited the use of "gag clauses" by PBMs that prevent pharmacies from providing drugs to patients at the lowest applicable prices.

A recent study of PBM profits found that, overall, gross profit increased by 12 percent, from $25 billion in 2017 to $28 billion in 2019.[16] The study also broke down the sources of PBM gross profit and tracked the change from 2017 to 2019.[17] Gross profit from:

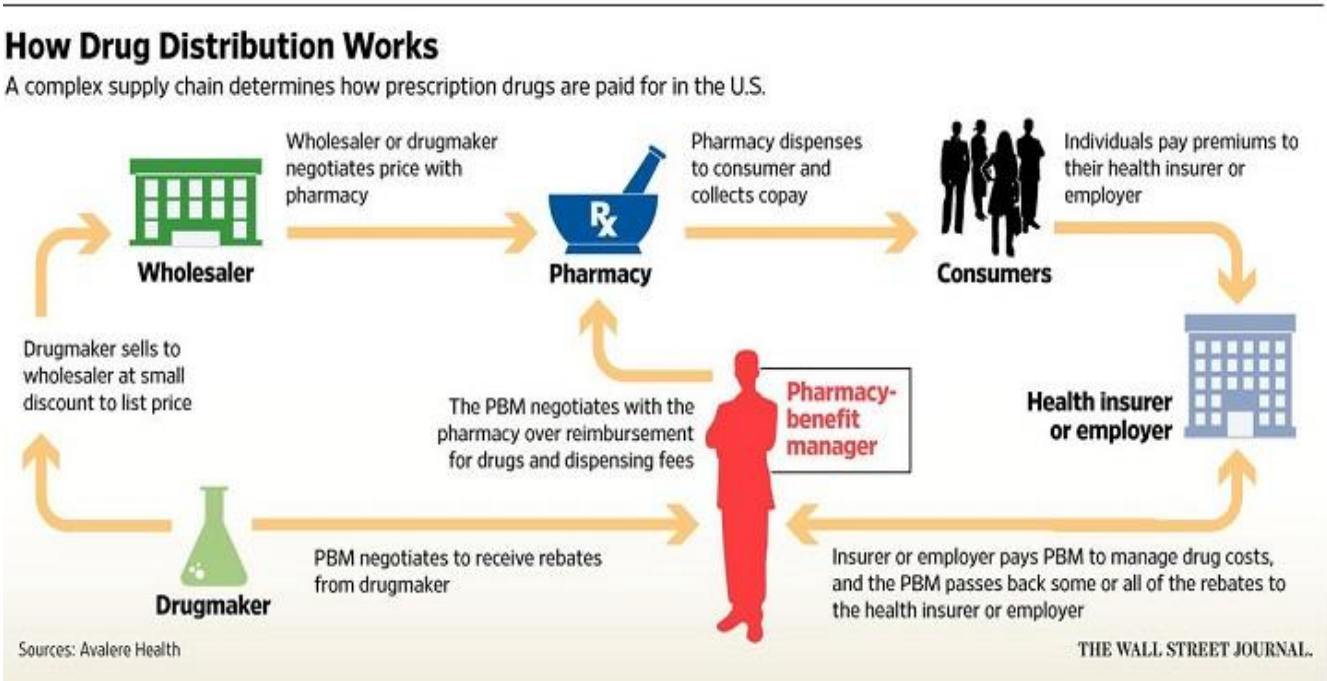
- Retained rebates paid by manufacturers decreased 61 percent, from $4 billion to $1.6 billion.
- Retained administrative fees paid by manufacturers increased 51 percent, from $3.8 billion to $5.7 billion.
- PBM-owned mail order and specialty pharmacies increased 14 percent from $8.9 billion to $10.1 billion.
- Other sources increased 26 percent from $8.5 billion to $10.7 billion.

PBMs negotiate with drug manufacturers, on behalf of health plan sponsors, in an effort to purchase drugs at reduced prices or with the promise of additional rebates. This often involves the development of drug formularies, which are tiered drug lists that incentivize the use of some drugs over others.[18] PBMs simultaneously negotiate with pharmacies to organize pharmacy networks and establish reimbursements for dispensing prescription drugs to patients. The Pharmaceutical Care Management

[16] PBM Accountability Project and 3 Axis Advisors, *Understanding the Evolving Business Models and Revenue of Pharmacy Benefit Managers*, December 2, 2021, pg. 4, available at https://www.3axisadvisors.com/projects/pbm-accountability-project-report-120221.
[17] Id.
[18] Academy of Managed Care Pharmacy, *Formulary Management*, https://www.amcp.org/about/managed-care-pharmacy-101/concepts-managed-care-pharmacy/formulary-management (last viewed on March 26, 2023); Pharmaceutical Care Management Association, *Pharmacy Contracting & Reimbursement*, available at https://www.pcmanet.org/policy-issues/pharmacy-contracting-reimbursement/ (last viewed on March 26, 2023).

Association indicates that PBMs save 40 percent to 50 percent on prescription drugs, an average of $962 per person per year.[19]

The U.S. pharmaceutical supply system is complex, and involves multiple organizations that play differing, but sometimes overlapping, roles in drug distribution and contracting. PBMs generally do not take physical possession of prescription drugs when performing their core pharmaceutical management functions, but they play an integral role in determining how much a health plan sponsor and a patient will pay for a given drug.[20] The following graphic offers a simplified glimpse of the prescription drug supply chain.

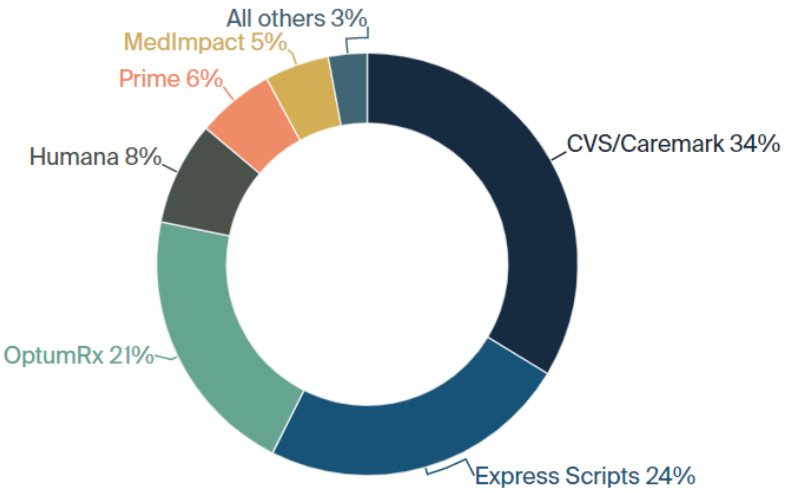


The three largest PBMs – CVS Caremark, Express Scripts, and Optum Rx – own their own pharmacies, while also controlling 80 percent to 85 percent of the PBM market.[21] Smaller PBMs also own their own pharmacies.

PBMs have become major participants in the pharmaceutical supply chain. These entities first emerged as claims processors in the late-1960s and early 1970s, but began to assume much more complex responsibilities in the 1990s in concert with advancements in information technology.[22] Currently, PBMs are responsible for managing the pharmacy benefits of about 270 million Americans.[23] The top six

[19] Bloomberg Law, Health Law & Business, *The Driver Dictating Prescription Drug Benefits: PBMs Explained*, March 3, 2022, available at https://news.bloomberglaw.com/health-law-and-business/the-driver-dictating-prescription-drug-benefits-pbms-explained (last viewed on March 26, 2023).
[20] Henry J. Kaiser Family Foundation, *Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain*, March 2005, available at https://www.kff.org/other/report/follow-the-pill-understanding-the-u-s/ (last viewed on March 26, 2023).
[21] Adam J. Fein, *The Top Pharmacy Benefit Managers of 2021: The Big Get Even Bigger*, Drug Channels Institute, April 5, 2022, available at https://www.drugchannels.net/2022/04/the-top-pharmacy-benefit-managers-of.html (last viewed on March 26, 2023).
[22] National Health Policy Forum, *The ABCs of PBMs: Issue Brief,* October 27, 1999, available at https://www.nhpf.org/library/issue-briefs/IB749_ABCsofPBMs_10-27-99.pdf (last viewed on March 26, 2023).
[23] Pharmaceutical Care Management Association, *The Value of PBMs*, available at https://www.pcmanet.org/the-value-of-pbms (last viewed on March 26, 2023).

PBMs nationwide handled more than 95 percent of total U.S. prescription claims.[24] The following graph shows the PBM market structure for 2020, based on total adjusted claims.[25]



Smaller PBMs are growing as well, and rising drug prices cause health plans to increase their reliance on PBMs. The global PBM market is projected to increase from $495 billion in 2022 to $740 billion by 2029, a 50 percent increase.[26]

PBM Revenue Streams

PBMs generate revenue from:

- Administrative fees from their clients (insurers, self-insured employers, union health plans, and government) for the administration of claims and drug dispensing;
- Rebates negotiated from drug companies–in some cases, the rebates are shared between the PBM and the health insurer or plan sponsor; and,
- Fees charged to pharmacies, which may include per prescription fees from network pharmacies and/or fees associated with participating in a PBM's network.[27]

Each PBM generates revenue from all or some combination of these sources.

Some PBMs also generate revenue using spread pricing arrangements. A pricing spread occurs when a PBM is reimbursed by a plan sponsor at one price for a given drug, but pays a dispensing pharmacy a lower price for that drug. In other words, the PBM retains some portion of the plan sponsor reimbursement as earned income.[28] PBM critics contend that these practices increase costs for health plan sponsors, or alternatively, results in lower reimbursements to pharmacies.[29]

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[24] Adam J. Fein, *The Top Pharmacy Benefit Managers of 2020: Vertical Integration Drives Consolidation*, Drug Channels Institute, April 1, 2021, available at https://www.drugchannels.net/2021/04/the-top-pharmacy-benefit-managers-pbms.html (last viewed on March 26, 2023).
[25] The Commonwealth Fund, *Controlling Health Care Costs, Are Pharmacy Benefit Managers the Next Target for Prescription Drug Reform*, April 20, 2022, available at Are Pharmacy Benefit Managers the Next Target for Prescription Drug Reform? | Commonwealth Fund (last viewed on March 26, 2023).
[26] Denise Myshko and Peter Wehrwein, *Beyond the Big Three PBMs*, Managed Healthcare Executive, December 14, 2022, available at https://www.managedhealthcareexecutive.com/view/beyond-the-big-three-pbms.
[27] Supra, FN 7.
[28] Prime Therapeutics, *Can You Follow the Money?*, March 17, 2017, available at https://www.primetherapeutics.com/en/services-solutions/connect/contributors/follow_the_money.html (last viewed on March 26, 2023).
[29] Health Affairs Blog, *Policy Options to Help Self-Insured Employers Improve PBM Contracting Efficiency*, May 29, 2019, available at https://www.healthaffairs.org/do/10.1377/hblog20190529.43197/full/ (last viewed on March 26, 2023).

PBMs also use direct and indirect remuneration (DIR) fees to supplement revenue. Such fees were originally conceived as a way for Centers for Medicare and Medicaid Services to track the amount of rebates and price adjustments negotiated by PBMs.[30] Over time, DIR fees became payments or payment adjustments made to PBMs after the point-of-sale that alter the cost of Medicare Part D covered drugs.[31] Examples of DIR fees include costs for pharmacies to participate in a Part D preferred network, price reconciliations based on contractual rates, and compliance fees for contract-based performance metrics.[32] DIR fees typically range from 1.5 percent to 11 percent of a drug's list price, assessed by PBMs to network pharmacy providers, typically three to six months after the provider has dispensed the medication, leaving no way for the pharmacy to recover its acquisition costs.[33] Between 2010 and 2020, retroactive DIR fees increased by more than 100,000 percent.[34]

Another post-sale clawback employed by PBMs is the generic effective rate (GER), which is a contractual rate set by PBMs for reimbursing generic claims. The GER is a method of guaranteeing pharmacies the rate paid for generic drugs over a certain period of time will, in the aggregate, equal a rate set in the contract, such as a factor of the average wholesale price (AWP). Reconciling to the AWP guarantee leads to post-payment adjustments. For example, a PBM might withhold payments to offset alleged overpayments above the GER threshold. PBM contracts increasingly include GER fees.[35] The fees are not based on pharmacy performance metrics, but instead are calculated based on a drug's Maximum Allowable Cost (MAC), or AWP.[36] GERs based on AWP may pay as low as AWP minus 85 percent to 89 percent.[37]

PBMs assert that their services result in significant savings for both insurers and patients.[38] In theory, the negotiating power of PBMs should translate into savings for patients, employers and insurers in the form of reduced drug costs. Health plan sponsors may benefit from sharing in the increased manufacturer rebates that PBMs are often able to realize,[39] which may also reduce premium costs for consumers and employers.

Some plan sponsors negotiate favorable terms when contracting with a PBM. For example, a recent survey of PBMs indicated that roughly 91 percent of rebates received from drug manufacturers were passed on to health plan sponsors in 2016.[40] However, small employers and less engaged plan sponsors may not receive such a large share of rebates negotiated by their contracted PBM.[41]

Regardless of the value to the insurance plan, some question the value of PBMs. In a statement prepared for the U.S. House Committee on Oversight and Government Reform, the National Community Pharmacists Association asserted that pharmacies have been subject to "take it or leave it" contracts with PBMs that include "clauses that restrict their (pharmacists) ability to communicate with

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[30] Supra, FN 8 at pg. 14.
[31] Id.
[32] Michael Gabay, *Direct and Indirect Remuneration Fees: The Controversy Continues*, 52(11) Hosp. Pharm., 740 (Dec. 2017).
[33] Frier Levitt, LLC, for the Community Oncology Alliance, *Pharmacy Benefit Manager Exposé: How PBMs Adversely Impact Cancer Care While Profiting at the Expense of Patients, Providers, Employers, and Taxpayers*, February 2022, pg. 22, available at https://communityoncology.org/wp-content/uploads/2022/02/COA_FL_PBM_Expose_2r2022.pdf.
[34] Darrell L. Wilyard and Alexis V. Fanshier, *PBM Fees Put the "GER" in Danger for Specialty Pharmacies*, Dec. 20, 2022, American Journal of Managed Care, Evidence-Based Oncology, vol. 28, iss. 8, available at https://www.ajmc.com/view/pbm-fees-put-the-ger-in-danger-for-specialty-pharmacies (citing American Pharmacists Association, *CMS eliminates retroactive DIR fees*, May 3, 2022, available at https://www.pharmacist.com/Pharmacy-News/cms-eliminates-retroactive-dir-fees).
[35] Id.
[36] Id.
[37] Id.
[38] Visante, *The Return on Investment (ROI) on PBM Services*, November 2016, available at https://www.pcmanet.org/wp-content/uploads/2016/11/ROI-on-PBM-Services-FINAL.pdf (last viewed on March 26, 2023).
[39] Id.
[40] Pew Charitable Trusts, *The Prescription Drug Landscape, Explored,* March 2019, available at https://www.pewtrusts.org/en/research-and-analysis/reports/2019/03/08/the-prescription-drug-landscape-explored (last viewed on March 26, 2023).
[41] Supra, FN 7.

patients".[42] In addition, PBM contracts with health plan sponsors have been criticized for being confidential and complex in nature.[43]

PBM Tools of Administration

The role of PBMs is not limited to processing and paying prescription drug claims. PBMs also provide bundled services related to pharmaceutical benefits administration, using tools such as drug formulary design and implementation, formulary management, negotiating drug rebates, and establishing a network of participating pharmacies. Each tool is discussed in more detail, below.

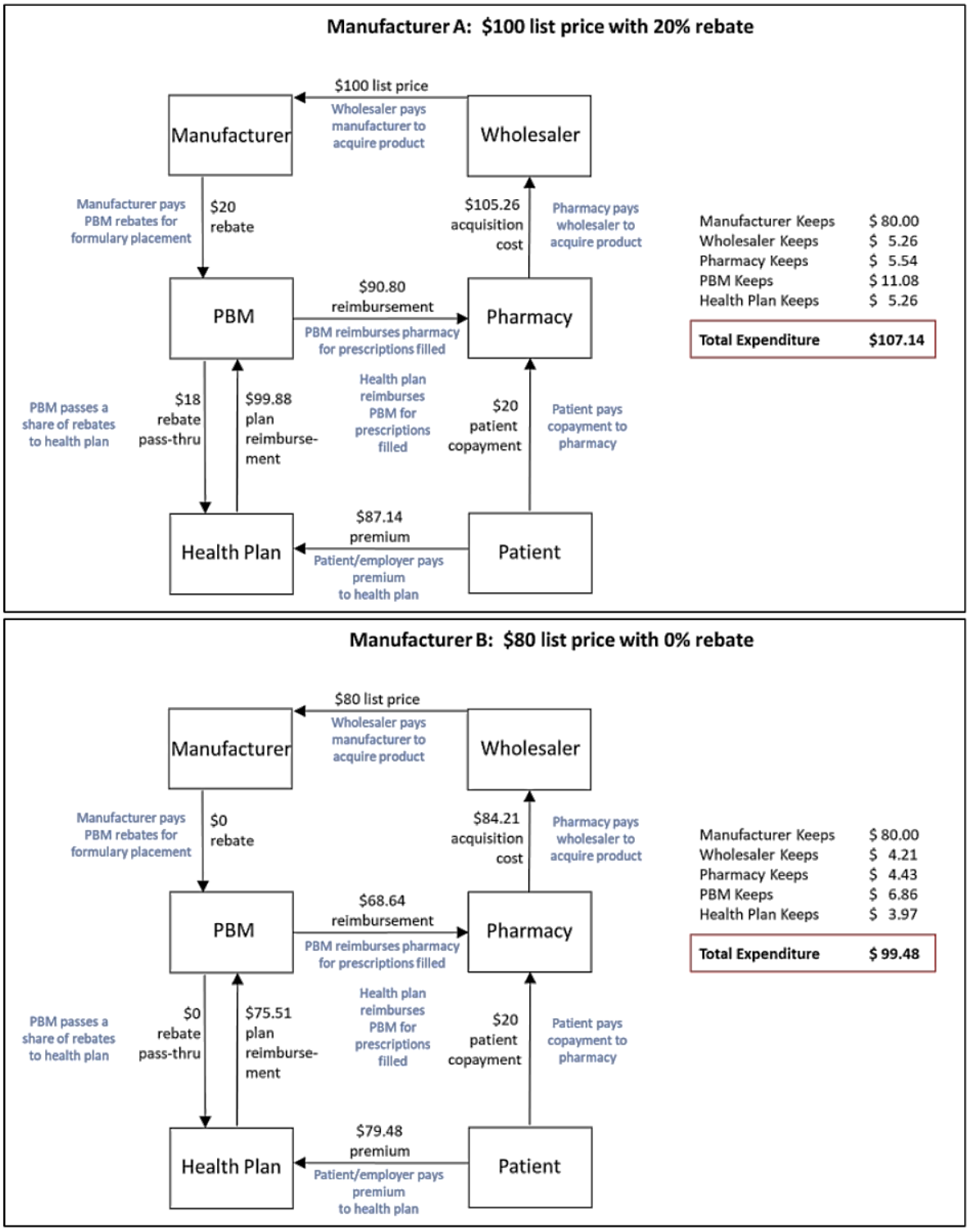
Maximum Allowable Cost

PBMs establish the upper limit a plan will pay for generic drugs and brand name drugs that have generic versions available.[44] Known as the "maximum allowable cost" or "MAC", it is the proprietary benchmark price set by PBMs for therapeutically equivalent multiple source generic drugs.[45] PBMs can determine which products, and their prices, are included on the MAC lists. Generally, MAC list rates are reviewed and updated at least every seven days.

Formularies and Utilization Management

PBMs also negotiate rebates with drug manufacturers through drug formularies and utilization management.[46] Manufacturers set the list price for their prescription drugs, and the PBMs negotiate price concessions for drugs dispensed to the beneficiaries of its plan sponsor clients, in exchange for having their prescription medications placed on a formulary and thereby given preferred status for plan subscribers. PBMs negotiate with drug manufacturers to get the lowest net cost through manufacturer discounts. Rebates are paid to PBMs after the point-of-sale, and can make up 40 percent or more of the drug's list price.[47] Essentially, manufacturers offer financial incentives to PBMs, as rebates or discounts, for achieving sales targets. However, the manufacturers may raise list prices to offset rebate agreements, with an inflationary result. According to a study by the University of Southern California's Schaeffer Center, a $1 increase in rebates equates to a $1.17 increase in prescription drug list price.[48] The following graphs provide two examples of how monies flow between manufacturers, PBMs, health plans, pharmacies, wholesalers, and patients for drug rebates.[49]

[42] National Community Pharmacists Association, *Statement for the Record: National Community Pharmacists Association*, U.S. House Committee on Oversight and Government Reform, February 4, 2016, available at http://www.ncpa.co/pdf/ncpa-ogr-statement.pdf (last viewed on March 26, 2023).
[43] Supra, FN 13.
[44] Supra, FN 8 at pg. 10.
[45] Id.
[46] Elizabeth Seeley and Aaron S. Kesselheim, *Pharmacy Benefit Managers: Practices, Controversies, and What Lies Ahead*, The Commonwealth Fund, March 26, 2019, available at www.commonwealthfund.org/publications/issue-briefs/2019/mar/pharmacy-benefit-managers-practices-controversies-what-lies-ahead.
[47] Id.
[48] Neeraj Sood, et al., *The Association Between Drug Rebates and List Prices*, USC Schaeffer Center (Feb. 11, 2020), available at https://healthpolicy.usc.edu/research/the-association-between-drug-rebates-and-list-prices/.
[49] USC Leonard D. Schaeffer Center for Health Policy & Economics, *Comment Letter to Chair Lina Khan, Federal Trade Commission, on the practices of PBMs and their impacts on patients, physicians, employers, pharmacies, and other participants in the healthcare system*, May 25, 2022, pg. 7, figure 1, available at https://healthpolicy.usc.edu/wp-content/uploads/2022/06/Van-Nuys-et-al.-Public-Comments-to-FTC-on-PBMs.pdf.



A formulary is a list of prescription drugs covered by a health plan's pharmacy benefit design. It dictates which drugs a health plan predetermines will be covered, and at what level, for reimbursement under the terms of its pharmacy benefit plan. Formularies distinguish between preferred or discouraged prescription drugs by dividing products into different tiers, designating different levels of patient out of pocket costs. A formulary may cover both generic and brand name prescription drugs. Formulary selection involves an assessment of both the clinical and financial elements of a prescription medication.[50]

[50] Cole Werble, *Health Policy Brief: Formularies*, Health Affairs 1 (Sept. 14, 2017).

Typically, PBMs employ Pharmacy and Therapeutics ("P&T") committees to assess and recommend formulary placement for individual drugs. These committees are typically comprised of clinicians, pharmacists, medical professionals, legal experts, and administrators. Formularies generally have two to five tiers. For example, a five-tier formulary includes generic, preferred brand, non-preferred brand, preferred specialty drugs and non-preferred specialty drug tiers.[51]

In addition to including therapeutic substitutions, a plan's formulary may require a patient to accept a generic substitution for the chemical equivalent of the brand name drug. Pharmacy benefit plans may also use "open" or "closed" formularies. In an "open" formulary, the plan sponsor pays a portion of the cost for all drugs, whereas in a "closed" formulary, the plan sponsor does not cover any non-formulary drugs, unless approved through a process.

Tier placement determines the amount a patient pays out of pocket for a prescription medication at the point-of-sale.[52] These costs are typically represented as coinsurance or copays.[53] Coinsurance is a percentage of the full cost of a drug; copays are a fixed amount per prescription.[54] Under this approach, the structure of the plan provides for lower out of pocket copays when preferred drugs are used.[55] In a three-tiered formulary copay structure, for example, a patient may have to pay $10 for generic prescriptions, $15 for preferred brand name prescriptions, and $30 for nonpreferred brand name prescriptions.[56] Prescription drugs that are on a plan's formulary often have lower copayment amounts, thereby providing incentives to plan beneficiaries to obtain prescriptions included on the formulary, or even on a lower tier, to reduce or eliminate their out of pocket costs.[57] Thus, PBMs can steer patients towards one prescription drug over another by making their out-of-pocket costs less. As a result, the placement of prescription drugs on a formulary can increase profits for the drug's manufacturer.[58]

PBMs negotiate with drug manufacturers to provide preferred formulary placement for the manufacturers' products, in exchange for discounts, rebates, and incentives. This scheme has led to contentions that PBM-negotiated manufacturer rebates cause PBMs to be more interested in maximizing their rebates—which they receive a monetary portion of—than in minimizing a payer's prescription drug costs.[59] Further, a recent study of Medicare Part D formularies found that PBMs might be creating formularies that "encourage the use of more expensive branded drugs by assigning them fewer utilization controls compared to generic equivalents."[60]

Compliance with a plan's formulary is crucial for a PBM because it demonstrates the ability of a PBM to guide beneficiaries to obtain drugs on the formulary. High compliance is important because it enables a PBM to show drug manufacturers that it "can induce use of formulary products and increase their market shares." PBMs utilize various strategies to ensure formulary compliance, including generic substitution, therapeutic interchange, step-therapy and prior authorization protocols.[61]

Generic Substitution

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[51] Id.
[52] Id.
[53] Id.
[54] Id.
[55] Allison Garett & Robert Garis, *Leveling the Playing Field in the Pharmacy Benefit Management Industry*, 42 Val. U. L. Rev. 33, 43 (2007).
[56] Robert I. Garis et al., *Examining the Value of Pharmacy Benefit Management Companies*, 61 Am. J. Health-Sys. Pharmacist, 81, 82 (2004).
[57] Federal Trade Commission, *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies,* 1, 6 (Aug. 2005).
[58] Id.
[59] Supra, FN 50.
[60] Letter from U.S. Sen. Charles E. Grassley, Chairman, Senate Finance Committee and U.S. Sen. Ron Wyden, Ranking Member, Senate Finance Committee to Timothy C. Wentworth, President, Express Scripts and Cigna Services (Apr. 2, 2019), (citing Mariana P. Socal, Ge Bari & Gerald F. Anderson*, Favorable Formulary Placement of Branded Drugs in Medicare Prescription Drug Plans When Generics Are Available*, Research Letter, JAMA Internal Med. (Mar. 18, 2019)).
[61] Supra, FN 50.

Generic substitution is the dispensing of a bioequivalent generic drug that contains the same active ingredients, and is chemically identical in terms of strength, concentration, dosage, and route of administration, to its brand-name drug. It generally occurs without prior physician authorization when a beneficiary presents a prescription for a brand name drug and the pharmacy dispenses it with a generic version of the product. Unless a state legally requires generic substitution, where applicable, or a physician orders a prescription to be dispensed as written ("DAW"), PBMs and pharmacists may have the discretion to substitute a generic drug for a brand name drug without prescriber prior approval.[62]

Therapeutic Interchange

Similarly, therapeutic interchange is the substitution of one drug for another in the same therapeutic class. However, in therapeutic interchanges, the drug is substituted for a therapeutically equivalent, but chemically distinct, drug product. The substitution can be brand drug to brand drug or an interchange of a generic version of a therapeutically similar brand drug for the prescribed brand drug. For example, in the latter scenario, generic Prozac is dispensed in lieu of prescription Zoloft.[63]

Step-Therapy and Prior Authorization

PBMs utilize step-therapy and prior authorization tools to reduce prescription drug costs by boosting formulary compliance.[64]

For some drugs, plans require the insured to try one drug first to treat the medical condition before they will cover another drug for that condition. For example, if Drug A and Drug B both treat a medical condition, a plan may require doctors to prescribe the most cost-effective drug, Drug A, first. If Drug A does not work for a beneficiary, then the plan will cover Drug B. This form of cost containment is commonly called step-therapy. Step-therapy is also known as "fail-first" as the insurer restricts coverage of expensive therapies unless patients have already failed treatment with a lower-cost alternative. This is intended to counteract the cost impact of new, patent-protected, expensive, and often heavily-marketed drugs, when other, older drugs in the same therapeutic class may perform as well for individual patients.

There is mixed evidence on the impact of step-therapy policies.[65] A review of the literature found that there is little good empirical evidence for or against cost savings and utilization reduction.[66] Some studies suggest that step-therapy policies have been effective at reducing drug costs without increasing the use of other medical services,[67] while other studies have found that step-therapy can increase total utilization costs over time because of increased inpatient admissions and emergency department visits.[68]

Typically, prior authorization requires a clinical justification for the use of prescription drugs that are prone to misuse or are more expensive.[69] Prior authorization also enables PBMs to influence patients' choices by requiring them to get special permission from their health plan to use certain drugs or by requiring patients to try a less expensive drug before being authorized to use the medicine initially prescribed by their physician.[70]

PBM Retail and Mail-Order Pharmacy Ownership

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[62] Id.
[63] Id.
[64] Id.
[65] Rahul K. Nayak and Steven D. Pearson, *The Ethics Of 'Fail First': Guidelines and Practical Scenarios for Step Therapy Coverage Policies*, Health Affairs 33, No.10 (2014):1779-1785.
[66] Motheral, B.R., *Pharmaceutical Step Therapy Interventions: A Critical Review of the Literature*, Journal of Managed Care Pharmacy 17, no. 2 (2011) 143-55, available at http://www.jmcp.org/doi/pdf/10.18553/jmcp.2011.17.2.143 (last visited on March 27, 2023).
[67] Supra, FN 65 at pg. 1780.
[68] Id.
[69] Id.
[70] Id.

Many PBMs also own and operate their own retail and mail-order pharmacies. A PBM is "vertically integrated" if it owns a pharmacy, whether it is retail or mail order.[71] A vertically integrated PBM may have a greater ability to control which prescription drugs are dispensed under the benefit plans it administers than a non-vertically integrated PBM,[72] and may be able to reduce costs for expensive specialty drugs. CVS Health, Express Scripts Inc., and OptumRx own and operate mail order pharmacy services.[73]

Vertical integration can reduce prescription drug costs by reducing transaction costs and avoiding double markups.[74] However, when a PBM administers the pharmacy benefits for a client and sells prescription drugs to a client's beneficiary via the PBM's owned mail order pharmacy, the possibility of a conflict of interest arises.[75] A health plan or employer may find sufficient value in the PBM's work despite that potential conflict, or may not be sophisticated enough to ensure any conflict works in the best interest, cost-wise, of the plan and its enrollees.

PBM Regulation

Until recently, PBMs operated largely in the absence of federal or state regulation, governed instead only by contract terms with their health plans and by state and federal regulation of those health plans. In the past 5 years, a plurality of state legislatures has passed laws to prohibit specific practices by PBMs.[76] Both the Legislature[77] and Congress[78] have prohibited the use of so-called "gag clauses" by PBMs. A gag clause refers to a contractual requirement that prevents a pharmacy or pharmacist from telling a patient when it would cost less to pay cash for a prescription than to pay the copayment under that patient's health insurance.

In 2018, the Legislature created a registration program for PBMs.[79] Since January 1, 2019, PBMs operating in the state are required to register with the Office of Insurance Regulation (OIR) by submitting a completed application form and fee. The registration requires that a PBM provide basic identifying information to the state, but does not authorize state oversight of PBM practices.[80] According to OIR, 71 PBMs are currently registered to operate in Florida, with two additional registrations pending.[81]

Current law also requires contracts between PBMs and insurers or HMOs to include specific limits on the cost sharing that will be incurred by patients. Each contract must specify that a patient's cost share shall equal the lower of the following prices:

- The applicable cost sharing obligation under a patient's insurance; or,
- The retail (or "cash") price of the drug prescribed.[82]

This prohibits PBMs from preventing patients from paying the lowest applicable price for a particular drug.

[71] Id.
[72] Id.
[73] Supra, FN 50.
[74] Id., Double markups, or "double marginalization" occurs when two independent, vertically related firms each have some ability to charge about the marginal cost.
[75] Id.
[76] National Conference of State Legislatures, *State Policy Options and Pharmacy Benefit Managers (PBMs)*, March 17, 2021 https://www.ncsl.org/research/health/state-policy-options-and-pharmacy-benefit-managers.aspx (last viewed on March 26, 2023).
[77] Ch. 2018-91, L.O.F. Ss. 627.64741, 627.6572, and 641.314, F.S.
[78] P.L. 115-263.
[79] Ch. 2018-91, L.O.F.
[80] S. 624.490, F.S.
[81] Email with Kevin Jacobs, Chief of Staff, Office of Insurance Regulation, March 13, 2023.
[82] Ss. 627.64741, 627.6572, and 641.314, F.S.

Federal Trade Commission PBM Inquiry

The Federal Trade Commission (FTC) announced in early June 2022 that it will launch an inquiry into PBM business practices, requiring the six largest PBMs to provide information and records.[83] The agency's inquiry will scrutinize the impact of vertically integrated PBMs on the access and affordability of prescription drugs. As part of this inquiry, the FTC plans to send compulsory orders to CVS Caremark; Express Scripts, Inc.; OptumRx, Inc.; Humana Inc.; Prime Therapeutics LLC; and MedImpact Healthcare Systems, Inc.

The FTC's inquiry will examine PBMs' role in the U.S. pharmaceutical system.[84] According to the FTC, many PBM functions depend on highly complicated, opaque contractual relationships that are difficult or impossible to understand for patients and independent businesses across the prescription drug system. The inquiry will focus on several practices that have drawn scrutiny in recent years, including:

- Fees and clawbacks charged to unaffiliated pharmacies;
- Methods to steer patients towards PBM-owned pharmacies;
- Audits of independent pharmacies;
- Methods to determine pharmacy reimbursement;
- The prevalence of prior authorizations and other administrative management techniques;
- The use of specialty drug lists and surrounding specialty drug policies; and
- The impact of rebates and fees from drug manufacturers on formulary design and the costs of prescription drugs to payers and patients.[85]

On June 16, 2022, the FTC unanimously voted to issue an enforcement policy statement putting PBMs on notice that the payment of rebates and fees by drug manufacturers to PBMs resulting in the exclusion of lower-cost drug alternatives offered by competitors from formularies may violate competition and consumer protection laws. The FTC announced that it intends to examine the impact of rebates and fees on patients and payers to determine whether any of these provisions have been violated. Importantly, however, the policy statement does not suggest that all such rebates and fees may be problematic and clarified that "nothing prevents drug manufacturers, PBMs, and health plans from negotiating good-faith rebates and fees for legitimate services that increase value to payers and patients."[86]

Florida Executive Order Number 22-164

In 2022, Governor DeSantis issued Executive Order Number 22-164, Increasing Transparency and Accountability in the Pharmaceutical Industrial Complex, which applies to the state Medicaid program and the state employee group health plan. The executive order:

- Required plans to amend all PBM contracts with 180 days of contract execution to prohibit spread pricing[87], require a pass-through pricing model[88], and prohibit financial clawbacks and reconciliation of offsets.[89]

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[83] Federal Trade Commission, *FTC Launches Inquiry Into Prescription Drug Middlemen Industry*, June 7, 2022, available at https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry (last viewed on March 26, 2023).
[84] Id.
[85] Id.
[86] Federal Trade Commission, *FTC to Ramp Up Enforcement Against Any Illegal Rebate Schemes, Bribes to Prescription Drug Middleman That Block Cheaper Drugs*, June 16, 2022, available at https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-ramp-up-enforcement-against-illegal-rebate-schemes
[87] Agency for Health Care Administration, *Implementation of Executive Order 22-164 – Pharmacy Benefit Managers*, Presentation to the Florida Senate Health Policy Committee, February 6, 2023, slide 14, available at https://ahca.myflorida.com/content/download/20780/file/Senate_Health_Policy_PBM_2.6.23.pdf.
[88] Id., In a pass-through drug pricing model, a managed care plan's payment to PBM for prescription drugs and any related dispensing fees are equivalent to the PBM payment to the dispensing pharmacy or provider.
[89] Id., at slide 15.

- Required plans to submit annual and quarterly reconciliation reports.[90]
- Required certain disclosures and inspections.[91]
    - Managed care plans must disclose to the Florida Agency for Health Care Administration (AHCA) all financial terms and arrangements for payment of any kind that apply between the plan or the plan's PBM and any provider of outpatient drugs, any prescription drug manufacturer, prescription drug wholesaler, or labeler.
    - Managed care plans must also disclose copies of its PBM pharmacy provider agreement and note any differences among commercial, preferred, or independently-owned pharmacies.
- Required an audit of financial records.[92]
- Imposed additional liquidated damages.[93]
    - Within 180 days following executing the amendment, all PBM subcontracts must be updated to reflect the requirements of the executive order.
    - A managed care plan that fails to update their contracts will be subject to liquidated damages, contractual sanctions, or any other actions deemed necessary by AHCA.
    - Failure to provide the necessary data or reports to AHCA will result in immediate action by the agency which may include, but is not limited to, sanctions, liquidated damages, or reduced capitated payments in the estimated amount of combined federal and supplemental drug rebates.

AHCA entered into a contract with Myers and Stauffer to investigate the organizational structures and contractual arrangements, including payment terms, of the PBMs used by the health plans participating in the Statewide Medicaid Managed Care (SMMC) program. There are three phases to the audit: risk assessment, detailed analysis, and detailed investigational analysis. The first quarterly report is due in July, 2023.

Florida Medicaid

Medicaid is the health care safety net for low-income Floridians. Medicaid is a partnership of the federal and state governments established to provide coverage for health services for eligible persons. The program is administered by AHCA and financed by federal and state funds. AHCA delegates certain functions to other state agencies, including the Department of Children and Families (DCF), which makes eligibility determinations.

The state uses a comprehensive managed care delivery model for primary and acute care services provided to most Medicaid enrollees, the SMMC program.[94] The SMMC program provides acute health care services through managed care plans contracted with AHCA in the 11 regions across the state. Specialty plans are also available to serve distinct populations, such as the Children's Medical Services Network for children with special health care needs, or those in the child welfare system. Medicaid recipients with HIV/AIDS, serious mental illness, dual enrollment with Medicare, chronic obstructive pulmonary disease, congestive heart failure, or cardiovascular disease may also select from specialized plans.

The managed care plans participating in the SMMC program may contract with PBMs for the administration of pharmacy benefits, or they may manage the benefit internally. It is currently unclear how PBMs may be generating revenues by virtue of serving the Medicaid population.

[90] Id., at slide 16.
[91] Id., at slide 17.
[92] Id., at slide 18.
[93] Id., at slide 19.
[94] S. 409.964, F.S.

In December 2020, Milliman issued a report commissioned by AHCA, "Pharmacy Benefit Manager Pricing Practices in Statewide Medicaid Managed Care Program,[95]" which revealed some interesting facts about how the SMMC program's PBM-administered pharmacy benefit in Medicaid managed care. Milliman and AHCA studied PBM usage and payment arrangements in the SMMC program, analyzing 22.6 million claims from a 12-month period. The report found:

- PBMs received over $2.1 billion from 15 plans for claims reimbursement, of which $2 billion was paid to pharmacies.[96]
- The net reimbursement to PBMs through a pass-through model and spread pricing was 4.1 percent ($89.6 million).[97]
- About two-thirds of Medicaid plans used spread pricing, representing about 45 percent of claims; the rest used a pass-through model.[98]
    - Since the report was issued, all but one plan moved to a pass-through model.
- PBMs using spread pricing may receive more overall compensation than those using a pass-through model.
    - Plans in spread pricing arrangements pay PBMs $94.08 per claim, and the PBMs pay pharmacies $85.42 per claim, generating approximately a 9.2 percent spread.[99]
    - Plans in pass-through arrangements pay PBMs $96.92 per claim and the PBMs pay pharmacies the same amount, resulting in zero spread. Instead, the plans pay an administrative fee to the PBMs equal to $1.45 per claim, or 1.5 percent of total plan payment.[100]
- In addition to spread pricing revenue, or pass-through pricing administrative fees, the PBMs collected approximately $5.8 million in transaction fees from participating pharmacies.[101]

State Group Insurance Program

The State Group Insurance Program (SGI Program) is outlined under s. 110.123, F.S., and is administered by the Division of State Group Insurance (DSGI) within the Department of Management Services (DMS). The SGI Program is an optional benefit for all state employees including all state agencies, state universities, the court system, and the Legislature, and includes health, life, dental, vision, disability, and other supplemental insurance benefits. The SGI Program typically makes benefits changes on a plan year basis, January 1 through December 31.

As part of the SGI Program, DMS is required to maintain the State Employee Prescription Drug Program (Prescription Drug Plan).[102] DMS contracts with CVS/Caremark, a PBM, to administer the Prescription Drug Plan.[103] DMS has negotiated contract language that prevents CVS/Caremark from using spread pricing at retail pharmacies. In addition, the contract stipulates that the PBM will pass through 100 percent of the rebates received from pharmaceutical manufacturers to DMS.[104] Private health plan sponsors may also use these types of contract clauses to define which types of revenue may be earned by contracted PBMs.

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[95] Milliman, *Florida Agency for Health Care Administration – Pharmacy Benefit Manager Pricing Practices in Statewide Medicaid Managed Care Program*, December 2020, available at https://cdn.ymaws.com/www.floridapharmacy.org/resource/resmgr/docs_2021_legislative_session/milliman_report.pdf.
[96] Id., at pg. 1.
[97] Id., at pg. 2.
[98] Id., at pg. 7.
[99] Id., at pg. 9.
[100] Id.
[101] Id., at pg. 12.
[102] S. 110.12315, F.S.
[103] Department of Management Services, *myFlorida, Prescription Drug Plan*, available at http://mybenefits.myflorida.com/health/health_insurance_plans/prescription_drug_plan (last viewed on March 26, 2023).
[104] Contract between CaremarkPCS Health, L.L.C. and Florida Department of Management Services, *Pharmacy Benefit Management Services*, available at https://www.dms.myflorida.com/content/download/107930/607791/2015_PBM_Contract_REDACTED_FINAL.pdf (last viewed on March 26, 2023).

Statewide Provider and Health Plan Claim Dispute Resolution Program

The Statewide Provider and Health Plan Claim Dispute Resolution Program (Program) was established in 2000 to provide assistance to contracted and non-contracted providers and health plans for resolution of claim disputes.[105] Under the Program, AHCA contracts with a resolution organization[106] to timely review and consider claim disputes submitted by providers and health plans and to recommend to AHCA an appropriate resolution of those disputes.[107] AHCA does not have authority to evaluate the recommendation of the resolution organization and must enter a final order adopting it within 30 days of receiving it.[108]

Although the vast majority of disputes under the Program are initiated by hospital facilities, a pharmacy may also seek resolution of claims disputes under the Program.

Insurance Administrators

Insurance administrators (administrators) are regulated under part VII of chapter 626, F.S. Administrators are required to obtain a certificate of authority, at which time they must demonstrate positive net worth, qualified management, and a valid business plan. After licensure, administrators must file an annual report containing its financial statements; providing information regarding the programs, funds, or plans for which the company is acting as an administrator; and disclosing officers, directors, shareholders, key personnel, and affiliated companies. Administrators are also required to file audited financial statements on an annual basis. To remain in compliance, administrators are required to maintain a positive net worth, notify OIR of any change in its ownership, and identify to OIR any ownership interest or affiliation of any kind with any insurance company responsible for providing benefits directly or through reinsurance to any plan for which the administrator provides administrative services.

Prescription Drug Manufacturers

Federal Regulation of Drug Manufacturers

The United States Food and Drug Administration (FDA) is responsible for ensuring that foods, drugs, biological products, and medical devices are effective and safe for public consumption.[109] The FDA regulates these areas under the authority of the Federal Food, Drug, and Cosmetic Act (FDCA).[110] The FDCA prohibits any drug from being introduced or delivered for introduction into interstate commerce unless approved by the FDA. The FDCA further prohibits adulterated or misbranded drugs and devices from being introduced, delivered for introduction, or received in interstate commerce.

As a condition of providing drugs under the Medicaid program, pharmaceutical manufacturers must also participate in the 340B program. The program, named after its section number in the Public Health Service Act, requires drug manufacturers to provide drugs to eligible facilities and pharmacies at substantially reduced prices.[111] Eligible facilities and pharmacies, referred to as "covered entities", are generally health care providers that serve low-income or otherwise disadvantaged populations. These

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[105] S. 408.7057, F.S.; Agency for Health Care Administration, *Statewide Provider and Health Plan Claim Dispute Resolution Program - 2020 Annual Report*, February 2021, https://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Commercial_Managed_Care/cdrp.shtml (last viewed on March 26, 2023).
[106] "Resolution organization" is a qualified independent third-party claim-dispute-resolution entity selected by and contracted with the AHCA under s. 408.7057(1)(c), F.S. AHCA selected MAXIMUS, Inc. as the resolution organization.
[107] S. 408.7057(2)(a), F.S.
[108] S. 408.7057(4), F.S.
[109] U.S. Food & Drug Administration, *What We Do*, available at https://www.fda.gov/AboutFDA/WhatWeDo/default.htm (last viewed on March 26, 2023).
[110] 21 U.S.C. § 355(a).
[111] 42 U.S.C. § 256b; Health Resources & Services Administration, *340B Drug Pricing Program*, available at https://www.hrsa.gov/opa/index.html (last viewed on March 26, 2023).

include qualifying hospitals, federal grantees from the Health Resources & Services Administration (HRSA), the Centers for Disease Control and Prevention (CDC), the Department of Health and Human Services' Office of Population Affairs, and the Indian Health Service.[112]

State Regulation of Drug Manufacturers

The Department of Business and Professional Regulation's (DBPR) Division of Drugs, Devices, and Cosmetics and the Department of Health's (DOH) Board of Pharmacy regulate prescription drugs in the state from manufacture to distribution and dispensing. All entities engaged in any process along this continuum must be either licensed or permitted to engage in such activity, subject to relevant laws and rules and enforcement authority of DBPR or DOH. Due to the overlap in these two industries, the law requires entities permitted or licensed under either DBPR or DOH to comply with the laws and rules of both.[113]

DBPR's Division of Drugs, Devices, and Cosmetics protects the health, safety, and welfare of Floridians from adulterated, contaminated, and misbranded drugs, drug ingredients, and cosmetics by enforcing the FDCA.[114] The FDCA conforms to FDA drug laws and regulations and authorizes DBPR to issue permits to Florida drug manufacturers and wholesale distributors and register drugs manufactured, packaged, repackaged, labeled, or relabeled in Florida.[115]

Florida has 18 distinct permits based on the type of entity and intended activity, and includes permits for entities within the state, out of state, or even outside of the United States.[116] DBPR has broad authority to inspect and discipline permittees for violations of state or federal laws and regulations, which can include seizure and condemnation of adulterated or misbranded drugs or suspension or revocation of a permit.[117]

Florida law contains a variety of provisions that make trade secret information exempt or confidential and exempt[118] from public record requirements. Some exemptions only protect trade secrets, while others protect "proprietary business information" and define that term to specifically include trade secrets. Current law makes trade secret information provided to DBPR in a prescription drug permit application confidential and exempt.[119]

Prescription Drug Manufacturer Permit

Drug manufacturing includes the preparation, deriving, compounding, propagation, processing, producing, or fabrication of any drug.[120] A prescription drug manufacturer permit is required for any

[112] Health Resources & Services Administration, *340B Eligibility*, available at https://www.hrsa.gov/opa/eligibility-and-registration/index.html (last viewed on March 26, 2023).
[113] Ss. 499.067 and 465.023, F.S.
[114] Florida Department of Business and Professional Regulation, *Division of Drugs, Devices, and Cosmetics,* available at http://www.myfloridalicense.com/DBPR/drugs-devices-and-cosmetics/ (last visited on March 26, 2023).
[115] S. 499.01, F.S.
[116] A permit is required for a prescription drug manufacturer; a prescription drug repackager; a nonresident prescription drug manufacturer; a prescription drug wholesale distributor; an out-of-state prescription drug wholesale distributor; a retail pharmacy drug wholesale distributor; a restricted prescription drug distributor; a complimentary drug distributor; a freight forwarder; a veterinary prescription drug retail establishment; a veterinary prescription drug wholesale distributor; a limited prescription drug veterinary wholesale distributor; an over-the-counter drug manufacturer; a device manufacturer; a cosmetic manufacturer; a third party logistics provider; or a health care clinic establishment. S. 499.01(1), F.S.
[117] Ss. 499.051, 499.062, 499.065. 499.066, 499.0661, and 499.067, F.S.
[118] There is a difference between records the Legislature designates as exempt from public record requirements and those the Legislature deems confidential and exempt. A record classified as exempt from public disclosure may be disclosed under certain circumstances. *WFTV, Inc. v. The School Board of Seminole*, 874 So. 2d 48, 53 (Fla. 5th DCA 2004), *review denied* 892 So. 2d 1015 (Fla. 2004); *City of Riviera Beach v. Barfield*, 642 So. 2d 1135 (Fla. 4th DCA 1994); *Williams v. City of Minneola*, 575 So. 2d 687 (Fla. 5th DCA 1991). If the Legislature designates a record as confidential and exempt from public disclosure, such record may not be released by the custodian of public records to anyone other than the persons or entities specifically designated in statute. Attorney General Opinion 85-62 (August 1, 1985).
[119] S. 499.012(3)(c), F.S.
[120] S. 499.003(28), F.S.

person that is a manufacturer of a prescription drug and that manufactures or distributes such prescription drugs in this state.[121] Such manufacturer must comply with all state and federal good manufacturing practices. A permitted prescription drug manufacturer may engage in distribution of its own manufactured drug without requiring a separate permit.[122] The distribution of drugs includes the selling, purchasing, trading, delivering, handling, storing, and receiving of drugs, but does not include the administration or dispensing of drugs.[123]

Nonresident Prescription Drug Manufacturer Permit

A nonresident prescription drug manufacturer permit is required for any person that is a manufacturer of prescription drugs located outside of this state or outside the United States that engages in the distribution in this state of such prescription drugs.[124] Such manufacturer must comply with all of the same requirements as prescription drug manufacturers operating in the state. The permittee must also comply with the licensing or permitting requirements of the state or jurisdiction in which it is located and must comply with federal and Florida laws and regulations when distributing any prescription drugs in the state. If the manufacturer intends to distribute prescription drugs for which it is not the original manufacturer, an out-of-state prescription drug wholesale distributor permit is required.[125]

Effect of Proposed Changes

CS/CS/CS/HB 1509 establishes a full regulatory system for PBMs in Florida. Also, it imposes drug price change notification requirements on all prescription drug manufacturer and nonresident drug manufacturer permitholders under chapter 499, F.S.

PBM Regulatory Structure

Insurance Administrator Model

The bill adds PBMs to the definition of insurance administrator under part VII of ch. 626, F.S., making PBMs subject to existing administrator regulations. Also, the bill revises the definition of "pharmacy benefit manager", while moving it to insurance administrator regulations, to mean a person or entity doing business in Florida, contracting to administer prescription drug benefits on behalf of a pharmacy benefits plan or program. The term includes, but is not limited to, a person or entity that performs one or more of the following services:

- Pharmacy claims processing.
- Administration or management of pharmacy discount card programs.
- Managing pharmacy networks or pharmacy reimbursements.
- Paying or managing claims for pharmacist services provided to covered persons.
- Developing or managing a clinical formulary, including utilization management or quality assurance programs.
- Pharmacy rebate administration.
- Managing patient compliance, therapeutic intervention, or generic substitution programs.
- Administration or management of a mail order pharmacy program.

The bill establishes a transition from the current PBM registration structure under s. 624.490, F.S., to the PBM insurance administrator certificate of authority (COA) structure under part VII of ch. 626, F.S. The bill maintains the current registration law in s. 624.490, F.S., for all PBMs registered with OIR as of

[121] S. 499.01(2), F.S.
[122] S. 499.01(2), F.S.
[123] S. 499.003(16), F.S.
[124] S. 499.01(2), F.S.
[125] S. 499.01(2), F.S.

June 30, 2023, and allows PBMs to continue operations without obtaining a COA until January 1, 2024. All PBMs must obtain a COA to operate as an insurance administrator by January 1, 2024. Failure to obtain the COA will result in a $10,000 fine per day, and all monies collected from PBMs and applicants for a COA go into the Insurance Regulatory Trust Fund. There appears to be no fee associated with this new COA for PBMs.

The bill also requires OIR, by January 15, 2024, to submit a report to the Governor and legislature detailing whether each PBM operating in Florida on January 1, 2024 obtained the required certificate of authority on or before that date.

PBM Certificates of Authority

To apply for a COA, a PBM must submit the following to OIR:

- A complete biographical statement on a form created by the Financial Services Commission, an independent investigation report, and fingerprints of the individuals employed or retained by the PBM who are responsible for conducting the PBM's affairs, including all members of the board of directors, board of trustees, executive committee, or other governing board or committee, and the principal officers in the case of a corporation or the partners or members in the case of a partnership or association.[126]
- Disclosure of any administrative, civil, or criminal complaints, settlements, or discipline of the PBM, or any of its' affiliates, relating to violating insurance law, including PBM laws, in any state.
- An attestation of compliance with pharmacy network requirements under s. 626.8825, F.S., beginning January 1, 2024.

In addition, a PBM applicant for a COA must make available to OIR, for inspection, copies of contract templates with any pharmacy and copies of all subcontracts supporting its' operations. The bill exempts PBM applicants for a COA from any fees for initial application and the annual filing fees.[127]

The bill requires PBMs to identify to OIR any ownership interest or affiliation of any kind with any pharmacy which, directly or indirectly, through one or more intermediaries, under Florida law:

- Has an investment or ownership interest in a PBM holding a COA;
- Shares common ownership with a PBM holding a COA; or
- Has an investor or a holder of an ownership interest which is a PBM holding a COA.

A PBM must notify OIR within 15 days after any administrative, civil, or criminal complaints, settlements, or discipline incurred in any state for violations of insurance laws, including PBM law.

The bill requires a PBM to report any change in the above information to OIR within 60 days after the change occurs

Lastly, PBMs are subject to step-therapy protocols under s. 627.42393, F.S.

Investigations and Examinations

The bill authorizes OIR to examine and investigate PBMs and COA applicants to act as a PBM. OIR is further required to review any referral made to it concerning apparent or potential violations of rules by a person or entity licensed by OIR.[128] Each PBM must be examined by OIR at least biennially

[126] S. 626.8805(2)(c), F.S.
[127] S. 624.501(a)(a), F.S., sets the filing fee for an application for an original COA at $1,500; S. 624.501(4)(a), F.S., sets the annual statement fee at $250.
[128] S. 624.307(10), F.S.

consistent with ch. 624, F.S.,[129] for the purpose of determining the PBM's compliance with all applicable statutes and rules. The first biennial cycle for examining PBMs begins on July 2, 2023.

If OIR finds a PBM or a COA applicant to act as a PBM has exhibited a pattern or practice of knowing and willful[130] violations of PBM transparency and accountability provisions under s. 626.8825, F.S., or PBM prohibited practices under s. 626.8827, F.S., OIR is authorized to order the PBM to file the following, related to such knowing and willful violations, for review and inspection for the following 36-month period:

- All contracts[131] between the PBM or applicant and pharmacies or pharmacy benefit plans or programs; and
- Any policies, guidelines, rules, protocols, standard operating procedures, instructions, or directives.

The preceding documents are public records and are not subject to trade secret protection under s. 119.07(1), F.S.

PBMs and COA applicants to act as a PBM must pay to OIR the costs of each examination and investigation. Such costs must include actual travel expenses; reasonable living expense allowance; compensation for the examiner, investigator, or other person doing the examination or investigation; and necessary OIR costs directly related to the examination or investigation. Although, the bill authorizes OIR to pay actual travel expenses, reasonable living expense allowance, and compensation to the examiner, investigator, or other person conducting the examination or investigation from the Insurance Regulatory Trust Fund (Trust Fund). All moneys collected from PBMs and COA applicants to act as a PBM for investigations and examinations must be deposited into the Trust Fund.

OIR may order PBMs to produce any records, books, files, contracts, advertising and solicitation materials, or other information, and may take statements under oath to determine any violations of law or actions that are contrary to the public interest. In addition, PBMs are required to maintain contracts for 5 years after the contract expires, and make those contracts available to OIR for inspection, examination, or investigation, as needed.

In addition to OIR's other enforcement authority, the office must impose an administrative fine of $5,000 for each violation of s. 626.8825, F.S., and s. 626.8827, F.S. There is no limitation on aggregate administrative fines resulting from such violations, and such monies must be deposited into the General Revenue Fund. A PBM that fails to pay expenses incurred due to examinations, investigations, or administrative fines is subject to denial, suspension, or revocation of its COA.

OIR must produce a report to the Governor and the Legislature summarizing results of the most recent 2-year cycle of investigations, including detailed descriptions of any violations committed by each PBM and detailed reporting of OIR actions taken against each PBM for such violations. The bill requires the first cycle of biennial examinations to begin on January 1, 2025, and by January 1, 2026 and each Jan.

[129] The bill subjects OIR, PBMs, and COA applicants to act as a PBM to the following provisions of chapter 624, F.S.:
- S. 624.318, relating to the conduct of examinations and investigations, access to records, correction of accounts, and appraisals.
- S. 624.319, relating to examination and investigation reports.
- S. 624.321, relating to witnesses and evidence.
- S. 624.322, relating to compelled testimony and immunity from prosecution.
- S. 624.324, relating to hearings.
- S. 624.34, relating to fingerprinting.
- Any other provision of chapter 624 applicable to the investigation or examination of a licensee under this part.

[130] The bill defines "knowing and willful" as any act of commission or omission which is committed intentionally, as opposed to accidentally, and which is committed with knowledge of the act's unlawfulness or with reckless disregard as to the unlawfulness of the act. It is unclear as to how these definitions will be interpreted by OIR, or who will be making such determinations to justify additional actions authorized in the bill.

[131] The bill defines "contract" as any contract to which s. 626.8825, F.S., applies, meaning contracts between a PBM and a pharmacy benefits plan or program and contracts between a PBM and a participating pharmacy.

15th thereafter, OIR must submit a report summarizing the prior year's examinations. Starting in 2027, and every 2 years after, the report must include OIR's compliance with exam timeframe requirements and specify the number and percentage of all exams completed within the timeframe.

PBM Prohibited Practices

The bill establishes a new section of law detailing prohibited PBM practices. Specifically, a PBM may not do any of the following:

- Prohibit, restrict, or penalize in any way a pharmacy or pharmacist from disclosing to any person any information that the pharmacy or pharmacist deems appropriate, including, but not limited to, information regarding any of the following:
    - The nature of or risks from treatment, or alternatives thereto.
    - The availability of alternative treatments, consultations, or tests.
    - The decision of utilization reviewers or similar persons to authorize or deny pharmacist services.
    - The process that is used to authorize or deny pharmacist services or pharmacy benefits.
    - Information on financial incentives and structures used by the pharmacy benefits plan or program.
    - Information that may reduce the costs of pharmacist services.
    - Whether the cost-sharing obligation exceeds the retail price for a covered prescription drug and the availability of a more affordable alternative drug, under s. 465.0244.
- Prohibit, restrict, or penalize in any way a pharmacy or pharmacist from disclosing information to the office, AHCA, DMS, a law enforcement officer, or a state or federal government official, provided that the recipient of the information has the authority, to the extent provided by state or federal law, to maintain proprietary information as confidential; and provided that, before the disclosure of information designated as confidential, the pharmacist or pharmacy marks as confidential any document in which the information appears or the pharmacist or pharmacy requests confidential treatment for any oral communication of the information.
- Communicate at the point-of-sale, or otherwise require, a cost-sharing obligation for the covered person in an amount that exceeds the lesser of:
    - The applicable cost-sharing amount under the applicable pharmacy benefits plan or program; or
    - The usual and customary price, as defined in s. 626.8825, of the pharmacist services.
- Transfer or share records relative to prescription information containing patient-identifiable or prescriber-identifiable data to an affiliated pharmacy for any commercial purpose other than the limited purposes of facilitating pharmacy reimbursement, formulary compliance, or utilization review on behalf of the applicable pharmacy benefits plan or program.
- Fail to make any payment due to a pharmacy for an adjudicated claim with a date of service before the effective date of a pharmacy's termination from a pharmacy benefit network unless payments are withheld because of actual fraud on the part of the pharmacy or otherwise required by law.
- Terminate the contract of, penalize, or disadvantage a pharmacist or pharmacy due to a pharmacist or pharmacy:
    - Disclosing information about PBM practices;
    - Exercising any of its rights under the law; or
    - Sharing any portion, or all, of the PBM contract with OIR pursuant to a complaint or a query regarding whether the contract complies with this part.
- Fail to comply with the requirements of s. 626.8825, F.S., relating to PBM transparency and accountability.

A violation of any of these prohibited acts subjects the PBM to administrative fines and denial, suspension, or revocation of its COA.

PBM Contracts – Transparency and Accountability

PBM Contracts with a Pharmacy Benefit Plans or Programs (Insurers)

All contracts between a PBM and a pharmacy benefit or program entered into, renewed, or otherwise amended on or after July 1, 2023, applying to pharmacist services on or after January 1, 2024, must include, in substantial form, terms that ensure compliance with the following requirements, which supersede any contractual terms to the contrary:

- Use a pass-through pricing model and prohibit a PBM from recouping direct or indirect remuneration fees, dispensing fees, brand name or generic effective rate adjustments through reconciliation, or any other monetary recoupments related to discounts, financial clawbacks, multiple network reconciliation offsets, adjudication transaction fees, or any other fee that may be recouped from a pharmacy.
    - Financial clawbacks and reconciliation offsets do not include:
        - Incentive payments from a PBM to a network pharmacy for meeting or exceeding performance measures.
        - Recoupment of an erroneous claim.
        - Fraud, waste, or abuse.
        - A claim adjudicated in error.
        - A MAC appeal pricing adjustment.
        - An adjustment made as part of an audit under s. 624.491, F.S.
- Prohibit direct or indirect spread pricing, unless the PBM is contractually required to pass along the entire amount of the pricing difference to the pharmacy benefit plan or program.
- Require funds received by the PBM for providing services to the pharmacy benefit plan or program be distributed only under the terms of the contract or by other applicable law.
- Require the PBM to pass through 100 percent of rebates negotiated with manufacturers to the pharmacy benefit plan or program, and require those rebate funds to be used only for offsetting defined cost sharing obligations and reducing premiums of covered persons.
    - Any additional funds left over must be used for offsetting copayments and deductibles.
    - These provisions expressly do not apply to SMMC plans.

Current law[132] regulates the use of step-therapy protocols by insurers and HMOs, whether or not they use a contracted PBM or manage the pharmacy benefit in-house. The bill expressly applies those step-therapy regulations to PBMs acting on behalf of insurers and health plans.

PBM Contracts with Pharmacies

The bill includes detailed technical claims processing and IT requirements governing a PBM's interaction and relationship with a pharmacy. Specifically, the bill requires:

- At the time of adjudication for electronic claims or the time of reimbursement for nonelectronic claims, the PBM to provide the pharmacy with a remittance[133] including such detailed information necessary for the pharmacy or pharmacist to identify the reimbursement schedule for the specific network applicable to the claim and which is the basis used by the PBM to calculate the amount of reimbursement paid.
    - This information must include, but is not limited to, the applicable network reimbursement identification or plan identification as defined in the most current version of the National Council for Prescription Drug Programs (NCPDP) Telecommunication Standard Implementation Guide[134] or its nationally recognized successor industry guide.

[132] S. 627.42393, F.S.
[133] The remittance, or remittance advice, is an explanation of the claim payment, and outlines payment details such as check number, check date, check amount, the specific prescription(s) included in the payment, and details of any adjustments made to an individual claim or the final payment amount. Depending on how many prescriptions are included in a payment, remittances could contain hundreds or thousands of lines of details.
[134] The NCPDP is a private entity that creates and promotes standards for electronic health care transactions. The Telecommunication Implementation Guide is one of NCPDP's proprietary products, and appears to be an industry standard for communications between PBMs and pharmacies. www.ncpdp.prg

- The PBM to ensure that any basis of reimbursement information is communicated to a pharmacy in accordance with the NCPDP Telecommunication Standard Implementation Guide, or its nationally recognized successor industry guide, when performing reconciliation for any effective rate guarantee, and that such basis of reimbursement information communicated is accurate, corresponds with the applicable network rate, and may be relied upon by the pharmacy.

Financial Clawbacks and Reconciliation Offsets

The bill bans PBMs from recouping direct or indirect remuneration fees, dispensing fees, brand name or generic effective rate adjustments through reconciliation, or any other recoupments related to discounts, financial clawbacks, multiple network reconciliation offsets, adjudication transaction fees, and any other fees that may be recouped from a pharmacy. For the purpose of this ban, financial clawbacks and reconciliation offsets do not include fraud recoupment and quality incentive payments.

PBM-Pharmacy Contract Changes and Termination

The bill prohibits a PBM from making unilateral contract changes.

Under the bill, a PBM must provide a pharmacy, on request, a list of plan or program networks to which the pharmacy belongs. Any updates to the list must be communicated to the pharmacy within 7 days.

A PBM is also prohibited from terminating a pharmacy contract because the pharmacy shared the PBM contract, disclosed PBM practices, or exercised rights under the bill. Relatedly, the bill bans gag clauses that prevent a pharmacy from disclosing information to patients, such as treatment, risks, treatment alternatives, coverage/claim denials, PBM financial incentives, cost-saving methods, and other information. In addition, PBMs cannot prevent a pharmacy from disclosing trade secret or confidential information to government agencies.

MAC Pricing and Reimbursement Administrative Appeal Process

PBMs must establish a reasonable appeal process for pharmacies to challenge MAC pricing and reimbursement made under the MAC as being below the acquisition cost available to an appealing pharmacy or pharmacist. The bill provides detailed requirements for the appeal process and outcomes, as follows:

- The administrative appeal procedure must include a telephone number and e-mail address, or a website, for submitting the appeal. The appeal may be submitted directly to the PBM or through a pharmacy service administration organization.
    - The pharmacy or pharmacist, or an agent, must be given at least 30 business days after a MAC update or after an adjudication for an electronic claim or reimbursement for a nonelectronic claim to file the administrative appeal.
- The PBM must respond to the appeal within 30 business days after receipt of the appeal.
- If the appeal is upheld, the PBM must:
    - Update the MAC pricing information to at least the acquisition cost available to the pharmacy;
    - Permit the pharmacy or pharmacist to reverse and rebill the claim in question;
    - Provide to the pharmacy or pharmacist the national drug code on which the increase or change is based; and
    - Make the increase or change effective for each similarly situated pharmacy or pharmacist that is subject to the applicable MAC pricing information.
- If the appeal is denied, the PBM must provide to the pharmacy or pharmacist the national drug code and the name of the national or regional pharmaceutical wholesalers operating in this state which have the drug currently in stock at a price below the MAC.

- If the drug with the national drug code provided by the PBM is not available below the acquisition cost to the pharmacy or pharmacist from the pharmaceutical wholesaler from whom the pharmacy or pharmacist purchases the majority of drugs for resale, the PBM must adjust the MAC pricing information above the acquisition cost to the pharmacy or pharmacist and permit the pharmacy or pharmacist to reverse and rebill each claim affected by the inability to procure the drug at a cost that is equal to or less than the previously challenged MAC.
- The PBM shall report to the office every 90 days the total number of appeals received and denied in the preceding 90-day period for each specific drug appealed.

Pharmacy Networks

The bill requires a PBM pharmacy network to meet or exceed Medicare Part D standards for convenient access to network pharmacies. Such standards include:

- At least 90 percent of plan beneficiaries, on average, in urban areas served by the plan sponsor live within 2 miles of a network pharmacy that is a retail pharmacy or a pharmacy;
- At least 90 percent of plan beneficiaries, on average, in suburban areas served by the plan sponsor live within 5 miles of a network pharmacy that is a retail pharmacy or a pharmacy; and
- At least 70 percent of plan beneficiaries, on average, in rural areas served by the plan sponsor live within 15 miles of a network pharmacy that is a retail pharmacy or a pharmacy.[135]

A PBM must annually attest to OIR its compliance with network requirements.

Affiliated Pharmacies and Contracting Requirements

A pharmacy network cannot be limited to PBM-affiliated pharmacies, meaning a pharmacy in which the PBM has a direct or indirect investment or ownership interest. The bill prohibits a PBM from incentivizing, directing, or advocating for patients to use PBM-affiliated pharmacies for the in-person administration of covered prescription drugs. A PBM cannot require *only* mail-order delivery of medication; and the patient-consumer must be permitted to opt-in, rather than opt out, of using mail-order pharmacy services, as long as the covered person is not penalized through additional cost-sharing obligations or a lower allowed-quantity limit for choosing not to participate in such a program. The bill provides an exception to the ban on mandatory participation in mail order or delivery programs in cases where a prescription drug cannot be acquired at any network pharmacy.

For in-person administration of covered prescription drugs, the bill prohibits a PBM from requiring a covered person to receive pharmacist services from an affiliated pharmacy or affiliated health care provider.

In addition, the bill allows PBMs to specify specialty networks only to the extent that the PBM requires enhanced standards for safety and competency to meet the FDA's limited distribution requirements for any drug that requires extraordinary special handling, provider coordination, or clinical care or monitoring that cannot be met by a network pharmacy.

The bill prohibits a PBM from requiring participation in other insurer products as a condition of participating in one product.

The bill also prevents PBMs from imposing network participation standards higher than pharmacy licensure standards. This provision prevents a PBM from requiring pharmacies to be accredited in order to participate in a network, if the accreditation standards are inconsistent with or more stringent than applicable state and federal law for licensing and operating a pharmacy in Florida.

[135] 42 CFR 423.120(a)(1).

A PBM must offer a standard contract to pharmacies sited in Medicaid regional essential providers[136] for infusion, biological and surgical products in its network, which includes federally qualified health clinics, teaching and trauma hospitals, hospitals with services 25 miles or more from similar services, and designated cancer centers of excellence under s. 381.925, F.S., organ transplant hospitals, children's specialty hospitals licensed under chapter 395, F.S., and regional perinatal intensive care centers as defined in s. 383.16(2), F.S. PBMs must also include pharmacies sited in designated Florida cancer hospitals for the purpose of drug infusion, intravenously injected drugs, covered parenteral drugs[137], and those drugs inhaled during a surgical procedure.[138]

The bill requires a PBM or the pharmacy benefit plan or program to provide updated formularies to a patient at least 60 days before plan year.

The bill requires a PBM or insurer, when revising the formulary during a plan year, to provide a 60-day continuity of care period to allow the insured to remain on the drug that is being revised from the formulary at the same cost. The 60-day period begins on the day the patient is notified of the change. The bill prohibits PBMs from removing a drug from a formulary during the plan year, regardless of manufacturer price changes. This "frozen formulary" requirement applies unless a prescription drug:

- Has been approved and made available over the counter by the FDA and has entered the commercial market as such;
- Has been removed or withdrawn from the commercial market by the manufacturer; or
- Is subject to an involuntary recall by state or federal authorities and is no longer available on the commercial market.

However, the bill expressly allows PBMs to add medications during plan year.

Lastly, beginning on January 1, 2024, the prescription drug plan or program must annually attest it complies with the requirements governing contracts between PBMs and the plans or programs.

Drug Manufacturer Price Increases

The bill creates s. 499.026, F.S., requiring all prescription drug manufacturer and nonresident prescription drug manufacturer permitholders to notify DBPR and AHCA of a drug price increase on the date the increase becomes effective. Such notification must be made through a department-approved form that includes:

- The proprietary and nonproprietary names of the drug.
- The wholesale acquisition cost (WAC) before the drug price increase. The WAC is the manufacturer's list price for the drug or biological product that U.S. wholesalers or direct purchasers pay, for the most recent month that information is available, as reported in a wholesale price guide or other drug product pricing publication, not including discounts, rebates or other price reductions.
- The dollar amount of the increase.
- Using the WAC before the increase, the percentage amount of the increase compared to the WAC.
- A statement indicating whether a change or improvement in the drug necessitates the increase. If so, the manufacturer must describe the change or improvement.

[136] S. 409.975(1)(a), F.S., requires SMMC plans to contract with all providers in the region that are classified by AHCA as essential Medicaid providers. Providers are essential if they offer services that are not available from any other provider within a reasonable access standard, or if they provided a substantial share of the total units of a particular service used by Medicaid patients within the region during the last 3 years and the combined capacity of other service providers in the region is insufficient to meet the total needs of Medicaid patients. As of the date of this analysis, AHCA has never classified any entity as a regional essential provider under this statute, so the requirement applies to no one.

[137] Parenteral drugs are medications that are administered intravenously and bypass the gastrointestinal system, usually for an individual requiring liquid nutrition and unable to use their digestive system.

[138] Under s. 409.975(1)(b), F.S., to be considered a statewide essential provider for purposes of SMMC plan contracting, thus guaranteeing participation in all managed care plan provider networks, Florida cancer hospitals must meet the provisions of 42 U.S.C. 1395ww(d)(1)(B)(v).

- The drug's intended uses.

The reporting requirement applies to drugs that cost more than $100 WAC for 30 days of care (or lesser time, if applicable) and to increases greater than 15 percent or more of WAC during the preceding 12 months or any cumulative increase of 30 percent or more of WAC in the previous three calendar years. To calculate the 30 percent threshold, it must be based on the WAC in effect at the end of the 3-year period compared to the WAC at the beginning of the 3-year period.

Nothing in s. 499.026, F.S., prohibits a manufacturer from notifying other parties, like PBMs, about a drug increase prior to its effective date.

By April 1 of each year, each drug manufacturer must submit an annual report to DPBR of all increases and cumulative increases on a DBPR form. At least, the report must include:

- A list of all drugs, each identified by the proprietary and nonproprietary name, impacted by a price increase over the last year, the amount of each increase, and the percentage increase relative to the drug's WAC.
- If more than one drug price increase form has been filed over the past year, the percentage increase of the drug price from the earliest form filed to the most recent filed form.
- Intended uses of each drug in the report, and whether the manufacturer has market exclusivity for each drug.
- The length of time each drug has been available for sale.
- A complete description of the factors contributing to each increase. DBPR is authorized to request additional information regarding these factors before accepting the report. It is unclear as to the impact of DBPR's refusal to accept an annual report, or the standard by which the department may refuse the report.
- Any action filed to extend a patent report after an initial extension is granted.

DBPR is required to send all forms and increases received under the bill to AHCA, which then must post the forms and increases on its health care data website. The bill prohibits a drug manufacturer from claiming a trade secret public records exemption for any information required by DBPR under s. 499.026, F.S. Lastly, the bill authorizes DBPR to adopt emergency rules, and provides general rulemaking authority to DBPR, in consultation with AHCA.

Failure to submit drug price increase forms as required by s. 499.026, F.S., created by the bill, accurately and timely is a prohibited act and subject to license discipline under ch. 499, including, but not limited to, administrative fines or the denial, suspension, or revocation of the manufacturer's permit.

State Employee Group Health Plan

The bill applies PBM regulation to the state group health plan.

Applicability to Other Programs

The bill applies PBM regulation to insurance plans including but not limited to:

- Health maintenance organizations,
- Health insurers,
- Self-insured employer plans,
- Discount card programs,
- Government-funded health plans,
- Medicare, and
- Medicaid

Workers compensation plans and programs under chapter 440, F.S., are exempted from PBM regulations in the bill.

The bill requires the Division of Financial Services (DFS) to designate an employee as the primary contact for consumer and pharmacy issues with PBMs. DFS must refer complaints of potential violations of part VII of ch. 626, F.S., regulating insurance administrators, or a PBM's failure to respond to a written request for documents and information from the division regarding a complaint[139] to OIR.

Statutory Construction

The bill specifically states that it is not intended, and may not be construed, to conflict with existing relevant federal law. To the extent that the bill does conflict with federal law, it is unclear what impact this statement will have on a court's interpretation of such laws in any future litigation.

The bill also provides a severability clause; if any provision of the bill or its application is deemed invalid by a court, such invalidity is limited to the offending portions of the bill and does not affect the other provisions or applications which can be given effect without the offending provision. In effect, this provision allows an offending provision to be declared invalid and removed, while leaving in place the remaining provisions.

Lastly, the bill contains several conforming changes to statutes to reflect the other changes in the bill.

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

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   OIR may see an increase in revenue from imposing fines established in the bill.

2. Expenditures:

   Office of Insurance Regulation and Division of Consumer Finance

   The bill provides an appropriation of $980,705 in recurring funds and $146,820 in nonrecurring funds from the Insurance Regulatory Trust Fund, and 10 full-time equivalent positions with an associated salary rate of 644,877, to OIR to implement the provisions in the bill.

   OIR is able to update its systems to allow PBMs to apply for a certificate of authority within existing resources. OIR will also need to update systems to allow pharmacy benefit plans and programs to annually submit their attestations of compliance with s. 626.8825(2), F.S.

   The bill requires the Department of Financial Services, Division of Consumer Services, to designate an employee to receive consumer and pharmacy PBM complaints. The division believes it can repurpose an employee from another division to serve in this role.

   Agency for Health Care Administration – Medicaid

[139] Failure to comply with the division's request for documents and information regarding a consumer complaint may result in a fine up to $2,500 per violation, $250 for the first violation, $500 for the second violation, and up to $1,000 for the third and any subsequent violation. S. 624.307(1)(b), F.S.

AHCA will need to update its computer systems and website functionality in order to post all forms and reports submitted by permitted prescription drug manufacturers to DBPR, which will then submit these forms and reports to AHCA. The Medicaid program will need to amend contracts with Medicaid managed care plans. AHCA has indicated these are minor, administrative fiscal impacts to the agency which can be absorbed within existing resources.[140]

Medicaid managed care plans, contracted by AHCA, will need to make changes to comply with some of the requirements of the bill.[141]

Medicaid plans will need to adjust pharmacy networks to meet the bill requirement for the networks to match federal Medicare Part D standards. Some plan networks may already align with these requirements; some may not.[142] One Medicaid managed care plan estimates this provision will cost that plan an additional $24 million annually for Florida Medicaid services, caused by the loss of volume-based pricing advantages available in the current, narrower network.[143]

It appears that several other provisions would require Medicaid changes, including the MAC appeal process and obligation to pay successful pharmacies (and "similarly situated" pharmacies) more for pharmacy claims; and the prohibition on requiring any standards higher than licensure standards for participation in the network; among others. The cost of these impacts will vary by plan, and is indeterminate.

Department of Business and Professional Regulation

The DBPR Division of Drugs, Devices, and Cosmetics estimates the need for one additional FTE to collect, review, and remit annual drug price reports from drug manufacturers to AHCA. However, the Division can transfer and fill a vacant position from another program area to the Division to perform this job function without incurring additional costs.

Department of Management Services – State Employee Group Health Plan

The bill may have a negative, potentially significant, fiscal impact to the state group health insurance plan in DMS, due to the bill's provisions limiting how the contracted PBM may administer the pharmacy benefit plan.

DMS estimates one provision of the bill will cost $2.2 million[144], related to the prohibition on the use of exclusive pharmacy networks for specialty drugs (see lines 802-803). The impact is caused by the loss of volume-based pricing advantages available in the current, narrow, pharmacy network for specialty drugs, and by anticipated loss of coupon revenue to the state. The final version of the bill limits application of the prohibition to drugs that require in-person administration, which may substantially eliminate this fiscal impact; DMS did not provide a revised analysis.

DMS has been unable to calculate a fiscal impact of the other provisions of the bill which affect the state employee group health plan.[145]

[140] Florida Agency for Health Care Administration, *Agency Analysis of 2023 House Bill 1509*, p. 7 (Apr. 18, 2023).
[141] Some bill provisions do not apply to Medicaid plans because of the prescription drug management model used by the agency. AHCA did not conduct an analysis of the impacts of the bill related to Medicaid managed care plans.
[142] The AHCA bill analysis does not compare the Medicare Part D network standards to current Florida Medicaid network adequacy requirements, or analyze plan networks to determine the impact.
[143] Email correspondence from Sunshine Health Plan, April 11, 2023 and April 17, 2023, on file with committee staff. The plan did not provide impact information on other bill provisions.
[144] Email correspondence from Jeff Ivey, Deputy Chief of Staff, Department of Management Services, March 24, 2023, on file with committee staff. House staff received no formal DMS analysis for HB 1509, or correspondence estimating the impact of the other provisions in the bill.
[145] Several provisions do not affect the state group health plan, as current DMS contracts already address those provisions.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

Local governments providing health care coverage to employees may experience indeterminate premium increases to comply with the bill provisions. Impact will vary depending on the individual plan contract terms.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill may have a negative fiscal impact on PBMs, insurers and employer health plans due to a likely net increase in payment rates to pharmacies as a result of the bill's MAC appeal process, both for appealing pharmacies and by extension to all "similarly situated pharmacies" as required by the bill, among other provisions.

One commercial insurer assessed three provisions of the bill, and estimated the following impacts for those provisions on its Florida employer clients. The actuary concluded that "these financial impacts would be considered into future premiums – increasing the cost of health insurance products offered in the Florida market".[146]

- $65.5 million annual impact due to expanding the pharmacy network. Pharmacies commonly provide better pricing for narrower networks. The estimated impact is based on calendar year 2022 utilization for commercial plan members comparing pricing for the current network to a broader network.

- $3.7 million annual impact due to the inability to recoup pharmacy payment unless it is for fraud, waste, and abuse, thus limiting the savings from findings and corrections resulting from an audit or investigation. The estimated impact is based on calendar year 2022 actual recoupments for Florida commercial plan members that would no longer exist in the future.

- $8.9 million annual impact due to language in the bill about applying the granted appeal price to similarly situated pharmacies.[147] The estimated impact is based on calendar year 2022 appeals data for commercial plan members with an estimate for potential drug cost increases assuming 100 percent appeal approval.

The bill may have a negative fiscal impact on pharmaceutical manufacturers due to the bill's requirements to notify the state of drug price increases with limited, rather than full, trade secret protection.

The bill may have a positive fiscal impact on pharmacies, due to: the bill's required MAC appeal process, which will result in higher net revenues to pharmacies; the bill's network contract choice provision, which may allow pharmacies to obtain more advantageous network contracts and fewer less advantageous contracts; and the bill's provisions regarding specialty pharmacy contracting which may allow pharmacies to obtain more network contracts to provide specialty drugs; among other impacts.

[146] Correspondence via Florida Blue from Erika Holmes, FSA, MAAA, Vice President, Forecasting and Actuarial Services, Prime Therapeutics, March 24, 2023.
[147] This is based on an assumption of what "similarly situated pharmacies" are, which may be incorrect; the bill does not define the term.

D. FISCAL COMMENTS:

None.