2023-0329 HB 357 ERISA EPIC Testimony.pdf
Uploaded by: Brian Hose
Position: FAV

Testimony offered on behalf of:

EPIC PHARMACIES, INC.

IN SUPPORT OF:
HB 357 – Pharmacy Benefits Managers – Definitions of Carrier, ERISA, and Purchaser.
House Health and Government Operations Committee
Hearing 3/29 at 1:00 PM

EPIC Pharmacies, Inc. **SUPPORTS HB 357** – Pharmacy Benefits Managers - Definitions of Carrier, ERISA, and Purchaser as amended.

We have been dealing with the repercussions of federal ERISA laws in Maryland as they related to PBMs for many years. The State and this committee have always taken the PBM assumption that their unscrupulous business practices were protected by ERISA laws as fact. Finally, federal cases have made their way through the court system and in 2020, the Supreme Court decided to hear Rutledge v. PCMA. This case was brought by the Arkansas Attorney General in defense of a 2015 law that regulates PBMs and mandates fair payments for all insurance plans they represent. In December of 2020, the court unanimously ruled on behalf of Rutledge and Arkansas. After that decision, we worked with the committee in 2021 to remove any mention or implication that ERISA preempted PBM legislation from MD law, but were discouraged by reluctance to broadly apply the ruling, choosing to only target reimbursement. Since 2021, it has become clear in an opinion from the Maryland Attorney General and a report from the Maryland Insurance Administration that the ruling most certainly should apply to all types of PBM regulation. HB 357 will clean up the MD statute and expand the regulation of PBMs to all plans and all sections of the law.

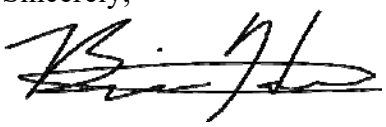
You will continue to hear from PCMA that this is not settled law, but in the most recent case from November of 2021, the 8th Circuit Court further upheld the Supreme Court ruling in the North Dakota case of PCMA v. Wehbi. This ruling went even further in rebuking the claims that PBMs cannot be regulated by allowing North Dakota's law to apply to Medicare Part D plans as well. The clear message from these decisions is that State Legislatures like this one can most certainly regulate the actions of PBMs. No matter what you may hear from PCMA today or going forward, this issue of ERISA preemption has been settled and they can no longer hide behind an almost 50 year old law.

In this Committee and Subcommittee hearings for as long as we can remember, we fought the efforts of PCMA to limit any State law regulating PBMs to a very small percentage of plans. The Supreme Court eliminated the ERISA excuse from this argument and has indicated that all PBM plans are subject to regulation by State Legislatures and committees such as this one. HB

357 will allow the State to enforce all current PBM laws in a way that more uniformly regulates the industry and allows for a more level playing field. This will ultimately benefit patients in Maryland.

I thank the committee for all the work they have done working through PBM legislation in the past and respectfully ask your support for HB 357 as amended.

Sincerely,



Brian M. Hose, PharmD
EPIC PharmPAC Chairman
301-432-7223
brian.hose@gmail.com

HB0357_Amended_EPIC-Hose_FAV.pdf
Uploaded by: DENNIS RASMUSSEN
Position: FAV

Testimony offered on behalf of:

EPIC PHARMACIES, INC.

IN SUPPORT OF:
HB0357 – Pharmacy Benefits Managers – Definitions of Carrier, ERISA, and Purchaser

SENATE FINANCE COMMITTEE
Hearing: 3/29/2023 at 1:00 PM

EPIC Pharmacies, Inc**.** offers its **SUPPORT of HB0357 – Pharmacy Benefits Managers – Definitions of Carrier, ERISA, and Purchaser, as amended in the House, without further amendments.**

We have been dealing with the repercussions of the Federal ERISA laws in Maryland as they related to PBMs for many years. The State and this Committee frequently supported as fact, the PBM assumption that their unscrupulous business practices were protected by ERISA laws. Finally, Federal cases have made their way through the court system and in 2020, the Supreme Court decided to hear ***Rutledge v. PCMA***. This case was brought by the Arkansas Attorney General in defense of a 2015 law that regulates PBMs and mandates fair payments for all insurance plans they represent. In December of 2020, the court unanimously ruled on behalf of Rutledge and Arkansas. After that decision, we worked with the Committee in 2021 to remove any mention or implication that ERISA preempted PBM legislation from Maryland law but were discouraged by the reluctance to broadly apply the ruling, choosing to only target reimbursement. Since 2021, it has become clear in an opinion from the Maryland Attorney General and a report from the Maryland Insurance Administration that the ruling most certainly should apply to all types of PBM regulation. ***HB0357*** will clean up the Maryland statute and expand the regulation of PBMs to all plans and all sections of the law.

You will continue to hear from PCMA that this is not settled law, but in the most recent case from November of 2021, the 8th Circuit Court further upheld the Supreme Court ruling in the North Dakota case of ***PCMA v. Wehbi***. This ruling went even further in rebuking the claims that PBMs cannot be regulated by allowing North Dakota's law to apply to Medicare Part D plans as well. The clear message from these decisions is that State Legislatures like the Maryland General Assembly can most certainly regulate the actions of PBMs. No matter what you may hear from PCMA today or going forward, this issue of ERISA preemption has been settled and they can no longer hide behind an almost 50-year-old law.

In this Committee and in House Committee hearings for as long as we can remember, we fought the efforts of PCMA to limit any State law regulating PBMs to a very small percentage of plans. The Supreme Court eliminated the ERISA excuse from this argument and has indicated that all PBM plans are subject to regulation by State Legislatures and the Maryland General Assembly. HB0357 will allow the State to enforce all current PBM laws in a way that more uniformly regulates the industry and allows for a more level playing field. This will ultimately benefit patients in Maryland.

EPIC Pharmacies thanks the sponsors, Delegate Nicholas Kipke, et.al., and the Senate Finance Committee for all the effort you have expended in working through PBM legislation in the past and respectfully asks for your **FAVORABLE SUPPORT ON *HB0357*, AS AMENDED IN THE HOUSE, WITHOUT FURTHER AMENDMENTS**.

Should the Committee require any additional information, please contact me or Dennis F. Rasmussen, **dfr@rasmussengrp.net** or 410-821-4445.

Respectfully,

Brian M. Hose, PharmD
EPIC Legislative Committee Chairman
brian.hose@gmail.com – 301-432-7223

Ohio v. PBMs Lawsuit - Unfair Pricing - 3-27-2023.
Uploaded by: DENNIS RASMUSSEN
Position: FAV

IN THE COURT OF COMMON PLEAS
DELAWARE COUNTY, OHIO

STATE OF OHIO, ex rel. DAVE YOST ATTORNEY GENERAL OF OHIO, 30 East Broad St., 17th Floor Columbus, Ohio 43215 Plaintiff, v. ASCENT HEALTH SERVICES LLC, c/o The Corporation Trust Company Corporation Trust Center 1209 Orange St. Wilmington, DE 19801 EXPRESS SCRIPTS, INC., One Express Way St. Louis, MO 63121 Also serve: Express Scripts Inc. c/o C T Corporation System 4400 Easton Commons Way Suite 125 Columbus OH 43219 CIGNA GROUP, 900 Cottage Grove Road Bloomfield, CT 06002 Also serve: Cigna Group c/o The Corporation Trust Company Corporation Trust Center 1209 Orange St. Wilmington, DE 19801 EVERNORTH HEALTH, INC., One Express Way St. Louis, MO 63121	CASE NO: _____ JUDGE _____ **COMPLAINT FOR DISGORGEMENT, INJUNCTIVE RELIEF AND DECLARATORY JUDGMENT**

:

Also serve: :
Evernorth Health, Inc. :
c/o C T Corporation System :
4400 Easton Commons Way :
Suite 125 :
Columbus, OH 43219 :
:

PRIME THERAPEUTICS LLC, :
2900 Ames Crossing Road :
Eagan, MN 55121 :
:

Also serve: :
Prime Therapeutics LLC :
c/o Corporation Service Company :
3366 Riverside Drive, Suite 103 :
Upper Arlington, OH 43221 :
:

HUMANA PHARMACY SOLUTIONS, :
INC., :
500 West Main St. :
Louisville, KY 40202 :
:

Also serve: :
Humana, Pharmacy Solutions, Inc.. :
c/o The Corporation Trust Company :
Corporation Trust Center :
1209 Orange St. :
Wilmington, DE 19801 :
:

and :
:

HUMANA INC. :
500 West Main St. :
Louisville, KY 40202 :
:

Also serve: :
Humana Inc. :
c/o C T Corporation System :
4400 Easton Commons Way :
Suite 125 :
Columbus OH 43219 :
:

Defendants. :

1. The State of Ohio, acting on the relation of its Attorney General Dave Yost, brings this action to obtain equitable and injunctive relief, and statutory forfeiture against Defendants.

INTRODUCTORY STATEMENT

2. Like the importation of kudzu to stop soil erosion, the creation of the pharmacy benefit manager ("PBM") was a solution that has become the problem. Through industry consolidation, the PBM landscape is dominated by three big players – including Defendant Express Scripts, Inc. ("Express Scripts" or "ESI"). With this dominance, they have created a black box that holds a complex administration system that allows the PBMs, including Express Scripts, to enrich themselves in multiple ways. This is all at the expense of consumers and other industry participants.

3. These ways include a complex "pay to play" rebate system that, perversely, pushes manufacturers to *increase* drug prices in order to be placed on or receive preferred placement on PBM formularies. The costs of Express Scripts' supracompetitive profits have been pushed onto those with the least power – including individuals whose prescription costs are calculated at, or as a percentage of, those same rising list prices. To paraphrase President Reagan, the scariest words in the pharmaceutical industry have become "I'm the PBM, and I'm here to help."

4. At one point, "Big Pharma" was justly criticized for overpricing medications. PBMs were created as a market response to that criticism. PBMs were introduced to negotiate drug prices on behalf of payors, or "Plan Sponsors," such as employers, and the individuals receiving the medications, the "insureds." This intermediary negotiator system worked until PBMs grew powerful enough to themselves extract exorbitant fees – and they did so. The solution became the problem.

5. Through industry consolidation, major PBMs affiliated with, and often became owned by, large health insurers and pharmacies. Now, the three largest PBMs – including Defendant Express Scripts – control more than 75 percent of the prescription drug market. The next three largest PBMs control the bulk of the rest. Because of the nature of this market, both drug buyers and sellers have little choice but to play the game by the PBMs' rules, allowing PBMs to extract both monopoly profits from individuals and monopsony profits from the market. The individual drug buyer faces a Hobson's choice of either buying medications through the insurer/PBM selected by their employer or paying an inflated "list" price. From the drug manufacturer's perspective, the insurer/PBM controls access to millions of covered lives. Moreover, pharmacies are often left not knowing whether they will book a profit or a loss on a transaction until long after they fill a prescription. The insurer/PBM controls it all.

6. As part of an ever-evolving effort to add complexity and opacity to the market, Express Scripts formed Ascent, a group purchasing organization or "GPO," in 2019. Ascent functions primarily to further expand Express Scripts' stranglehold on the price of medications. It also allows Express Scripts to coordinate pricing and other activities with its competitors.

7. Also in 2019, Express Scripts invited its putative competitor, Prime Therapeutics LLC ("Prime Therapeutics"), into Ascent's ownership. Express Scripts remains the majority and controlling owner of Ascent. Ascent's owners use it as a vehicle to share pricing, to the detriment of the other market participants, including individual purchasers of medications like insulin. Through Ascent, it is believed that Express Scripts, Prime Therapeutics, and Ascent customer Humana Pharmacy Solutions are able to share drug pricing and rebate information with one another, as well as to fix rebate prices among them. It is further believed that – contrary to their stated business purpose – Ascent, Express Scripts, and Prime negotiate with manufacturers

with the intent of increasing the price of pharmaceuticals, including insulins, biologics, and cancer-fighting drugs.

8. PBMs also use their market power to hurt competing pharmacies, and particularly independent pharmacies. In order to stay in insurance networks – and remain able to service patients with private insurance – pharmacies are often forced to accept drug reimbursement rates significantly below what the pharmacies have to pay for those drugs. Little, if any, of these cost savings are passed on to the Plan Sponsors or covered individuals. Instead, those customers pay contracted rates, which generally exceed what the pharmacy is paid for the drug. The PBM then pockets the "spread" between the prices, or diverts these funds to PBM-owned or affiliated pharmacies through so-called performance payments.

9. Moreover, pharmacies in under-served areas or rural communities in Ohio, which often operate as a patient's first line of treatment, are struggling to stay in business due to these punishing price demands by the PBMs. PBMs with affiliated pharmacies – either brick-and-mortar or mail-order – further benefit by pushing customers away from their local pharmacies into one that the PBM, or a company related to the PBM, controls.

10. Defendants know that Ohioans in need of medication, particularly life-saving medication, will pay the asking price. The choice is binary – pay or suffer. Defendants also know that because of the predominance of prescription insurance, pharmacies and manufacturers will agree to the pricing demands of large PBMs and GPOs to gain access to the lives that the latter entities control. Defendants have morbidly manipulated both sides of the market, demanding higher drug prices while negotiating larger fees from the manufacturers. Patients pay more, manufacturers get less, and the PBMs profit. Handsomely.

11. This process also drastically reduces the sales of generic medications and bio-similars because those inexpensive medications are excluded from PBM formularies precisely because low prices leave less room for rent-seeking.

NATURE OF THIS ACTION

12. Express Scripts, one of the nation's three largest PBMs, sits in a powerful and lucrative position at the center of the prescription drug distribution system. For nearly 40 percent of the Ohioans covered by commercial insurance, Express Scripts effectively controls which drugs will be covered by insurance and what portion of the price of those drugs will be covered, as well as how much the pharmacies that fill those prescriptions will be reimbursed for doing so.

13. Express Scripts, in marketing its PBM services to Ohio health insurers and employers that offer prescription drug coverage to their employees, touts its ability to leverage its significant market power to extract lower drug prices from drug manufacturers. Express Scripts' promise is that it will deliver cost savings to those health insurers and employers. But a look at Express Scripts' business model reveals that this promise is knowingly false. Conversely, Express Scripts increases prices to employers and patients.

14. Shrouded by a veil of non-disclosure agreements and confidentiality clauses, Express Scripts has instituted a profitable pay-to-play system in which it uses its market power as a sword to force drug manufacturers to play a perverse game. Rather than use its bargaining power to place drugs on formularies based on lower price and better efficacy, Express Scripts effectively forces brand-name drug manufacturers to set *higher* list prices in exchange for desirable formulary positions, while limiting patients' access to low-cost generics and other cheaper alternatives.

15. Express Scripts' counterintuitive demand for higher priced drugs can be understood only from Express Scripts' unique vantage point. In simple terms, Express Scripts demands "rebates," "value," or "fees" from drug manufacturers, which it claims to pass on to its clients. Whatever these payments are called, one thing remains constant – they are tied to a list price, and higher list prices bring higher payments into Express Scripts' black box. Vague contract terms permit Express Scripts to pass on to the health insurers and employers it serves only that portion of the rebates that it – in its sole discretion – chooses, keeping the rest for itself. By charging those clients additional fees calculated on those rebates, Express Scripts reaps even more profits from the higher list prices. Clients, for their part, do not know the mechanism or extent of all of these self-payments; only Express Scripts can see each part of the transaction.

16. Express Scripts' covert practices harm other participants in the prescription drug market in Ohio. For many Ohioans, insurance co-pays are derived from a drug's "List Price." List Price is generally expressed through some version of the "wholesale acquisition cost" or WAC, defined by federal law as "the manufacturer's list price for [a] drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price[.]" 42 U.S.C. § 1395w-3a(c)(6)(B). In those cases, the higher the price – inflated by Express Scripts' demands – the higher the co-pay charged to the consumer. In addition, health insurers, employers, and other plan sponsors in Ohio face rising prescription drug costs, due to the fees, costs, and other charges that never escape Express Scripts' black box. Finally, Express Scripts uses its bargaining leverage to force pharmacies, which play a crucial role providing pharmaceutical drugs and care to underserved parts of the State, to accept ever-decreasing reimbursement rates for pharmaceutical drugs. Often, these

reimbursement rates are below what Express Scripts charges the plan for those same drugs, and Express Scripts pockets the difference.

17. While the semantic game-playing and dearth of transparency that are a part of this scheme harm health insurers and employers by denying them the value promised by Express Scripts, the true harm is far more insidious. For the roughly 758,000 Ohioans who are uninsured, those who are underinsured, those with high deductible plans, or those whose out-of-pocket drug costs are calculated as a percentage of List Price, the prices yielded by Express Scripts' demands in exchange for formulary placement create a sometimes unbearable financial burden by increasing their cash outlay exponentially for what is often life-sustaining medication.

18. For example, an estimated 1.1 million Ohioans are diabetics. For hundreds of thousands of them, daily insulin injections are essential to their survival. Express Scripts' well-concealed scheme to force drug prices upward has resulted in insulin prices that have increased from around $20 per unit in the late 1990s to between $300 and $700 per unit today, even though there seems to be near universal agreement that the per unit price to a patient should be around $35.

19. The impact on diabetics who are uninsured, underinsured, or whose co-pays increase with List Price has been devastating, ranging from financial hardship to insulin-rationing, resulting in severe health consequences or even death.

20. Having hobbled the competitive process through its black box system of pricing and fees and its coerced agreements with drug manufacturers that force List Prices upward, Express Scripts uses its unique position to pressure retail pharmacies into accepting often below-cost reimbursements for the drugs they dispense. Express Scripts also forces those retail pharmacies to agree to pay exorbitant "administrative" fees and acquiesce to contract terms that

give Express Scripts virtually unbridled audit rights, including Express Scripts' rights to "claw back" reimbursements paid to the pharmacies. Many pharmacies have no real choice but to accept Express Scripts' take-it-or-leave-it contracts, driving many to the brink of insolvency or closure.

21. These egregiously one-sided contracts restrain and neutralize the competitive process by yielding windfall revenues to Express Scripts at the expense of community pharmacies. When local community pharmacies close their doors, Express Scripts benefits yet again by leaving patients with no feasible options other than Express Scripts' mail order pharmacies.

22. So confident is Express Scripts in its market power that it regularly and flagrantly charges pharmacies millions of dollars in illegal "clawbacks."

23. The closure of independent or small chain pharmacies is a growing health crisis. These pharmacies are often the "front line" of patient care in underserved parts of Ohio.

24. Having tapped a rich vein of revenue from both drug manufacturers and pharmacies through a series of opaque and anticompetitive agreements, Express Scripts' profits soared.

25. But when public outcry about runaway drug prices led to adverse media attention and Congressional hearings about the role of Express Scripts and other PBMs in the drug pricing and distribution system, Express Scripts feared its scheme was being threatened.

26. In response, Express Scripts created an entity – Ascent Health Services ("Ascent"). Self-described as a group purchasing organization or "GPO," Ascent took over Express Scripts' pricing and rebate negotiations with Manufacturers. Prime Therapeutics, a rival PBM, joined the ownership of Ascent later in 2019, pushing Express Scripts' bargaining power

even higher. Ascent boasts publicly that it controls negotiations for 100 million covered lives in the United States. But the creation of Ascent has yielded two additional important advantages to the companies that control it.

27. First, Express Scripts and Prime Therapeutics have been able to move large portions of their respective black box rebate and discount operations into the new company. Express Scripts relocated much of these operations from St. Louis to Switzerland, further concealing the ongoing pricing and rebate schemes by making them even less transparent and even more difficult for their clients to audit.

28. Second, on information and belief, Ascent has provided a convenient vehicle for Express Scripts, Prime Therapeutics, and Ascent's PBM customers to aggregate and access each other's pricing, discount, rebate, and negotiations information. These PBM customers have included some of the most powerful healthcare companies in the world, such as Humana.

29. Armed with this wealth of competitively-sensitive pricing and negotiations information about each other and additional rivals, Express Scripts, Prime Therapeutics, and Ascent's PBM customers have been able to act in concert to harmonize their Manufacturer negotiations and demands, effectively eliminating all competition between themselves and further ensuring that they continue to profit from supracompetitive drug prices.

30. Under the Valentine Act, the Ohio Attorney General is charged with combating Defendants' pervasive abuses of the marketplace. The Valentine Act holds that any "combination of capital, skill, or acts by two or more persons" is an unlawful trust if the combination is for one or more of the improper purposes enumerated in the statute. ***Any*** person who enters into a combination of capital, skill, or acts for an improper subjective purpose has

violated the Valentine Act. The Valentine Act authorizes the Attorney General to bring an action to restrain and enjoin ***any*** violation of the Valentine Act.

31. Thus, the Ohio Attorney General is empowered to restrain or enjoin corrupt combinations even if such combinations have not yet achieved their desired effects – the participants' ***intent*** to harm the competitive marketplace in Ohio is sufficient. Of course, as alleged herein, Defendants' actions have already caused substantial and serious harm to Ohio's citizens, and through this action the Attorney General is drawing a line in the sand: This is where it stops.

32. The Attorney General brings this action to put a stop to Defendants' secret and anticompetitive conduct and strong-arm tactics that have prevented free market forces from ensuring that Ohio's most vulnerable citizens can afford the prescription drugs on which their lives depend. The Defendants have harmed not just markets and pocketbooks, but Ohioans' health and lives.

JURISDICTION AND VENUE

33. The State of Ohio brings this action to prevent and restrain violations of Ohio Revised Code §§ 1331.01, *et seq.* The Court has subject matter jurisdiction over this action pursuant to Ohio Revised Code §§1331.03, 1331.06 and 1331.11.

34. The State of Ohio further brings this action for declaratory and injunctive relief pursuant to Ohio Revised Code §§109.81 and 2721.02 et seq.

35. The Court has personal jurisdiction over the Defendants because they regularly transact business in the State of Ohio, contract to supply goods and services within the State of Ohio, have caused tortious injury by acts or omissions in the State of Ohio, and have caused tortious injury in the State of Ohio by acts or omissions outside the State directed at this State

while regularly doing or soliciting business, engaging in other persistent courses of conduct, and deriving substantial revenue from goods used or consumed or services rendered in the State of Ohio.

36. Venue is proper in this county pursuant to Ohio Revised Code §1331.11, R. Civ. Pro. 3(C)(3), 3(C)(5), 3(C)(6), 3(F), 4(B), and Ohio Revised Code §2721.14.

37. Plaintiff, having reasonable cause to believe that violations of Ohio's antitrust laws have occurred, brings this action in his sovereign and quasi-sovereign capacity as *parens patriae* pursuant to Ohio Revised Code §109.81 to protect the State of Ohio, its markets, and its citizens.

38. An actual controversy exists between the State of Ohio and Defendants within the meaning of Ohio Revised Code §2721.02, et seq., regarding whether Defendants' practice of imposing clawbacks on Ohio retail pharmacies constitutes a violation of Ohio Revised Code §3959.20(C)(2) and Ohio Revised Code §§1331.01 et seq.

THE PARTIES

39. The State of Ohio brings this action in its sovereign and quasi-sovereign capacity on relation of the Ohio Attorney General as the chief law enforcement officer of the State of Ohio.

40. The State of Ohio has an interest in ensuring that its citizens who pay out-of-pocket for prescription drugs because they are uninsured, underinsured, or have co-pays or deductibles calculated on the basis of list price of the prescribed drugs, pay no more for prescription drugs than they would pay in a competitive market. The State of Ohio has an interest in ensuring that employers in the state pay no more for providing prescription drug benefits to their employees than they would pay in a competitive market. The State of Ohio has

an interest in ensuring that lives and the health of Ohioans and competitive markets in the State are not impeded by unlawful activities, and that such activities do not harm the general economy of the State or the economic or physical well-being of its citizens.

41. Pursuant to Ohio Revised Code §1331.11, the Ohio Attorney General is authorized to institute and prosecute actions on behalf of the State to enforce the provisions and remedies of Ohio's antitrust laws, codified in Ohio Revised Code Chapter 1331. Pursuant to Ohio Revised Code §109.81, the Ohio Attorney General is authorized to do all things necessary to properly conduct any antitrust case and to seek equitable relief as provided in Revised Code §§109.81 and 1331.11.

42. Express Scripts, Inc. ("Express Scripts") is a corporation organized and existing under the laws of Delaware, with its principal place of business in St. Louis, Missouri. Express Scripts is a subsidiary of Evernorth Health, Inc. ("Evernorth"), which is a wholly-owned subsidiary of Cigna Group ("Cigna"). Express Scripts is engaged in the business of, *inter alia,* providing PBM and mail order pharmacy services to commercial health plans, self-insured employers, and government programs in the State of Ohio and elsewhere. Evernorth is engaged in the business of, *inter alia*, offering PBM services provided by Express Scripts for sale.

43. Prime Therapeutics LLC ("Prime Therapeutics") is a corporation organized and existing under the laws of Delaware, with its principal place of business in Eagan, Minnesota. Prime Therapeutics is engaged in the business of, *inter alia,* providing PBM services to commercial health plans, self-insured employers, and government programs in the State of Ohio and elsewhere. Prime Therapeutics is owned jointly by numerous Blue Cross and Blue Shield Plans, subsidiaries or affiliates.

44. Humana Pharmacy Solutions, Inc. ("Humana Pharmacy Solutions") is a corporation organized and existing under the laws of Kentucky, with its principal place of business in Louisville, Kentucky. It is a wholly-owned subsidiary of Humana Inc. ("Humana"). Humana Pharmacy Solutions is engaged in the business of, *inter alia*, providing PBM and mail order prescription services.

45. Ascent Health Services LLC ("Ascent") is a limited liability company organized and existing under the laws of Delaware, with its principal place of business in Schaffhausen, Switzerland. Ascent is engaged in the business of, *inter alia,* acting as a group purchasing organization for the negotiation of rebates with drug manufacturers on behalf of PBMs. Ascent's ownership includes, among others, both Defendants Express Scripts and Prime Therapeutics. Humana Pharmacy Solutions is an Ascent customer. Based upon the composition of its membership, Ascent is considered a citizen of the State of Ohio.

46. At all relevant times herein, Ascent, Express Scripts, Prime Therapeutics, Evernorth, Cigna, Humana Pharmacy Solutions, and Humana have transacted business in or affecting the State of Ohio.

47. Various drug manufacturers, retail pharmacies, and individuals not named here as defendants have been parties to the agreements and combinations that form the basis of the violations alleged in this Complaint.

FACTUAL ALLEGATIONS

The pharmaceutical distribution system

48. PBMs first appeared in the 1960s, when they served predominantly as claims processors for the transactions that arose when an individual covered by a prescription drug insurance benefit had a prescription filled at a retail pharmacy ("Retail Pharmacies"). Gradually,

they began to fill additional roles, including handling negotiations with the manufacturers of brand name prescription drugs ("Manufacturers") on behalf of the employers who paid for the purchase of those drugs.

49. Today, PBMs contract with commercial health insurers and with employers ("Plan Sponsors") who offer prescription drug benefit plans to their employees to provide a variety of services ("PBM Services"). The mix of PBM Services provided under such contracts varies by PBM and Plan Sponsor. Among the PBM Services commonly provided by PBMs to Plan Sponsors are: (1) creation and maintenance of networks of Retail Pharmacies at which covered employees can fill their prescriptions ("Pharmacy Networks"); (2) design of the list of drugs that will be covered by a Plan Sponsor's pharmacy benefit plan, including the extent of coverage for each drug (the "Formulary"); and (3) negotiation of drug prices, discounts, and other terms of sale with Manufacturers on behalf of Plan Sponsors.

Pharmacy Networks

50. Most employer-provided prescription drug benefit plans set forth a list of preferred pharmacies at which employees and their families ("Covered Lives" or "Covered Patients") who are covered by a Plan Sponsor's prescription drug benefit can have prescriptions filled for a lower co-pay than would be required at non-preferred pharmacies. These groups of pharmacies – Pharmacy Networks – often include a mix of large Retail Pharmacies owned by PBMs or related companies, small-to-medium-sized chains, independent pharmacies, grocers, big box stores, and the like. PBMs negotiate with Retail Pharmacies for inclusion in these Pharmacy Networks, demanding in return discounts on the amount of reimbursement and dispensing fees the PBM will pay to the pharmacy for each prescription dispensed, as well as other fees.

51. Retail Pharmacies that are part of a PBM's Pharmacy Network purchase drugs from a Manufacturer or wholesaler, and after these drugs are dispensed to a Covered Patient, the PBM reimburses the Retail Pharmacy under the pharmacy's contract with the PBM.

52. Inclusion in the Pharmacy Networks of a large PBM provides a Retail Pharmacy with access to significant numbers of Covered Lives who have strong financial incentives to have their prescriptions filled at in-network pharmacies. Conversely, exclusion from the Pharmacy Networks of a large PBM can be financially devastating to Retail Pharmacies, especially small chains or independents, as it deprives them of an essential source of potential customers.

53. Each of the nation's largest and most dominant PBMs – Defendants Express Scripts and Humana Pharmacy Solutions, in addition to Caremark and Optum – also owns and operates an in-house mail-order pharmacy that Covered Patients may opt to use, or in some cases may be required by their PBM to use, to fill their prescriptions for chronic drug therapies. These mail-order pharmacy operations compete with Retail Pharmacies.

Formularies

54. PBMs often design, create, and maintain Formularies for the Plan Sponsors with which they contract as a part of the PBM Services they agree to provide. A PBM's national or default Formulary has a large degree of clout in determining which drugs are generally covered throughout its Covered Lives.

55. PBMs generally offer both standard Formularies and customized Formularies to Plan Sponsors. In light of the complexities involved in Formulary development and maintenance, nearly three-quarters of all Plan Sponsors cede control to their PBMs by selecting

the standard Formulary. Even for those Plan Sponsors that opt for a customized Formulary, the PBM has huge influence and control over the process of creating and revising that Formulary.

56. Drugs appearing on a Plan Sponsor's Formulary generally have a lower co-pay than those not on the Formulary, a fact that tends to drive Covered Patients to preferred drugs.

57. Many Formularies are structured with multiple tiers, providing graduated co-pays among the various tiers, which further drives Covered Patients to preferred drugs. Most Formularies have between two and five tiers, with drugs appearing in the lowest tier having the lowest out-of-pocket cost to the Covered Patient, and drugs in the highest tier requiring the Covered Patient to be responsible for a far greater percentage of the price.

58. Plan Sponsors enlist the services of PBMs in connection with Formulary design and maintenance both to keep their drug costs in check and to provide high quality care to their employees. As such, Plan Sponsors rely on the understanding that PBMs typically develop their Formularies on the advice and input of a pharmacy and therapeutics committee ("P&T Committee") comprised of pharmacists, doctors, and nurses who consult the latest FDA protocols and published clinical trials in providing their recommendations.

59. Plan Sponsors, therefore, rely heavily on PBMs to construct Formularies that provide the best possible combination of efficacy and price for the prescription drugs available to those covered by the plans.

Negotiations with Manufacturers

60. Another facet of the total package of PBM Services that most PBMs agree to provide, pursuant to their contracts with Plan Sponsors, is the negotiation of drug prices with Manufacturers. As a part of such negotiations, PBMs commonly seek discounts in the form of a refund of a portion of the purchase price paid for the drug (a "Rebate"). Rebates are paid by the

Manufacturer to the PBM. They are commonly calculated as a percentage discount off of the Manufacturer's price for a given drug as reported in wholesale price guides or similar industry publications, which is often referred to as the wholesale acquisition cost or "WAC," or simply as the Manufacturer's list price (herein "List Price"). Formulary placement is often conditioned on or correlated with the amount of the rebate offered, with the highest rebates often reserved to the most exclusive placement.

61. Some portion of these Rebates is usually retained by the PBM, with the remainder passed on to the Plan Sponsor. The portion of the Rebates that may be retained by the PBMs is typically spelled out in contracts between the PBM and the Plan Sponsor.

62. Frequently, however, Rebates do not lower the cost for prescription drug benefits. Instead, the PBMs take the lion's share of the financial rewards from the Rebates.

Consolidation in the PBM industry has given Express Scripts immense power in the marketplace

63. Express Scripts began operations in 1986.

64. By 2010, it had one of the top three highest market shares among PBMs nationwide, along with competitors Medco Health Solutions and Argus Health Systems. Those three PBMs controlled approximately 48% of U.S. Covered Lives. And yet, more than half of the Covered Lives in the nation were served by a myriad of other PBMs at that time.

65. The PBM market has undergone rampant consolidation over the past two decades. Express Scripts has been a significant contributor to that consolidation, consummating multiple mergers and acquisitions of rival PBMs, including its April 2012 merger with industry giant Medco Health Solutions. By the end of 2017, Express Scripts described itself as the "largest independent PBM company in the United States." Its $67 billion merger with Cigna Corp.,

consummated in late 2018, took another rival – Cigna's PBM – out of the market and exponentially enhanced its power through vertical integration with a massive health insurer.

66. Cigna and its subsidiary Evernorth participate in their own capacities in Express Scripts' business and operations. By way of example, Evernorth and its employees are directly involved in the sale of Express Scripts' PBM services to plan sponsors.

67. By 2020, the nation's top three PBMs (Express Scripts, CVS Caremark, and OptumRx) controlled 77% of the Covered Lives in the U.S., with all other competitors battling for the scant remaining 23%. Express Scripts remained firmly entrenched in the top three at that time, and remains so today.

68. In 2021, Express Scripts controlled one-quarter of all adjusted pharmaceutical claims in the U.S.

69. In 2022, Express Scripts controlled 88 million Covered Lives in the United States, compared to CVS Caremark's 81.3 million and OptumRx's 40.1 million.

70. In October 2022, Express Scripts announced an agreement with managed care organization Centene Corporation that will put Express Scripts in control of the pharmacy benefits for 20 million Centene members starting in January 2024. The deal will push the total number of Covered Lives controlled by Express Scripts nationwide to well over 100 million.

71. Today, Express Scripts controls access to roughly 38% of the rebate negotiations in the State of Ohio. In nearly every metropolitan statistical area (MSA) in Ohio, Express Scripts dominates over its rivals in the delivery of PBM services such as rebate negotiation, retail pharmacy network management, and claims adjudication, controlling nearly 60% of those markets in the Cleveland-Elyria and Weirton-Steubenville MSAs, and well in excess of 40% in numerous others, according to a 2020 study by the American Medical Association.

72. Thus, for Manufacturers and Retail Pharmacies alike, access to the Covered Lives controlled by Express Scripts is a "must have."

Express Scripts coerces Manufacturers to alter their pricing models by threatening to deny formulary placement, resulting in higher List Prices

73. Drug Manufacturers generally need their drugs to be placed on a PBM's Formulary in order to be covered by insurance. When a patient is prescribed a drug that is excluded from their PBM's Formulary, they have three options: (1) pay the entire cost of the drug out-of-pocket; (2) appeal the denial of coverage; or (3) obtain a prescription for an alternative drug from her physician. For many patients, switching to an alternative drug is the least painful option. Thus, Formulary exclusion can be the death-knell to a prescription drug. This fact gives large PBMs like Express Scripts great leverage over Manufacturers.

74. Even the mere demotion of a drug to an inferior tier – where the patient's co-pay is much larger than it would be on a more favorable tier – can have a massive negative impact on adoption of, and thus revenue from, that drug.

75. In other cases, patient access to a prescribed drug can be blocked or delayed even if the drug is not excluded from the formulary, through barriers such as "fail first" requirements. Under such requirements, patients must first attempt an alternative drug treatment before they can obtain the drug prescribed by their provider. In many cases, the initial drug required in this "fail first" therapy is favored because it has a higher nominal price and, by extension, offers higher rebates to the PBM.

76. In its January 2021 report, the United States Senate Finance Committee recognized that "[p]harmaceutical companies are sensitive to the sheer size of PBMs and the resulting product volumes they can affect, which allows the middlemen to extract higher rebates from manufacturers through the use of formulary exclusion tactics."

77. Express Scripts is no exception, wielding its size and market power to effectuate a pay-to-play system that awards Formulary placement to the highest bidder. The "payment" that Express Scripts extracts includes Rebates that, in theory, benefit the Plan Sponsors by lowering their net price for the drugs prescribed to their Covered Lives.

78. But while Express Scripts touts publicly that the system it has established is the embodiment of competitive forces at work, the opposite is true.

79. Express Scripts has structured its contractual relationships with Manufacturers around the concept of List Price. It requires the Manufacturers – as a condition of appearing on Express Scripts' Formularies – to pay administrative fees and Rebates, frequently calculated with List Price as a material part of the equation.

80. During its negotiations with Manufacturers, Express Scripts threatens to deny favorable Formulary tier position to – or to outright exclude from the Formulary – any drug on which the Manufacturer will not pay the demanded level of fees and Rebates.

81. The result is a matter of simple math – because Express Scripts' contracts with Manufacturers set Rebates through calculations in which List Price is a material factor, the only way that Manufacturers can satisfy Express Scripts' demand for higher Rebates is to raise List Prices.

82. The higher List Prices that Express Scripts extracts from Manufacturers in exchange for Formulary placement raise out-of-pocket costs for Covered Patients, often resulting in reduced compliance with medication regimens, and thus a sicker overall population for Plan Sponsors.

83. The carrot of favorable Formulary placement, combined with the stick of Formulary exclusion that Express Scripts uses to force List Prices upward, constrict the choices

of medications available to Covered Patients, in a way that frequently excludes more reasonably-priced drugs. Express Scripts has also excluded more affordable "authorized generic" forms of medications, significantly increasing cash outlays by patients needing those life-saving drugs.

84. Express Scripts' use of outright Formulary exclusion has accelerated rapidly in recent years. From 2014 to 2022, the number of brand drugs excluded from its Formularies increased from 57 to 563 – a stunning 888% increase. Express Scripts' exclusionary Formulary tactics force Manufacturers to compete *to enter the market in the first place*, according to rules set by Express Scripts, rather than compete *in* the market for patients, according to patient needs and preferences. The power to exclude is the power to destroy, allowing PBMs to extract massive rebates from Manufacturers fearful of exclusion and even larger rebates from Manufacturers seeking to exclude others.

85. If Express Scripts were to use its market power to secure the best combination of low cost and high efficacy for Plan Sponsors as it claims, the result would be an example of the proper functioning of a competitive market. But that is not how Express Scripts leverages its power. On the contrary, Express Scripts squeezes off the air supply of the competitive process – information and transparency – thus insulating itself from the competitive pressures that would result if Plan Sponsors were able to assess accurately the true quality-adjusted price of its services.

86. Smaller, less powerful PBMs that might challenge Express Scripts' position in the market by offering a more favorable combination of cost and efficacy in the Formularies they create are foreclosed by this contortion of the competitive process, and therefore have limited chance to compete.

87. Inside the secret, opaque, protective shell that Express Scripts maintains, its contracts and negotiations with Manufacturers fix and increase the price of drugs to Covered Patients, increase the quality-adjusted price of PBM Services to Plan Sponsors, and thus preclude the free flow of trade and commerce among all participants in this complex drug distribution system.

Express Scripts' pay-to-play scheme pushes insulin prices to extreme levels and denies Ohio diabetics access to lower-priced alternatives

88. There is no clearer illustration of Express Scripts' contortion of the competitive process and the devastating impact of that contortion on vulnerable Ohioans than in the distribution and pricing of insulin.

89. Approximately 1.1 million Ohioans are diabetics.

90. Diabetes is a disease characterized by abnormally high blood glucose, or blood sugar. While the pancreas normally secretes sufficient quantities of the hormone insulin to control the rate at which food is converted to glucose that provides energy to human cells, a lack of insulin or a suppressed ability for cells to respond to insulin means glucose is unable to enter the cells, leading to high blood sugar levels.

91. Roughly 90-95% of diabetics develop the disease when their bodies stop producing sufficient amounts of insulin or become resistant to the insulin they do produce. This form of the disease is known as Type 2 diabetes and can be treated in early stages by medication. Most Type 2 diabetics eventually require insulin injections, however.

92. For the remaining 5-10% of the diabetic population, their bodies do not produce any insulin, and thus regular insulin injections are essential to life. This form of the disease is known as Type 1 diabetes.

93. Disruptions in an insulin regimen often have severe consequences for Type 1 diabetics and insulin-dependent Type 2 diabetics. Missed injections or injections of less than the prescribed dosages can cause hypoglycemia and possibly diabetic ketoacidosis. If untreated, diabetic ketoacidosis can lead to death within a matter of days.

The development of insulin products

94. In 1996, Eli Lilly developed the first rapid-acting analog insulin, Humalog. Analog insulin is laboratory-grown and genetically-altered insulin. Analogs make the injected treatment act more like the insulin naturally produced and regulated by the body than human insulin. Moreover, it allowed for substantially faster absorption times.

95. Other rapid-acting analogs are Novo Nordisk's Novolog and Sanofi's Apidra, with similar profiles. Diabetics use these rapid-acting insulins in combination with longer-acting insulins, such as Sanofi's Lantus (introduced in 2000) and Novo Nordisk's Levemir (introduced in 2005).

96. In 2015, Sanofi introduced Toujeo, another long-acting insulin also similar to Lantus, however Toujeo is highly concentrated, making injection volume smaller than Lantus.

97. In 2016, Eli Lilly introduced Basaglar, which is a long-acting insulin that is biologically similar to Sanofi's Lantus.

98. Eli Lilly, Novo Nordisk, and Sanofi remain the only manufacturers of insulin in the United States today.

99. For Type 1 patients, insulin analogs are unquestionably the best course of treatment. Doctors uniformly prescribe analogs for Type 1 patients.

100. For patients with Type 2 diabetes, the ADA describes long-acting analog insulin as the most convenient initial insulin regimen. Likewise, doctors prefer to prescribe analog

insulins to Type 2 patients. As of 2010, among adults who filled more than one prescription for insulin, 91.5% filled prescriptions for insulin analogs. Type 2 patients use human insulin less frequently: only 18.9% of Type 2 adults taking insulin filled a prescription for human insulin in 2010, down from 96.4% in 2000. In the wake of analog insulin, human insulin, like Novolin or Humilin, has nearly become obsolete.

101. In 2020, the top three selling insulins in the United States were all analogs: Sanofi's long-acting Lantus garnered $1.14 billion in U.S. net revenue; Novo Nordisk's rapid-acting Novolog earned $1.18 billion in U.S. net revenue; and Eli Lilly's rapid-acting Humalog earned $1.67 billion in U.S. net revenue.

Express Scripts' scheme pushes insulin prices sharply upward

102. In 2012, infused with the exponential increase of its market power as a result of the Medco merger, Express Scripts approached drug Manufacturers with a new form agreement ("Master Agreement") governing their relationship.

103. The Master Agreement and its amendments over the coming decade required that the Manufacturers pay per-unit Rebates to the PBM for each prescription dispensed for their products. In a section entitled "Rebate Calculations," the Master Agreement further dictated that Formulary placement would be tied to the amount of the Rebates, providing "Rebates will be based upon Product utilization *and the corresponding Formulary Positioning* and the Benefit Control (each as defined above) applicable to each Plan and in place on the date the applicable Product is dispensed or administered." (Emphasis added).

104. Moreover, Express Scripts' Master Agreement required that "[a]ll Rebates percentages shall be stated as a percentage of WAC [List Price]."

105. Accordingly, the Pricing Grid appended to each Manufacturer's Master Agreement with Express Scripts specified in detail a different percentage Rebate – stated as a percentage of WAC/List Price – based upon the Formulary position that that Rebate would allow the product to have.

106. Since then, prices for analog insulins have skyrocketed. Some prices have increased 172%, from $144.84 to $248.51, in about one and a half years' time. These extremely high prices are unique to the United States. Indeed, many of these exact same insulins are sold in Canada for less than 25% of the U.S. price.

107. Recently, some manufacturers – including Eli Lilly, Novo Nordisk, and Sanofi – have announced programs to, at some future date, limit the out-of-pocket monthly costs for patients who need insulin to a set figure, such as $35 a month. These programs come in the wake of efforts in both state and federal government to provide similar cost limitations. These programs represent drastic efforts to limit the harms of systemic PBM abuses on patients' reasonable access to necessary treatment.

108. The ultimate effectiveness of these programs will not be known for some time. In the past, attempts to provide discounts to patients have met resistance from insurers and PBMs, thus reducing the effectiveness of those programs. In addition, it is not clear how these programs will affect the overall cost of pharmacy benefits for Plan Sponsors or the continuing problems the PBM industry imposes on local and independent pharmacies.

109. But attempts to limit patients' out-of-pocket costs on only one category of treatment are akin to putting a band-aid on a wound that is already infected. The rising price of insulin is but one symptom of the harms that PBMS have inflicted upon the marketplace, and these remedial measures do not reach the root cause of the disease.

Express Scripts favors more expensive drugs through step therapy or "fail first" requirements

110. PBMs, including Express Scripts, also use the Rebates scheme to favor higher-priced drugs through "step therapy" or "fail first" requirements. These requirements often favor drugs with higher nominal prices – and by extension higher Rebates – over drugs that have lower net costs or that might be more appropriate for a patient's particular therapy. In many cases, step therapy and Formulary restrictions that favor the most profitable medications for PBMs – those with the highest Rebates – result in patients having delayed access to treatment prescribed by the patients' physicians.

111. The result of these schemes is that the first-line treatment decision can be driven by the financial interests of the PBM and not the evidence-based judgment of a qualified physician. A 2021 study regarding 10 diseases commonly subject to step therapy by commercial health plans concluded that only 34 percent of the step therapy protocols for those diseases were consistent with corresponding clinical guidelines.

112. Beyond simply delaying the prescribed treatment, step therapy can also result in increased disease activity, disability, or irreversible disease progression.

113. A February 6, 2023, *Washington Post* article provided some illustrative examples of how step therapy – a one-size-fits-all system – can negatively affect patients. A seventh grader in Arizona with juvenile rheumatoid arthritis was forced to stay on a Formulary-favored drug – which was not the drug prescribed by her physician – for six months, while her symptoms worsened and her arthritis spread through her body. A dermatologist at the University of Pennsylvania observed that frequently patients with severe, debilitating skin conditions are required to undergo step therapy, leading to months of delayed treatment while their symptoms worsen.

114. Patients also experience these costs in lost time. By one estimate, 28 percent of patients who experienced step therapy spent three or more hours trying to obtain second-line drugs from their physicians. In other cases, cost savings from the step therapy treatment are more than offset by increased costs for treatment that might have been prevented if the patient had access to appropriate treatment from the beginning. For example, a study found that step therapy regarding pharmaceutical treatment for schizophrenia saved $20 per month in drug costs on average but also incurred an average of $32 per month in additional outpatient service costs. And finally, the step therapy process can be so discouraging to patients – whether due to worsened symptoms, treatment delays, the burden of frequent doctor visits, the costs of already having paid for drugs that were not effective, or a frustrating appeals process – that many stop seeking treatment entirely.

115. But these effects are perhaps most starkly illustrated in the context of cancer drugs, where delays in treatment can have the most dire consequences. Treatment delays after a cancer diagnosis have been linked to worse or prolonged symptoms, spread of the disease, and even an increased risk of death. A 2016 study noted that treatment delays of eight or more weeks decreased overall survival for patients with stage I breast cancer, and delays of 12 or more weeks decreased overall survival for patients with stage II breast cancer.

116. For example, patients with bone metastases or hypercalcemia may be prescribed Denosumab to prevent skeletal-related events. In order to obtain access to that drug, however, patients are often required to fail to the level of serious, bone-related complications – such as broken bones – that might have been prevented if they had obtained the appropriate treatment initially. In addition, a "double step" therapy is often required by chemotherapy-induced nausea

drugs, requiring patients to experience violent vomiting before they can obtain the more effective anti-nausea drug.

117. Moreover, the rise of step therapy has coincided with rapid growth in the prices among cancer drugs.

118. Gleevec, a drug used to treat chronic myeloid leukemia, was priced in 2020 at $123,000 for a standard annual course of treatment, and sales of the drug generated $330 million in net revenue in 2019. In 2003, a 400 mg tablet of Gleevec was priced at $68.16. This price increased 22 times through 2020, for a cumulative price increase of 395 percent. The 100 mg tablet cost $93.64 in 2020, a similarly large increase from its 2001 price of $17.04.

119. Rebates for Gleevec have kept pace with this growth. From 2009 to 2015, the average of all discounts, Rebates, returns, and copayment amounts totaled just 15% of gross sales. This number suddenly rose to 40.8% in 2016, but no real savings were realized – the average net price for Gleevec in 2016 was almost double the average net price in 2009. By 2018, the average net price was *more* than double the average net price in 2009.

120. Imbruvica, which treats mantle cell lymphoma and five other cancers or conditions, experienced similar price increases in the same time period. In 2013, a single tablet of Imbruvica cost $91.11. This cost grew to $165.78 in 2020, after nine separate price increases. In 2020, Imbruvica generated $4.3 billion in U.S. net revenue.

Express Scripts' Rebate scheme also limits competition from lower-cost generics

121. Generic drugs play an important role in providing affordable health care to patients by providing cheaper, effective alternatives to brand-name drugs. There is a significant public interest, therefore, in avoiding delays in the adoption of effective generic alternatives by health plans.

122. Historically, generics have been adopted at a rate of 80%or more within only a few months. In 2021, however, the top 10 new generics averaged 70% market share of total prescriptions. This slower adoption is a result of PBM influence. Due to the Rebates system, PBMs, including Express Scripts, are incentivized to prefer higher-priced brand name drugs over their more affordable generic counterparts.

123. In 2016, first generics – the first approval that allows a manufacturer to market a generic drug in the United States – were covered only 46% of the time. Those drugs reached 90%coverage in 2022, six years after they first came to market. These delays restrict patient access to lower-priced generics and expose patients to unnecessarily high cost-sharing.

124. PBMs limit access to generic drugs through a number of strategies. PBMs often have "do not substitute" or "DNS" strategies that prevent consumers from obtaining low-cost generics in favor of more profitable brand-name drugs with high Rebates. In addition, PBMs may decide not to stock generic equivalents of drugs in the pharmacies that they or an affiliated company own. Further, PBMs have been known to train call center representatives to discourage beneficiaries from filing Formulary exceptions for generic drugs.

125. For example, generic versions of Advair Diskus – used to treat people with asthma and chronic obstructive pulmonary disease – took five years to exceed 30% adoption. When a generic version of the Advair inhaler was made available at a 70% discount, Express Scripts continued to require pharmacies to dispense the more expensive brand. Individuals covered by Express Scripts whose payments were based on the net price of the drug – for examples, those with high-deductible health plans – were therefore forced to purchase the more expensive brand over the effective, approved generic. Broadly, new generics on average take up to seven years to reach more than 80%Formulary coverage on commercial plans.

Express Scripts conceals its scheme from Plan Sponsors

126. Keenly aware that the veil of secrecy that keeps competition at bay and its power unchecked is pivotal to maintaining its massive revenue stream, Express Scripts uses its market power to maintain opacity through multiple means. Each of the means described below has the purpose of suppressing the competitive process and fostering the pay-to-play agreements that Express Scripts uses to force drug prices upward.

Renaming Rebates

127. Prior to 2017, more than half of the Plan Sponsors that contracted with Express Scripts allowed Express Scripts to retain some portion, often impossible to quantify, of their Rebates through the PBM's opaque black box process.

128. Beginning around 2017, some Plan Sponsors began to push back on the mysterious withholding of a portion of the Rebates to which their contracts with Express Scripts entitled them. By 2021, in an effort to pacify its clients, Express Scripts had upped the percentage of its clients receiving full pass-through of Rebates to 75%. This apparent victory for Plan Sponsors, however, was a fiction – produced by a semantic sleight-of-hand by Express Scripts.

129. Fearing that Plan Sponsors' suspicions about its practice of withholding sizeable chunks of their Rebate dollars would threaten this steady and highly lucrative revenue stream, Express Scripts began to rename and recategorize large portions of the monies flowing in from Manufacturers. Suddenly, Express Scripts was receiving more "administrative service fees," "inflation fees," "service fees," or similarly labeled payments from Manufacturers.

130. Once again, Express Scripts' impenetrable black box prevented Plan Sponsors from seeing the value that they were getting – or more accurately, the value they were not getting

– from their contracts with the powerful PBM. Having denied Plan Sponsors this vital piece of information, Express Scripts severely hamstrung the competitive process.

Refusal to give Plan Sponsors access to their own data

131. Plan Sponsors heavily rely on Express Scripts to negotiate favorable drug prices and create Formularies that include cost-effective drugs for their members. But Express Scripts refuses to readily provide Plan Sponsors with the necessary data for Plan Sponsors to make fully informed cost decisions. This data revolves around Express Scripts' Rebate agreements with Manufacturers and the cost-effectiveness of the drugs placed on Express Scripts' Formularies. This guarded data is often data that Plan Sponsors are promised the ability to access (via audits) under their contracts with Express Scripts.

132. Plan Sponsors need access to claim-level Rebate information to understand exactly how their contractual Rebates are working for their plans and their covered members. But PBMs like Express Scripts do not naturally provide Plan Sponsors with itemized billing statements that show how the Rebates were applied at the claim level. Instead, Express Scripts requires Plan Sponsors to undergo onerous audit protocols to access that data.

133. Depending on the Plan Sponsors' contracts with Express Scripts, Plan Sponsors may be required to travel to Express Scripts' St. Louis headquarters for an on-site audit visit. The Express Scripts contract may require Plan Sponsors to hire a CPA from a top 100 accounting firm to perform the Rebate audit. Once presented with the data, Plan Sponsors may be prevented from taking detailed notes of their analysis. Express Scripts claims that rigorous audit protocols are necessary to protect sensitive information, but in reality, they exist to hinder Plan Sponsors from assessing their Formulary drug Rebates and holding Express Scripts accountable for muddying the drug pricing waters.

134. Express Scripts also prevents Plan Sponsors from understanding Express Scripts' contractual relationships with drug Manufacturers and Retail Pharmacies. By concealing drug utilization and Rebate data and Maximum Allowable Cost lists, Express Scripts ensures that Plan Sponsors cannot accurately measure the cost and efficacy of their Formulary drug plans.

135. Express Scripts passes on drug utilization data to Manufacturers, but Plan Sponsors have no way of knowing how their plan's utilization data is then used by Express Scripts and the Manufacturers. Plan Sponsors' Rebates may be tied to drug utilization, but only Express Scripts has access to the full pricing picture involving Manufacturer contracts and the Plan Sponsors' drug claims and utilization data. This lack of transparency means that Plan Sponsors do not have the information necessary to adequately choose Formularies that are cost-effective and obtain Rebates that work best for their plans and members.

136. Express Scripts also shrouds its Maximum Allowable Cost (MAC) lists in secrecy. These MAC lists represent the amount a PBM will reimburse a Retail Pharmacy for dispensing generic drugs and the amount it charges Plan Sponsors for drugs. PBMs control MAC lists and ensure that only the drugs they are making money on remain on the lists. These lists can change by the hour or even by the minute. Without access to these lists and reimbursement data, Plan Sponsors cannot understand the value of Express Scripts' drug pricing, making Plan Sponsors even more dependent on how Express Scripts sets and enforces drug prices. By keeping Plan Sponsors in the dark, Express Scripts can comfortably maintain higher drug prices which then harms Plan Sponsors' members with high-deductible plans.

137. But the self-serving renaming of revenue received from Manufacturers but not passed on to Plan Sponsors and the refusal to give Plan Sponsors access to their own utilization

data are not Express Scripts' only deceptions, and are certainly not the ones that do the most harm to competition and to Ohioans that purchase and rely upon prescription drugs.

Misrepresentations about cost-effectiveness

138. Throughout the period covered by this Complaint, Express Scripts has made repeated misrepresentations to Plan Sponsors and to the public about its use of its clout in the marketplace to place the most cost-effective drugs on its Formularies for the benefit of Plan Sponsors and their employees. Express Scripts' statements are patently false, as it knowingly omits any mention of its pay-to-play system involving coercion of List Price hikes by Manufacturers and its frequent denials of Formulary placement to the most cost-effective drugs.

139. Express Scripts actively promotes its PBM Services to Ohio Plan Sponsors as being an effective tool to help them navigate the complex prescription drug distribution system to find the best possible combination of lower costs and healthy outcomes for their employees. On its website, Express Scripts makes the following promise to Plan Sponsors: "The challenges you face in improving the health of your members may seem daunting. From ensuring quality care while managing cost, to keeping up with emerging therapies and technology, we're here for you."

140. Also on its website, Express Scripts maintains a five-page white paper explaining its Formulary development process. That white paper states, *inter alia,* "The processes Express Scripts uses to develop formularies have been constructed to ensure that clinical considerations are paramount and fully taken into account *before* cost considerations." White Paper: Formulary Development at Express Scripts, December 2020 (emphasis in original).

141. In 2021, an Express Scripts spokesperson issued a statement to the *Managed Healthcare Executive* publication claiming that "[c]linical appropriateness of the drug – not cost – is our foremost consideration."

142. Express Scripts' misrepresentations that conceal its pay-to-play schemes' elevation of dollars over drug quality and efficacy are made not only to Plan Sponsors, but also directly to Covered Patients themselves. For example, in its 2022 Formulary document prepared for and distributed to members of an Ohio public employee retirement plan, Express Scripts tells members that it has chosen the drugs on the Formulary "in consultation with a team of healthcare providers, which represents the prescription therapies believed to be a necessary part of a quality treatment program."

143. Contrary to these lofty promises, Express Scripts not only imposes a higher dollar net cost on Ohio Plan Sponsors than their contracts require through stealthy unilateral renaming of Rebates received, but also systematically and secretly subjugates considerations of drug efficacy and patient well-being to the well-being of its own corporate bottom line.

Express Scripts coerces non-PBM-affiliated Retail Pharmacies to agree to accept extremely low reimbursement rates and harsh, one-sided contract terms

144. Express Scripts' immense power in the pharmaceutical distribution system is evidenced equally clearly in its heavy-handed, take-it-or-leave-it contract negotiations with regional and local Retail Pharmacy chains and independents. It wields the threat of exclusion from its pharmacy networks – and thus foreclosure from access to its pharmacy customers in the State of Ohio – to extract severely lop-sided contract terms from the Retail Pharmacies who need those customers in order to remain in business.

145. As is the case with respect to its Rebate and fees negotiations with Manufacturers, Express Scripts uses opacity and confidentiality requirements to hide its anticompetitive practices towards Retail Pharmacies and to prevent market forces from working to correct this egregious imbalance.

146. Express Scripts extracts these one-sided agreements from Retail Pharmacies for two purposes. For those Retail Pharmacies that manage to remain in business on the scant margin that the Express Scripts contract terms allow, Express Scripts earns even greater revenue on each prescription filled there. And for those Retail Pharmacies that end up shuttered because of these onerous contract terms, many of their customers are left no choice but to turn to Express Scripts' mail order pharmacy. The Retail Pharmacy agreements, therefore, reinforce and amplify Express Scripts' already vast market power, reduce consumer choice, and restrain trade in Ohio Retail Pharmacy services markets.

147. Express Scripts uses a three-pronged attack against Retail Pharmacies. First, it under-reimburses Retail Pharmacies by coercing them into contracts with exceedingly low – often below-cost – reimbursement rates. Second, Express Scripts imposes exorbitant and constantly-increasing administrative fees and other egregious contract terms upon them. Third, it regularly imposes oppressive and often mysterious fees and adjustments that are assessed and "clawed back" weeks or months after the drug is dispensed to the consumer with little or no explanation or notice.

Under-reimbursement

148. Express Scripts' position as a massive buyer prompts Ohio Retail Pharmacies to agree to reimbursement levels far lower than they would ever entertain in a competitive market.

149. Moreover, through the manipulation of generic drug rates – or MAC pricing – Retail Pharmacies are actually often dispensing drugs below cost.

150. The magnitude of Express Scripts' market power and the devastating effect of its practice of forcing Retail Pharmacies to swallow below-cost reimbursement rates was revealed with striking clarity in September 2022, when large national grocer and Retail Pharmacy chain The Kroger Co. announced its withdrawal from all Express Scripts networks for commercial customers effective December 31, 2022. Kroger's announcement explained that "[t]he Express Scripts contract would have required Kroger to fill our customers' prescriptions below our cost of operation…." Significantly, Kroger estimated that the loss of Express Scripts Covered Lives for the remainder of the fiscal fourth quarter – *only one month* – would reduce sales revenue by approximately $100 million.

151. Upon information and belief, Express Scripts is coordinating with Ascent to remove Kroger, as a PBM exclusively for its own employees, from being an Ascent customer in retaliation for Kroger withdrawing from Express Scripts networks.

152. While Kroger's position as one of the nation's largest grocery chains, with over 2,700 stores and more than $137 billion in revenue in 2021, allows it to survive the loss of $100 million in revenue in a single month in order to stand up to Express Scripts' onerous demands, there are few Retail Pharmacies that can do so.

153. Not only are the reimbursement rates that Express Scripts demands that Retail Pharmacies accept exceedingly low in the first instance, but the problem is compounded by Express Scripts' customary reservation of a contractual right to lower these rates even further – without notice – at its whim. For example, a 2019 rate amendment to a Retail Pharmacy's

Provider Agreement contains the following term: "ESI has the right to passively amend any portion or all of any rate exhibit with prior written notice."

Fees, audits, and other onerous contract terms

154. The great imbalance in bargaining power in Express Scripts' favor also yields contracts with Retail Pharmacies that contain egregious fees and penalty provisions that the latter are powerless to reject due to the devastating consequences of losing access to Express Scripts' Covered Lives.

155. Express Scripts demands that Retail Pharmacies agree to give it virtually unbridled audit rights. It frequently audits the pharmacies in its networks with little or no notice, and often withholds significant funds on the basis of small, hyper-technical errors.

156. Many of the fee and penalty provisions to which Express Scripts requires Retail Pharmacies to acquiesce are far too vague for the Retail Pharmacy to have any meaningful way of assessing the real costs and benefits of the provision. But the Retail Pharmacies cannot push back and insist on more certainty, as Express Scripts' market power allows it the luxury of taking a take-it-or-leave-it stance. For example, one 2015 Pharmacy Provider Agreement between Express Scripts and an Ohio Retail Pharmacy included this murky fee provision: "…for every transaction a Provider (or its Pharmacy(ies)) transmits to ESI, ESI shall charge such Provider a service fee of *up to an average of* $0.15 per transaction." (Emphasis added.) By 2021, Express Scripts had not only maintained this vague and self-serving language, but had doubled the maximum charge to $0.30.

Clawbacks

157. The third tactic Express Scripts uses to extract supracompetitive revenue from Retail Pharmacies and to steer more Covered Patients to its mail order pharmacy is known as a "Clawback."

158. A Clawback occurs when a PBM demands the return of money that has been paid, or has been promised to be paid, to Retail Pharmacies after the point of sale to a Covered Patient (or "Adjudication").

159. Express Scripts, using its bargaining leverage as one of the nation's largest PBMs, has been able to force Retail Pharmacies to turn over increasing Clawbacks, which further contribute to Express Scripts' bottom line. At all relevant times addressed in this Complaint, it has regularly and frequently engaged in Clawbacks in its dealings with the Retail Pharmacies in its networks. Express Scripts' Clawbacks generally take one of the following three forms.

160. *Clawbacks attributed to a specific claim:* Express Scripts pays or promises to pay a Retail Pharmacy an amount certain at Adjudication via a computer transaction that occurs when a Covered Patient appears at the pharmacy counter to pick up a prescription. But on numerous occasions during the time period addressed in this Complaint and continuing to the present, Express Scripts reduces the amount to which the Retail Pharmacy is entitled for that particular adjudicated claim at some date after Adjudication, either by requiring a payment back from the Retail Pharmacy, or by reducing Express Scripts' next payment to the Retail Pharmacy.

161. Clawbacks of specific claims often occur weeks or months after Adjudication and constitute a fee that cannot be determined at the time of Adjudication.

162. *Clawbacks assessed on a lump-sum basis:* On numerous occasions during the time period addressed in this complaint and continuing to the present, Express Scripts reduces

the amount to which a Retail Pharmacy is entitled to be paid for an aggregated set of prescriptions with a variety of assessed amounts and reasons comprising a lump-sum Clawback. The prescriptions, amounts, and reasons are not itemized or identified.

163. Lump-sum Clawbacks often occur weeks or months after Adjudication and constitute a fee that cannot be determined at the time of Adjudication.

164. *Clawbacks assessed pursuant to a BER or GER contract provision:* Some Express Scripts contracts with Retail Pharmacies set reimbursement rates using BER (brand effective rate) or GER (generic effective rate) methodologies. A BER provision dictates that claims for branded drug reimbursement from a pharmacy or a group of pharmacies will be reimbursed at an effective rate of Average Wholesale Price ("AWP") minus a stated percentage.

165. At the end of the year, or at other regular intervals, Express Scripts examines whether the pharmacy or group of pharmacies have been underpaid or overpaid relative to the BER. If the Retail Pharmacy or group of pharmacies has been reimbursed at an effective rate of AWP minus *less than* the stated percentage on brand drugs over the past year, it is deemed to have been overpaid and Express Scripts requires it to repay the difference between the amount it received and an aggregate payment of AWP minus the stated percentage in the contract.

166. Express Scripts' GER provisions operate in the same manner for generic drugs.

167. Agreements containing BER and GER provisions may make assessments on the basis of data aggregated from numerous Retail Pharmacies and numerous payor types. For this reason, it is extremely difficult for an individual pharmacy or group of pharmacies to trace the effect of a particular provider, payor type, or claim on any amount that is ultimately clawed back by Express Scripts long after Adjudication of any of the individual claims that are rolled up into the BER or GER calculation.

168. An Ohio statute, R.C. §3959.20 (the "Claims Statute"), prohibits a PBM from doing either of the following: (1) Retroactively adjusting "a pharmacy claim for reimbursement for a prescription drug unless the adjustment is the result of . . . (a) A pharmacy audit conducted in accordance with R.C. §§3901.811 to 3901.814 [or] (b) A technical billing error" (R.C. §3959.20 (C)(1)); or (2) Charging "a fee related to a claim unless the amount of the fee can be determined at the time of claim adjudication." (R.C. §3959.20(C)(2)).

169. All three of the types of Clawbacks employed by Express Scripts against Ohio Retail Pharmacies violate both subparts of the Claims Statute (R.C. §3959.20 (C)(1) and (C)(2)).

170. Express Scripts' brazen use of Clawbacks, an unlawful means of extracting supracompetitive revenues from Ohio Retail Pharmacies, and driving some of them from the market entirely, in order to capture more Covered Lives for its mail order pharmacy business demonstrates that it believes its market power to be impenetrable, and reveals the lengths to which it will go to ensure that it remains so.

171. As a direct result of Express Scripts' exercise of market power – its extreme market power over the purchase of pharmaceutical medications – Retail Pharmacies in Ohio are struggling to survive. Many are exiting the market entirely, creating "pharmacy deserts" in the State where vulnerable populations – the poor, the elderly, the chronically or seriously ill – are deprived of reasonable access to a local pharmacy and the guidance of a local pharmacist.

172. One Retail Pharmacy chain with 45 stores in Ohio has halted all plans to include pharmacies in its future Ohio locations in part because plummeting reimbursements and skyrocketing administrative fees have made the losses from its pharmacy operations simply too unprofitable to be viable.

173. Express Scripts' ability to dictate price and terms to Retail Pharmacies and to change the rules of the game at its whim, along with the Retail Pharmacies' acquiescence to those often financially disastrous terms and actions, are striking evidence of Express Scripts' unbridled power.

Express Scripts and its competitor Prime Therapeutics band together to form Ascent to preserve the scheme when Congress and media attention threaten to undermine it

174. In early 2019, Express Scripts sensed a threat to its chokehold on the pharmaceutical distribution and payment system, and hence to its rich revenue stream. In January, the U.S. Department of Health and Human Services proposed a rule that would eliminate the safe harbor exemption from anti-kickback rules for post-point-of-sale Rebates for prescription drugs. Moreover, at that time the Lower Health Care Costs Act was under debate in Congress. That legislation included transparency language that further threatened Express Scripts' lucrative, opaque business model.

175. Express Scripts actively and vehemently opposed these proposals, as its highly-profitable business model was in jeopardy.

176. But in addition to lobbying against these proposed statutory and regulatory changes, Express Scripts scrambled to find a way to protect its revenue stream in the event such changes came to fruition. In May 2019, it launched Ascent, a group purchasing organization ("GPO") that it hoped would shield the Rebate system from being upended by looming governmental action. In order to further shield its activities, portions of Ascent's operations were moved to Switzerland. In addition to sheltering Express Scripts from the fallout from possible PBM reform in Congress, Ascent served as another middleman inserted into the

already-complicated drug distribution process, making the negotiation and pass-through of Rebates even less transparent and harder for Plan Sponsors to audit.

177. Express Scripts soon realized Ascent's potential to magnify its pay-to-play revenue even more. It began talks with rival PBM Prime Therapeutics to join forces in a "three-year collaboration" that was announced on December 19, 2019. Prime Therapeutics joined Ascent's ownership at or about that time. The joint press release described the combination as enhancing "pharmaceutical manufacturer value" – in other words, the companies' combined Covered Lives would create increased clout that would intensify the pressure on Manufacturers to pay even greater Rebates or "value." Despite the original three-year term, the collaboration agreement contemplated that there would be multiple extensions, carrying the deal forward indefinitely.

178. Just one month before announcing that Prime Therapeutics joined Ascent's ownership, Express Scripts assigned its commercial rebate agreement with at least one major manufacturer to Ascent.

179. Express Scripts and Prime Therapeutics trumpeted their new alliance as an important step towards delivering "more affordable health care." But in reality, the alliance between these two competitors has further escalated out-of-pocket drug costs to many Ohioans, while Express Scripts and Prime Therapeutics reap the true benefits. It added roughly 28 million Covered Lives to Express Scripts' bargaining leverage, making Express Scripts' power in the marketplace even more formidable than before.

180. Ascent has played a key role in the Express Scripts/Prime Therapeutics arrangement from the outset. The terms of the collaboration provide that Rebate negotiations

with Manufacturers for drugs covered by a commercial Plan Sponsor's pharmacy benefit are handled jointly by Ascent.

181. The practical function of Ascent is largely to help Express Scripts, Prime Therapeutics, and potentially other PBMs to consolidate their Rebate scheme and grant the PBMs even greater bargaining leverage, with the benefits flowing to the PBMs' bottom lines. This fact is perhaps best illustrated by the fact that the Ascent Rebate agreements contain substantially the same framework that Express Scripts so successfully utilized.

182. First, Ascent is compensated through administrative fees and Rebates paid by Manufacturers that are calculated as a percent of List Price.

183. Second, Rebate amounts depend upon a product's Formulary status, and Formulary eligibility and status depends upon a Manufacturer's Rebate bid.

184. Third, Ascent protects its Rebates and margins by requiring Manufacturers to sign inflation agreements or provide inflation guarantees that ensure Ascent – and by extension, the PBMs – is shielded from rising prices.

185. Fourth, Ascent requires parties to agree to broad confidentiality provisions that extend to wide categories of information, including the terms of the Rebate agreement and even the existence of the agreement itself.

186. Having joined forces to increase their marketplace clout with both Manufacturers and Retail Pharmacies, Express Scripts and Prime Therapeutics saw an opportunity for even greater power. Under their ownership and control, Ascent solicited other PBMs to become customers, further ratcheting their negotiating leverage upward by adding more and more Covered Lives.

187. Through Ascent, Express Scripts and other PBMs can continue to obscure the fees contained in the black box by further complicating the web of relationships and adding additional layers to shield their behavior from customer and regulatory scrutiny.

The Express Scripts-Prime Therapeutics alliance provides an effective price-fixing tool

188. After uniting under the Ascent banner, Express Scripts and Prime Therapeutics soon learned that increased leverage in the marketplace was not the only profitable by-product of the collaboration. Ascent was, they realized, the perfect vehicle with which to harmonize and increase drug prices, Rebates, fees, and Retail Pharmacy reimbursements. Eventually, certain Ascent customers – such as Defendant Humana Pharmacy Solutions – also participated in and benefited from this combination.

189. In 2021, Prime Therapeutics President and CEO Ken Paulus, stated publicly in an interview with *Managed Healthcare Executive:* "We were 15% behind the marketplace on cost of goods sold, easily, maybe more. So we needed a crystallizing event. This [the formation of Ascent] definitely served as that event." Moreover, Paulus made clear that the formation of Ascent allowed Prime Therapeutics to harmonize its prices and terms with those of its rival Express Scripts with respect to both Manufacturers and Retail Pharmacies, explaining: "Cost of goods sold is broken into two pieces. It's the rebates in pharmacy and buying medications and its pharmacy dispensing and the networks, if you will. We were off on both of those."

190. Paulus's statements in that interview leave little doubt that a significant purpose of the collaboration with Express Scripts was to depress reimbursement rates paid to Retail Pharmacies and to increase the administrative fees charged to those pharmacies by Prime Therapeutics. He stated that Prime Therapeutics was "…the highest paying retail pharmacy

network pharmacy payer in the marketplace. We realized, wow, we probably need to sharpen our pencil there a little bit."

191. The process of harmonizing and increasing prices and fees (and suppressing reimbursement rates) was not a one-time adjustment by Prime Therapeutics upon joining forces with its competitor. On the contrary, Paulus described an ongoing process of harmonizing prices and terms between the competitors that has continued after the "crystallizing event," saying: "Again, it's not that we're sitting down and strategizing with [Express Scripts], but we are taking advantage of alignment when it occurs, opportunistically." Clearly, the creation of Ascent has allowed these two rivals and other competitors to "align" their prices and terms with ease, eliminating competition between them, without the need for lengthy strategy sessions or exchanges of price lists.

Harm

192. Express Scripts exercises its power to restrain and prevent competition for PBM services and Retail Pharmacy services, thus harming Ohio's uninsured, underinsured, and those whose co-pays are calculated based upon a percentage of List Prices of the prescription drugs they purchase. This harm comes in the form of higher out-of-pocket prices for these drugs. As of 2019, roughly 30% of Americans who had prescription drug coverage through their employers were enrolled in high-deductible health plans (HDHP), which (according to the IRS definition) carry with them an annual deductible of at least $1,400 for an individual or at least $2,800 for a family, a heavy burden for employees who likely enrolled in HDHPs mainly for the purpose of making their premiums more affordable.

193. The collusive conduct of Express Scripts, Prime Therapeutics, Cigna, Evernorth, Humana Pharmacy Solutions, Humana, and Ascent described herein has denied Ohio's

uninsured, underinsured, and those whose co-pays are calculated based upon a percentage of List Prices of the prescription drugs they purchase, the benefits of free and unrestricted competition in the marketplace by suppressing the information and transparency that would allow meaningful comparisons among competing PBMs, and by forming and carrying out agreements with Manufacturers that have the purpose and effect of fixing and increasing the out-of-pocket prices these individuals must pay for their prescription drugs, and denying these individuals access to the most efficacious and best-in-class medications.

194. The collusive conduct of Express Scripts, Prime Therapeutics, Cigna, Evernorth, Humana Pharmacy Solutions, Humana, and Ascent described herein has denied Ohio Plan Sponsors the benefits of free and unrestricted competition in the marketplace by suppressing the information and transparency that would allow meaningful comparisons among competing PBMs, and by forming and carrying out agreements with Manufacturers that have the purpose and effect of fixing and increasing the quality-adjusted prices paid by Plan Sponsors.

195. Higher out-of-pocket obligations create serious risks to the health of Ohio's uninsured, underinsured, and those whose co-pays are calculated based upon a percentage of List Prices of the prescription drugs they purchase. As out-of-pocket obligations increase, adherence to medication routines often decreases, including non-compliance or drug rationing. Studies show that if out-of-pocket obligations increase by $50.00, patients are four times more likely to stop taking their medication completely. Ohioans have, therefore, suffered significant physical harm – even death – as a result of Defendants' conduct described herein.

196. Express Scripts' exercise of its market power and the collusive conduct of Express Scripts, Prime Therapeutics, Cigna, Evernorth, Humana Pharmacy Solutions, Humana, and Ascent involving Formulary exclusions and the pay-to-play system of which they are a part

at times lead to non-medical switching – the change from a patient's originally prescribed drug to another medication for reasons other than efficacy. In some cases, patients who are stable and responding favorably on a prescribed drug cannot be switched to an alternative drug without negative health consequences. While patients can, in theory, get coverage for excluded drugs, Defendants generally require prior authorization – a lengthy and difficult process that the sickest and most vulnerable Ohio patients find difficult or impossible to endure. Thus, Defendants' conduct described herein has caused physical harm to such individuals.

197. Express Scripts' exercise of its market power and the collusive conduct of Express Scripts, Prime Therapeutics, Cigna, Evernorth, Humana Pharmacy Solutions, Humana, and Ascent involving the pay-to-play system and the denial of favorable Formulary tier placement to more efficacious, safer, more innovative, or more cost-effective drugs at times leads to patients being denied the benefits of the best drug for their health and well-being.

198. Express Scripts' exercise of its market power, and the collusive conduct of Express Scripts, Prime Therapeutics, Cigna, Evernorth, Humana Pharmacy Solutions, Humana, and Ascent have caused harm to competitive pharmaceutical markets in Ohio by destroying transparency and eliminating the proper flow of information needed for markets to operate an allocate resources efficiently.

199. Express Scripts' exercise of its market power has harmed competitive pharmaceutical markets in Ohio by causing a drastic loss of independent and small regional pharmacies in the state, reducing consumer choice and creating significant hardships to those Ohioans in rural communities where the only pharmacy within a reasonable distance was an independent driven out of the market by Express Scripts' oppressive and abusive exercises of power.

200. For example, Kaiser Health News recently reported:

> "In 2018, Novo Nordisk, amid public rancor over rising insulin prices, considered a 50% cut, according to the report. But the company's board decided against it, noting that 'many in the supply chain will be negatively affected ($) and may retaliate.' The company also feared that irate insurers might retaliate against Novo's blockbuster diabetes and weight-loss drugs like Ozempic, which compete against Lilly's Mouniaro." (*Why Does Insulin Cost So Much? Big Pharma Isn't the Only Player Driving Prices*, Mar. 9, 2023, available at https://khn.org/news/article/insulin-costs-pharmacy-benefit-managers-drug-manufacturers/)

201. Express Scripts' powerful position at or near the top of this highly-concentrated market and its anticompetitive acts and agreements – solely and in combination with its co-Defendants – have not only inflicted the forgoing harms on Ohio and its markets, but they have also allowed it to reap supracompetitive profits. Its gross profit on an adjusted prescription averaged $4.16 in 2012, and $6.68 in 2015, an increase of roughly 62% in just three years following the Medco merger and the institution of the new Master Agreement with Manufacturers. Its gross profits skyrocketed from $3.2 billion in 2011 (the year before the Medco merger and the start of the new Master Agreement) to $8.4 billion in 2015. The other Defendants have similarly enjoyed supracompetitive process due to the above-referenced combination.

202. Defendants' actions as described in this Complaint are continuous and inflict continuing and accumulating harm.

CAUSES OF ACTION

Count I
Combination by Express Scripts, Cigna, and Evernorth to fix prices for prescription drugs in violation of the Valentine Act

203. Plaintiff incorporates by reference each and every allegation contained the above Paragraphs as if fully set forth herein.

204. Plaintiff brings this action pursuant to Sections 109.81, 1331.01, 1331.03, 1331.04, 1331.06, and 1331.11 of the Ohio Revised Code and the common law of Ohio for equitable and injunctive relief.

205. The Defendants Express Scripts, Cigna, and Evernorth have engaged in a combination of capital, skill, or acts to create or carry out restrictions in trade or commerce or to fix and raise prices of numerous drugs, including but not limited to insulin.

206. This combination had the purpose of creating or carrying out restrictions in trade or commerce and establishing the List Price of such drugs so as to preclude free competition in the sale of these drugs.

207. This combination constitutes an unlawful trust under Ohio's Valentine Act, R.C. Section 1331.01(C)(1)(a), (d) and (e).

208. This combination constitutes a conspiracy against trade under R.C. Section 1331.04 and thus is illegal.

209. Ohio purchasers of drugs who are uninsured, under-insured, or have co-pays or deductibles calculated on the basis of List Price of the prescribed drugs have been injured because of the supracompetitive prices of drugs set by this combination.

210. Defendants Express Scripts, Cigna, and Evernorth have realized and enjoyed ill-gotten gains as a direct result of the increased Rebates the Manufacturers are required to pay under

agreements with Defendant Express Scripts, resulting in supracompetitive List Prices, and as a further direct result of Defendant Express Scripts' deceptive tactics in mischaracterizing Rebates received in order to avoid passing those Rebates on to Ohio Plan Sponsors.

211. Defendant Express Scripts' agreements that are the result of an illegal trust are void pursuant to R.C. §1331.06.

212. Defendants Express Scripts, Cigna, and Evernorth have engaged in one or more overt acts in furtherance of the combination alleged herein.

213. Such conduct will likely continue or recur in the absence of appropriate injunctive relief.

Count II
Combination by Defendant Prime Therapeutics to fix prices for prescription drugs in violation of the Valentine Act

214. Plaintiff incorporates by reference each and every allegation contained in the above Paragraphs as if fully set forth herein.

215. Plaintiff brings this action pursuant to Sections 109.81, 1331.01, 1331.03, 1331.04, 1331.06, and 1331.11 of the Ohio Revised Code and the common law of Ohio for equitable and injunctive relief.

216. Defendant Prime Therapeutics has entered into, maintained, and acted in accordance with a combination of capital, skill, or acts to create or carry out restrictions in trade or commerce or fix and raise prices of numerous drugs, including but not limited to insulin.

217. Defendant Prime Therapeutics' combination had the purpose of establishing the List Price of such drugs so as to preclude free competition in the sale of these drugs.

218. Defendant Prime Therapeutics' combination constitutes an unlawful trust under Ohio's Valentine Act, R.C. Section 1331.01(C)(1)(a), (d) and (e).

219. Defendant Prime Therapeutics' combination constitutes a conspiracy against trade under R.C. Section 1331.04 and thus is illegal.

220. Ohio purchasers of drugs who are uninsured, under-insured, or have co-pays or deductibles calculated on the basis of List Price of the prescribed drugs have been injured because of the supracompetitive prices of drugs set by Defendant Prime Therapeutics' combination.

221. Defendant Prime Therapeutics has realized and enjoyed ill-gotten gains as a direct result of the increased Rebates the Manufacturers are required to pay under agreements with Defendant Prime Therapeutics, resulting in supracompetitive list prices, and as a further direct result of Defendant Prime Therapeutics' deceptive tactics in mischaracterizing Rebates received in order to avoid passing those Rebates on to Ohio Plan Sponsors.

222. Defendant Prime Therapeutics' agreements that are the result of an illegal trust are void pursuant to R.C. §1331.06.

223. Defendant Prime Therapeutics has engaged in one or more overt acts in furtherance of the conspiracy alleged herein.

224. Such conduct will likely continue or recur in the absence of appropriate injunctive relief.

Count III

Unlawful combination among Express Scripts, Prime Therapeutics, Humana Pharmacy Solutions, Humana, and Ascent to increase the price of prescription drugs, to place the management and control of such combination in the hands of a trustee, and to preclude free and unrestricted competition among themselves in violation of the Valentine Act

225. Plaintiff incorporates by reference each and every allegation contained in the above Paragraphs as if fully set forth herein.

226. Plaintiff brings this action pursuant to Sections 1331.01, 1331.02, 1331.03, 1331.04, 1331.06, and 1331.11 of the Ohio Revised Code and the common law of Ohio for equitable and injunctive relief.

227. Beginning at least as early as December 2019 and continuing in some cases through the present, the Defendants Express Scripts, Prime Therapeutics, Humana Pharmacy Solutions, Humana, and Ascent have engaged in a combination of capital, skill, or acts to create or carry out restrictions in trade or commerce or to fix, harmonize, and raise prices of numerous drugs, including but not limited to insulin.

228. Defendants' combinations had the purpose of creating or carrying out restrictions in trade or commerce for the purpose of establishing the List Price of such drugs so as to preclude free competition in the sale of these drugs.

229. Defendants' combinations constitute unlawful trusts under Ohio's Valentine Act, R.C. Section 1331.01(C)(1)(d), (e), and (f).

230. Defendants' combinations have the purpose and effect of placing the management and control of their trusts, and the products and services controlled by them, in the hands of a trustee – Defendant Ascent – with the intent of restraining trade, fixing the price of drugs and diminishing the output of retail pharmacy services, in violation of R.C. Section 1331.02.

231. Defendants' combination also is established for the purpose of excluding from their Formularies the drugs of Manufacturers that refuse to increase the Rebates, fees or "value" paid to Defendants, and to increase the List Prices of their drugs, thus violating R.C. Section 1331.01(C)(1)(f).

232. Defendant Ascent is a foreign corporate entity under R.C. Section 1331.01(C)(1)(f).

233. Defendants' combinations constitute conspiracies against trade under R.C. Section 1331.04 and thus are illegal.

234. Ohio purchasers of these drugs who are uninsured, under-insured, or have co-pays or deductibles calculated on the basis of List Price of the prescribed drugs have been injured because of the supracompetitive prices of these drugs set by Defendants' agreements.

235. Defendants have realized and enjoyed ill-gotten gains as a direct result of the increased Rebates, fees, or "value" the Manufacturers are required to pay under agreements with Defendants, resulting in supracompetitive List Prices, and as a further direct result of Defendants' deceptive tactics in mischaracterizing Rebates received in order to avoid passing those Rebates on to Ohio Plan Sponsors.

236. Defendants' agreements that are the result of an illegal trust are void pursuant to R.C. §1331.06.

237. Defendants have engaged in one or more overt acts in furtherance of the conspiracy alleged herein.

238. Such conduct will likely continue or recur in the absence of appropriate injunctive relief.

COUNT IV
Deceptive Acts by Express Scripts
in violation of the Deceptive Trade Practices Act

239. Plaintiff incorporates by reference each and every allegation contained in the above Paragraphs as if fully set forth herein.

240. Defendant Express Scripts, at all times relevant to this action, is and was a "person" as defined by R.C. 4165.01(D).

241. The State of Ohio and its public entities, including all public entities that offer employee benefit plans that include prescription drug benefits, are "persons" as defined by R.C. 4165.01(D).

242. Defendant Express Scripts has knowingly and willfully made repeated misrepresentations to Ohio Plan Sponsors regarding the characteristics and benefits of the PBM Services that it sold to such Ohio Plan Sponsors.

243. On information and belief, Defendant Express Scripts has knowingly and willfully made repeated misrepresentations to Ohio Plan Sponsors regarding the quality of the PBM Services that it sold to such Ohio Plan Sponsors.

244. On information and belief, Defendant Express Scripts has knowingly and willfully made false statements of fact to Ohio Plan Sponsors concerning the reasons for, existence of, or amounts of price reductions it was securing on behalf of, and passing on to, Ohio Plan Sponsors.

245. Defendant Express Scripts' misrepresentations and misleading statements constitute deceptive trade practices which are in violation of R.C. 4165.02.

246. The Attorney General has standing to bring this action in his capacity as *parens patriae* to enjoin and remedy the wrongful and deceptive acts described herein that have been perpetrated upon Ohio Plan Sponsors that have resulted in harm to the State's general economy and to a substantial segment of its natural person residents.

247. Unless enjoined, Defendant Express Scripts is likely to continue to commit the wrongful and deceptive acts described herein against Ohio Plan Sponsors, and such acts will likely continue to result in harm to the State's general economy and to a substantial segment of its natural person residents.

Count V
Declaratory Judgment and Injunctive Relief

248. Plaintiff incorporates by reference each and every allegation contained in the above Paragraphs as if fully set forth herein.

249. As alleged in detail in this Complaint, Defendant Express Scripts regularly and systematically adjusts pharmacy claims for reimbursement for prescription drugs retroactively under circumstances other than a pharmacy audit conducted in accordance with R.C. §§ 3901.811-3901.814 or a technical billing error.

250. As alleged in detail in this Complaint, Defendant Express Scripts regularly and systematically charges fees related to pharmacy claims in a manner in which the amount of the fee cannot be determined at the time of the claim adjudication.

251. The Attorney General is entitled to a declaration that such retroactive adjustments and fees constitute violations of R.C. §3959.20(C)(1) and (2).

252. Defendant Express Scripts should be permanently enjoined from obtaining illegal Clawbacks in violation of Ohio law.

253. Declaratory relief from this Court will resolve these controversies and limit the uncertainties created by Defendant's actions.

Count VI
Unjust Enrichment

254. Plaintiff incorporates by reference each and every allegation contained in the above Paragraphs as if fully set forth herein.

255. As a result of the conduct described in this Complaint, Defendants Express Scripts, Prime Therapeutics, Cigna, Evernorth, Humana Pharmacy Solutions, Humana, and Ascent have received certain funds to which they were not entitled.

256. By their acts described in this Complaint, Defendants Ascent, Express Scripts, Prime Therapeutics, Cigna, Evernorth, Humana Pharmacy Solutions, and Humana have been unjustly enriched at the expense of uninsured and underinsured consumers in the State of Ohio, as well as at the expense of Ohio consumers whose out-of-pocket expenditures for prescription drugs are calculated on the basis of Manufacturers' List Prices, under circumstances dictating that, in equity and good conscience, the money should be returned to such consumers.

Count VII
Civil Conspiracy

257. Plaintiff incorporates by reference each and every allegation contained in the above Paragraphs as if fully set forth herein.

258. The conduct described in this complaint, engaged in in concert by Defendants Express Scripts, Prime Therapeutics, Cigna, Evernorth, Humana Pharmacy Solutions, Humana, and Ascent, constitutes a malicious combination and conspiracy with the purpose and effect of injuring uninsured and underinsured consumers in the State of Ohio, as well Ohio consumers whose out-of-pocket expenditures for prescription drugs are calculated on the basis of Manufacturers' List Prices.

259. Defendants have engaged in one or more overt acts in furtherance of the conspiracy alleged herein.

260. Such conduct will likely continue or recur in the absence of appropriate injunctive relief.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff State of Ohio prays as follows:

A. That the Court adjudge that the combinations and agreements engaged in by and among Defendants to raise the List Price of prescription drugs in exchange for preferred Formulary

placement constitute unlawful combinations or conspiracies in unreasonable restraint of trade in violation of the Valentine Act, R.C. 1331.01 and 1331.04;

B. That the Court adjudge that the combinations and agreements engaged in by and among Defendants and their co-conspirators to constitute an unlawful combination or conspiracy in violation of the Valentine Act, R.C. 1331.01 and 1331.04;

C. That the Court adjudge that Defendant Express Scripts has willfully engaged in a trade practice listed in division (A) of R.C. 4165.02 knowing it to be deceptive;

D. That the Court enter a declaratory judgment finding that Express Scripts' practice of extracting Clawbacks from pharmacies violates R.C. §3959.20(C)(1) and (2);

E. For an award of attorneys' fees, costs, and interest as permitted by law;

F. That the Court enter a permanent injunction in such form that the Court deems just and proper and reasonably necessary for the purpose of restraining Defendants and anyone acting in concert with them from further violating the Valentine Act, R.C. 1331.01 *et seq.*;

G. For a permanent injunction restraining Defendant Ascent from: Communicating or agreeing to communicate competitively sensitive information of any PBM to a competing PBM unless such information is: (a) greater than three months old, (b) is communicated to the competitor(s) in a manner that does not identify the party conveying the information, and (c) is aggregated or summary information;

H. For an order requiring Defendant Express Scripts to forfeit to the State, pursuant to R.C. §1331.03, the sum of $500 per day for each day that the combinations described herein were in effect;

I. For an order requiring Defendant Prime Therapeutics to forfeit to the State, pursuant to R.C. §1331.03, the sum of $500 per day for each day that the combinations described herein were

in effect;

J. For an order requiring Defendant Cigna to forfeit to the State, pursuant to R.C. §1331.03, the sum of $500 per day for each day that the combinations described herein were in effect;

K. For an order requiring Defendant Evernorth to forfeit to the State, pursuant to R.C. §1331.03, the sum of $500 per day for each day that the combinations described herein were in effect;

L. For an order requiring Defendant Humana Pharmacy Solutions to forfeit to the State, pursuant to R.C. §1331.03, the sum of $500 per day for each day that the combinations described herein were in effect;

M. For an order requiring Defendant Humana to forfeit to the State, pursuant to R.C. §1331.03, the sum of $500 per day for each day that the combinations described herein were in effect;

N. For an order requiring Defendant Ascent to forfeit to the State, pursuant to R.C. §1331.03, the sum of $500 per day for each day that the combinations described herein were in effect;

O. For an Order requiring each Defendant to disgorge all ill-gotten proceeds said Defendant derived from engaging in the unlawful conspiracies against trade described in this Complaint; and

P. Such other relief as the Court may deem appropriate.

Dated: March 27, 2023

Respectfully Submitted,
DAVE YOST
Ohio Attorney General (0056290)
SHAWN BUSKEN (0083585)
Deputy First Assistant Attorney General

/s/Charles M. Miller
CHARLES MILLER (0073844)
Deputy Attorney General for Major Litigation
(Trial Attorney)
JENNIFER L. PRATT (0038916)
Director of Major Litigation
30 East Broad Street, 17th Floor
Columbus, Ohio 43215
Telephone: (614) 752-8237
Fax: (614) 466-5087
Charles.Miller@OhioAGO.gov
Jennifer.Pratt@OhioAGO.gov

Beth A. Finnerty (0055383)
Section Chief, Antitrust Section
Edward J. Olszewski (0082655)
Principal Assistant Attorney General, Antirust Section
Jason W. Palmer (0088336)
Senior Assistant Attorney General,
Antitrust Section
30 East Broad Street, 26th Floor
Columbus, Ohio
Telephone; (614) 466-4328
Fax: (614) 995-0266
Beth.Finnerty@OhioAGO.gov
Edward.Olszewski@OhioAGO.gov
Jason.Palmer@OhioAGO.gov

Counsel for the State of Ohio, ex rel., Attorney General Dave Yost

HB357.XOver.LOS.pdf
Uploaded by: Heather Forsyth
Position: FAV

ANTHONY G. BROWN
Attorney General

CANDACE MCLAREN LANHAM
Chief of Staff

CAROLYN QUATTROCKI
Deputy Attorney General

WILLIAM D. GRUHN
Chief
Consumer Protection Division

Writer's Fax No.
410.576.6571

STATE OF MARYLAND
OFFICE OF THE ATTORNEY GENERAL
CONSUMER PROTECTION DIVISION

Writer's Direct Dial No.
410.576.6513

March 28, 2023

TO: The Honorable Melony Griffith, Chair and
Members of the Senate Finance Committee

FROM: Office of the Attorney General
Health Education and Advocacy Unit

RE: HB357 (On Crossover) – Pharmacy Benefits Managers - Definition of Purchaser and Alteration of Application of Law: **Support**

The Office of the Attorney General's Health Education and Advocacy Unit (HEAU) supports House Bill 357, which allows the State to apply various pharmacy benefit consumer protections (and independent pharmacy protections) to Pharmacy Benefit Managers (PBMs) in accordance with the U.S. Supreme Court decision in *Rutledge v. Pharmaceutical Care Management Association*, 1415 S. Ct. 474 (2020). *In Rutledge*, the Court ruled that the federal Employee Retirement Income Security Act (ERISA) did not preempt Arkansas's law regulating pharmacy benefit managers (PBMs), the intermediaries that administer prescription drug benefits for health plans, "merely because state regulations increase costs or alter incentives [without] forcing plans to adopt any particular scheme of substantive coverage." *Id*. at 480.

Until recently, Subtitle 16 of the Maryland Insurance Article only applied to PBMs when they were acting on behalf of a carrier, and did not apply when the PBM was acting for a self-funded plan exempt from regulation under ERISA because ERISA preempted any state action that placed a direct obligation on the plan itself. However, *Rutledge* recognized that PBMs are not health benefit plans as defined under ERISA and, thus, that the regulation of PBMs is not preempted by ERISA. *Rutledge* confirmed that this is so, even when the purchaser of PBM services is an ERISA plan, as long as the state's regulation of the PBM does not effectively regulate the ERISA plan itself. While that line has been the subject of much litigation, as a general rule this means that state

200 Saint Paul Place ♦ Baltimore, Maryland, 21202-2021
Main Office (410) 576-6300 ♦ Main Office Toll Free (888) 743-0023
Consumer Complaints and Inquiries (410) 528-8662 ♦ Health Advocacy Unit/Billing Complaints (410) 528-1840
Health Advocacy Unit Toll Free (877) 261-8807 ♦ Home Builders Division Toll Free (877) 259-4525 ♦ Telephone for Deaf (410) 576-6372
www.marylandattorneygeneral.gov

laws that direct the decisions of the ERISA plan itself, such as requiring certain benefits, benefit structures, or benefit determinations, are preempted; while state laws regulating PBMs that may also happen to impact ERISA plan costs and design structures or that might result in some lack of uniformity in plan design are not preempted.[1]

This legislation expands the protections the General Assembly has provided regardless of on whose behalf the PBM is acting. HB357 applies these protections without "forcing plans to adopt any particular scheme of substantive coverage." For example, the bill would not allow a PBM to prohibit a pharmacy or pharmacist from telling consumers the retail price of a prescription drug or if a more affordable drug is available, nor require a consumer to use a specific pharmacy if the PBM has an ownership interest in the pharmacy.

Amendments made to the original bill addressed concerns raised by the Maryland Insurance Administration and we urge a favorable report from the committee for HB357.

[1] See also, *Wilke v. Pharmaceutical Care Management Association*, where trade association representing PBMs brought action in North Dakota alleging that ERISA and Medicare Part D preempted ND statutes regulating PBMs. The District Court, 326 F. Supp. 3d 873, entered partial summary judgment in favor of state officials. The Association appealed. The Court of Appeals, 968 F.3d 901, *aff'd* in part, *rev'd* in part, and remanded with directions. On *writ of certiorari*, the Supreme Court vacated and remanded, 141 S. Ct. 1364, directing the lower court to reconsider its decision in light of *Rutledge*. On remand, 18 F. 4th 956, the Court of Appeals held, on the issue of ERISA preemption, that preemption did not apply to the extent that statutes did not require payment of specific benefits or otherwise have impermissible connections with an ERISA plan (rehearing and rehearing *en banc* denied, 2022 WL 419848 (Feb. 11, 2022)).

IPMD - HB 357-2023-Senate.pdf
Uploaded by: James Doyle
Position: FAV

INDEPENDENT PHARMACIES OF MARYLAND

WORKING TOWARDS A STRONGER HEALTH

HB 357 (2023)

Pharmacy Benefit Managers- Definitions of Carrier, ERISA, and Purchaser

Position of Independent Pharmacies of Maryland (IPMD): FAVORABLE

WHAT THIS BILL DOES:

- **This Bill will subject ERISA Pharmacy Benefit Managers (PBMs) to all of the provisions of the Insurance Code, set out in Title 15, subtitle 16, that non-ERISA PBMs must already comply with.** Under this bill, all of the provisions of the Insurance Code dealing with PBMs will apply equally to ERISA PBMs. This bill will treat and regulate PBMs equally under the Insurance Code.

- **This Bill is legally supported by the decision of the U.S. Supreme Court in *Rutledge v. Pharmaceutical Care Management Association*, 141 S. Ct. 474 (2020).** *Rutledge* held, unanimously, that states have broad authority to regulate ERISA PBMs. As a result, states throughout the country are placing ERISA PBMs under state regulation.

- In the 2021 session, in Chapter 358, the General Assembly carved out or exempted ERISA PBMs from several sections of Title 15, subtitle 16 of the Insurance Code, because of claims by the PBMs that the *Rutledge* decision was very limited and did not allow full application of the Insurance Code to ERISA PBMs. To clarify the issue, the General Assembly wisely required an MIA study.

- **The resulting MIA study completely rejected the position of the PBMs that ERISA pre-emption would prohibit or restrict application of Title 15, subtitle 16, to ERISA PBMs:**

  "It is the view of the MIA that, should the legislature elect to make all of the current provisions of Title 15, Subtitle 16 [of the Insurance Code] applicable to PBMs when contracted with an ERISA plan, the enforcement of those laws by the MIA would not be preempted by ERISA. Relying on *Rutledge*, we conclude that none of the Maryland PBM laws if applied to a PBM contracted to an ERISA plan would have an impermissible connection with or an impermissible reference to ERISA plans." MIA report at page 17, emphasis added.

- Passage of this bill is important to independent pharmacies, as it will finally require ERISA PBMs to comply with the same rules as non-ERISA PBMs. As the Fiscal and Policy Note states, passage of this bill will: eliminate gag clauses, where PBMs prohibit pharmacies from giving information on the costs of drugs to consumers; allow choice of a pharmacy by the consumer; equalize reimbursement between independent and PBM affiliated pharmacies; deal with rebate sharing contract requirements; put pharmacy audit rules in place; and other reforms relating to PBM conduct.
- This bill will eliminate the carve-outs and favorable treatment given to PBMs in the 2021 session that were given due to the misstatement of the law by the PBMs, and apply provisions of the Insurance Code equally to ERISA PBMs, as is now clearly permitted by the unanimous decision of the U.S. Supreme Court in *Rutledge.*

NCPA FAV HB 357 Senate.pdf
Uploaded by: Joel Kurzman
Position: FAV

March 29, 2023

The Honorable Melanie Griffith
Chair, Senate Finance Committee
3 East
Miller Senate Office Building
Annapolis, MD 21401

Re: Support for HB 357

Dear Chair Griffith and Members of the Committee:

The National Community Pharmacists Association (NCPA) is writing to express its strong support of the effort to clarify definitions of carrier and purchaser, especially as they would pertain to pharmacy benefit management companies (PBMs) as crafted in HB 357. NCPA represents the interest of America's community pharmacists, including the owners of more than 19,400 independent community pharmacies across the United States and more than 330 independent community pharmacies in Maryland. These pharmacies employed more than 4,000 individuals and they filled nearly 21 million prescriptions in 2021.

With the definition clarifications found in HB 357, the State of Maryland is more closely aligning itself with recent court decisions clarifying a state's ability to regulate pharmacy benefit managers (PBMs) administering benefits for health plans that fall within the scope of federal law known as the Employee Retirement Income Security Act (ERISA). In Rutledge v. PCMA, the Supreme Court held the federal law, the Employee Retirement Income Security Act of 1974 does not prevent states from enacting laws regulating the abusive payment practices of pharmacy benefit managers, the controversial middlemen that manage prescription drug benefits for health insurers, employers and some government programs.[1] *Rutledge* clarified that States may regulate PBMs even when they serve ERISA plans, and ERISA preemption is concerned primarily with State laws only when they "requir[e] payment of specific benefits" or "bind plan administrators to specific rules for determining beneficiary status.'"[2] Typical State laws regulating PBMs do neither of these things—even if they are extended to apply to PBMs when they are serving ERISA plans.

If enacted, HB 357 will ensure both consistency with the highest law of our land and fair reimbursement to community pharmacies in the face of egregious PBM practices recognized by the State's 2021 enactment of HB 601. Further, as noted by the Maryland Insurance Administrator in its 2022 report required by HB 601:

> It is the view of the MIA that, should the legislature elect to make all of the current provisions of Title 15, Subtitle 16 applicable to PBMs when contracted with an ERISA plan, the enforcement of those laws by the MIA would not be preempted by ERISA. Relying on *Rutledge*, we conclude that none of the Maryland PBM laws if applied to a PBM contracted to an ERISA plan would have an

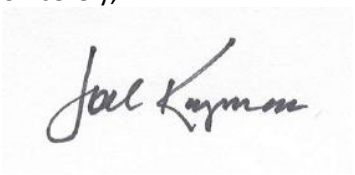
[1] 18-540 Rutledge v. Pharmaceutical Care Management Assn. (12/10/2020) (supremecourt.gov)
[2] *Rutledge*, 141 S. Ct. at 480.

100 Daingerfield Road
Alexandria, VA 22314-2888
703.683.8200 PHONE
703.683.3619 FAX

impermissible connection with or an impermissible reference to ERISA plans. The laws in question are concerned primarily with PBM-pharmacy relationships. They do not require an ERISA plan to pay specific benefits or bind plan administrators to specific rules for determining beneficiary status, adopt particular benefits, force ERISA plans to report detailed information, or otherwise control the benefit design and administration of an ERISA plan. And, they apply whether the PBM is contracted to an ERISA plan or a non-ERISA plan.[3]

We urge your support of HB 357. Thank you for your time and consideration of this important issue. If you have any questions, please do not hesitate to contact me at (703) 600-1186 or joel.kurzman@ncpa.org.

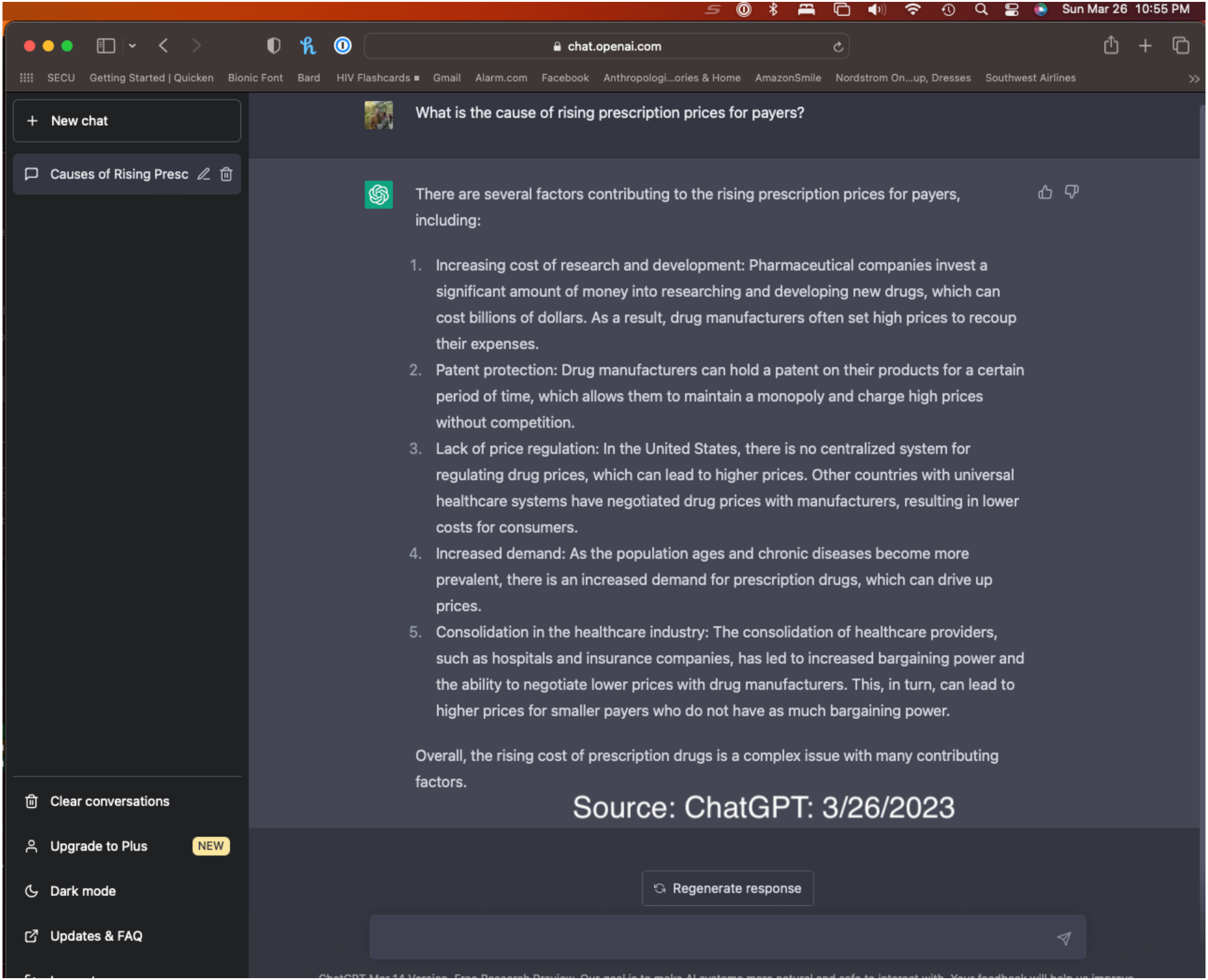
Sincerely,

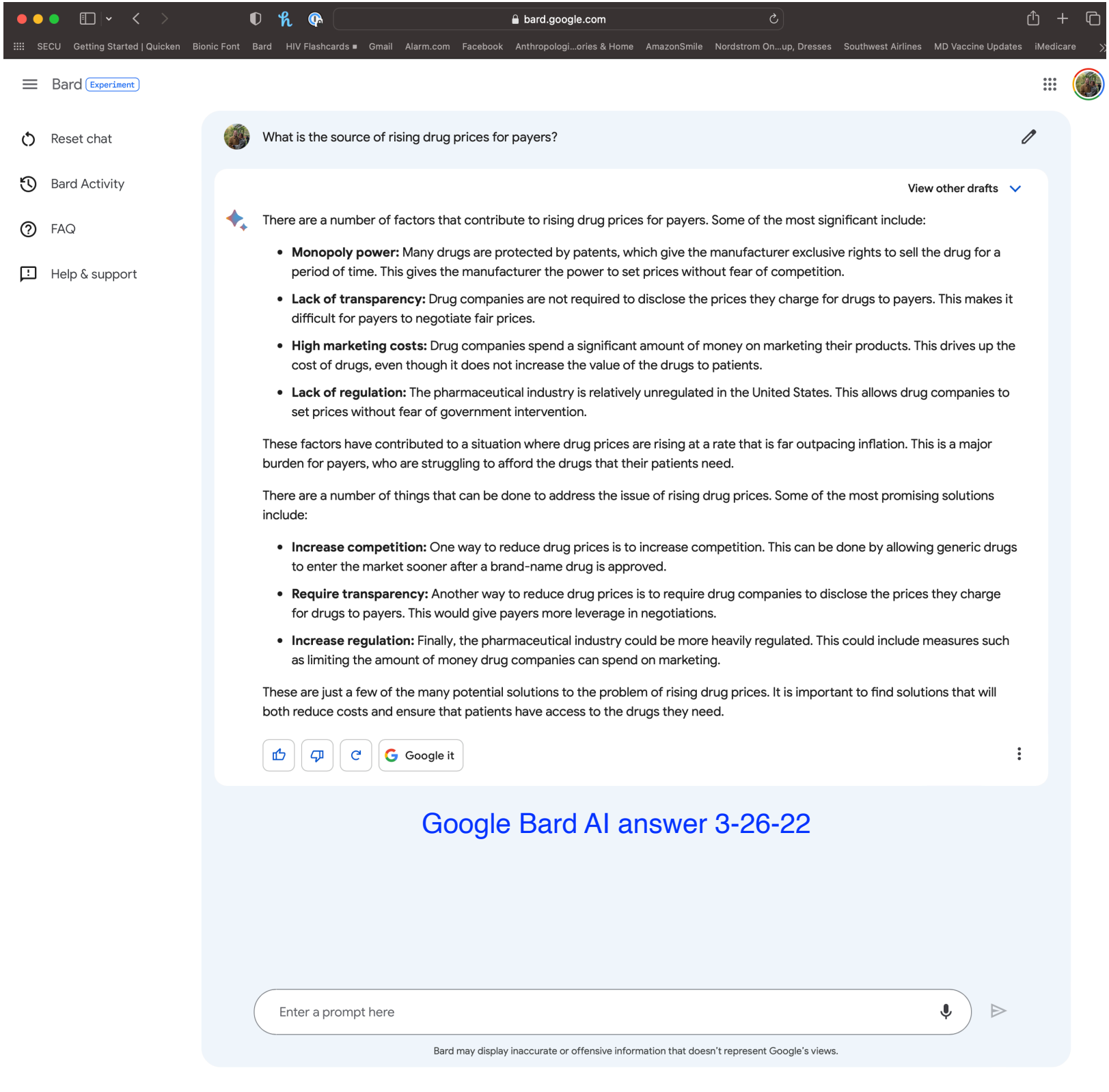


Joel Kurzman
Director, State Government Affairs

3 https://insurance.maryland.gov/Consumer/Appeals%20and%20Grievances%20Reports/Report-of-the-MIA-on-Rutledge-vs-Pharmaceutical-Care-Mgt-Assn-and-its-impact-on-Title-15-MSAR-13329.pdf

HB0357_Amended_MVP_Weinner_Fav_Aux_Doc.pdf
Uploaded by: Stephen Wienner
Position: FAV


Sun Mar 26 10:55 PM
chat.openai.com
SECU
Getting Started | Quicken
Bionic Font
Bard
HIV Flashcards
Gmail
Alarm.com
Facebook
Anthropologi...ories & Home
AmazonSmile
Nordstrom On...up, Dresses
Southwest Airlines
New chat
Causes of Rising Presc
What is the cause of rising prescription prices for payers?
There are several factors contributing to the rising prescription prices for payers, including:
1. Increasing cost of research and development: Pharmaceutical companies invest a significant amount of money into researching and developing new drugs, which can cost billions of dollars. As a result, drug manufacturers often set high prices to recoup their expenses.
2. Patent protection: Drug manufacturers can hold a patent on their products for a certain period of time, which allows them to maintain a monopoly and charge high prices without competition.
3. Lack of price regulation: In the United States, there is no centralized system for regulating drug prices, which can lead to higher prices. Other countries with universal healthcare systems have negotiated drug prices with manufacturers, resulting in lower costs for consumers.
4. Increased demand: As the population ages and chronic diseases become more prevalent, there is an increased demand for prescription drugs, which can drive up prices.
5. Consolidation in the healthcare industry: The consolidation of healthcare providers, such as hospitals and insurance companies, has led to increased bargaining power and the ability to negotiate lower prices with drug manufacturers. This, in turn, can lead to higher prices for smaller payers who do not have as much bargaining power.
Overall, the rising cost of prescription drugs is a complex issue with many contributing factors.
Source: ChatGPT: 3/26/2023
Clear conversations
Upgrade to Plus
NEW
Dark mode
Updates & FAQ
Regenerate response


bard.google.com
SECU
Getting Started | Quicken
Bionic Font
Bard
HIV Flashcards
Gmail
Alarm.com
Facebook
Anthropologi...ories & Home
AmazonSmile
Nordstrom On...up, Dresses
Southwest Airlines
MD Vaccine Updates
iMedicare
Bard Experiment
Reset chat
Bard Activity
FAQ
Help & support
What is the source of rising drug prices for payers?
View other drafts
There are a number of factors that contribute to rising drug prices for payers. Some of the most significant include:
Monopoly power: Many drugs are protected by patents, which give the manufacturer exclusive rights to sell the drug for a period of time. This gives the manufacturer the power to set prices without fear of competition.
Lack of transparency: Drug companies are not required to disclose the prices they charge for drugs to payers. This makes it difficult for payers to negotiate fair prices.
High marketing costs: Drug companies spend a significant amount of money on marketing their products. This drives up the cost of drugs, even though it does not increase the value of the drugs to patients.
Lack of regulation: The pharmaceutical industry is relatively unregulated in the United States. This allows drug companies to set prices without fear of government intervention.
These factors have contributed to a situation where drug prices are rising at a rate that is far outpacing inflation. This is a major burden for payers, who are struggling to afford the drugs that their patients need.
There are a number of things that can be done to address the issue of rising drug prices. Some of the most promising solutions include:
Increase competition: One way to reduce drug prices is to increase competition. This can be done by allowing generic drugs to enter the market sooner after a brand-name drug is approved.
Require transparency: Another way to reduce drug prices is to require drug companies to disclose the prices they charge for drugs to payers. This would give payers more leverage in negotiations.
Increase regulation: Finally, the pharmaceutical industry could be more heavily regulated. This could include measures such as limiting the amount of money drug companies can spend on marketing.
These are just a few of the many potential solutions to the problem of rising drug prices. It is important to find solutions that will both reduce costs and ensure that patients have access to the drugs they need.
Google it
Google Bard AI answer 3-26-22
Enter a prompt here
Bard may display inaccurate or offensive information that doesn't represent Google's views.

HB0357_Amended_MVP_Weinner_Fav_Aux_Doc2.pdf
Uploaded by: Stephen Wienner
Position: FAV

One trick pony: Same argument against any and all PBM legislation

Visante®

Increased Costs Associated With Proposed State Legislation Impacting PBM Tools

Prepared for

PCMA

January 2023

Not part of 3 crossover bills: But still the same old argument:

Table of Contents

I. Executive Summary

Visante was commissioned by the Pharmaceutical Care Management Association (PCMA) to estimate the potential cost impact of four types of state legislation impacting pharmacy benefit management (PBM) tools: PBM disclosure mandates, PBM fiduciary mandates, limits on prior authorization (PA) and step therapy (ST), and any willing specialty pharmacy requirements. As a general rule, such state legislation would affect only plan sponsors for commercial, fully insured plans. These plans provide prescription drug benefits to an estimated 77 million Americans. To make our estimates, we conducted a comprehensive review of the published evidence on how much PBM tools save as they are currently used in the marketplace and created an economic model of the impact of legislative proposals on the use of these tools and the resulting impact on projected drug expenditures for the fully insured commercial market for the next 10 years.

Proposals to restrict the use of PBM tools limit options that plan sponsors can use to manage their drug benefit costs. Some legislation may prohibit the use of a PBM tool entirely, driving savings to zero. Other legislation may negatively affect the full use of PBM tools and compress the range of savings achieved in the marketplace. We modeled how the savings from those tools would be reduced and how projected drug expenditures might increase over the next 10 years as a result.

Major Findings:

- **PBM Disclosure Mandates:** Proposed disclosure mandates include legislative and regulatory measures that would require PBMs to divulge the contractual price concessions they have negotiated with drug manufacturers and pharmacies. According to the Federal Trade Commission (FTC), disclosure mandates could result in tacit collusion and standardization of contract terms. We predict that disclosure mandates **would increase projected drug expenditures by an estimated 5.2% over the next 10 years**.

- **PBM Fiduciary Mandates:** Fiduciary mandates are state proposals to designate PBMs as fiduciaries for their health plan/employer clients. Such mandates would reduce savings from many PBM tools, including PA, ST, and other PBM tools that improve formulary performance and manage drug utilization. Fiduciary mandates would also likely increase PBM costs for liability insurance. We predict that fiduciary mandates **would increase projected drug expenditures by an estimated 6.7% over the next 10 years**.

- **Limitations on Prior Authorization and Step Therapy:** Some states are considering proposals to limit or prohibit the ability of health plans and their PBMs to implement PA and ST protocols. We predict that prohibiting the use of PA and ST **would increase projected drug expenditures by an estimated 6.75% over the next 10 years**.

- **Any Willing Specialty Pharmacy Requirements:** Some states are considering proposals to restrict the ability of health plans and PBMs to selectively contract for the provision of specialty pharmacy services by imposing any willing pharmacy requirements on such contracts. Such proposals would likely reduce specialty pharmacy network discounts and negatively impact the use of PBM tools that improve formulary performance and manage drug utilization. We predict that any willing specialty pharmacy requirements **would increase projected drug expenditures by an estimated 3% over the next 10 years**.

In this report, we review the evidence and methods underlying these estimates.

II. Costs Associated With Proposed State Legislation Impacting PBM Tools

A. PBM Disclosure Mandates

Issue: Proposed disclosure mandates include legislative and regulatory measures that would require PBMs to divulge the contractual price concessions they have negotiated with drug manufacturers and pharmacies.

Cost Impact of Disclosure Mandates: Mandatory disclosure would reduce savings from manufacturer rebates and pharmacy network discounts. Savings delivered by these PBM tools are significant. Some brand drugs have rebates of more than 80%. Preferred pharmacy networks deliver incremental discounts of more than 2 percentage points greater than traditional retail networks. We predict the following cost impacts:

- Disclosure mandates would likely result in tacit collusion among manufacturers, creating less variability and standardization around the lower end of the current range of rebates in the market. We predict that this compression in rebates would reduce average rebates by about 3% across all brand drugs.
- Disclosure mandates would also negatively impact pharmacy network discounts, with standardization and a compression of the range of network discounts toward the low end of the current marketplace range. Pharmacy network discounts would be compressed for different pharmacy channels and types of networks. Average retail network discounts (baseline discounts) would be cut by a half of a percentage point relative to cash prices charged to uninsured patients, while the incremental discounts over baseline associated with other pharmacy options such as preferred pharmacies, specialty, and mail-service would be cut in half.
- Combined, these negative effects on rebates and network discounts would increase projected drug expenditures by an estimated 5.2% over the next 10 years.
- PBM clients that currently maximize the use of the affected PBM tools would experience a much greater negative impact than others. These clients would see their projected drug expenditures increase by 10.4%, double the market average.

Discussion: Transparency remains a watchword in the healthcare cost debate. State policymakers have considered various proposals to mandate the disclosure of intermediate prices and discounts within the drug supply chain, including the price concessions that PBMs negotiate with drug manufacturers and pharmacies. However, a recent analysis from the USC School of Public Policy found that most states with transparency laws targeted PBMs and "no state passed laws that together revealed true transaction prices or profits across all supply chain segments."[1] This suggests these laws will fail in their intent because they a focusing on PBMs and not examining the entire supply chain. Moreover, government agencies—including the Congressional Budget Office (CBO) and the Federal Trade Commission (FTC)—have cautioned that such proposals can raise costs.

CBO Says Disclosure Mandates Could "Compress" Rebates and Discounts

CBO has noted that disclosure requirements could allow firms to "observe the prices charged by their rivals, which could lead to reduced competition."[2] According to CBO, the "disclosure of rebate data would probably cause the variation in rebates among purchasers to decline," leading to a "compression in rebates."[3] This compression would likely most adversely impact large program sponsors that would otherwise be able to extract the largest discounts.[4] At the inception of the Part D program, CBO estimated that PBM disclosure mandates would have increased costs in that program by $40 billion over 10 years.[5]

[1] "Ryan, Martha S., and Neeraj Sood. "Analysis of State-Level Drug Pricing Transparency Laws in the United States." JAMA network open 2.9 (2019): e1912104-e1912104.
[2] "Increasing transparency in the pricing of health care services and pharmaceuticals," Congressional Budget Office, Jun. 5, 2008.
[3] Letter to Rep. Joe Barton and Rep. Jim McCrery, U.S. House of Representatives, Congressional Budget Office, Mar. 12, 2007.
[4] "Assessing the budgetary implications of increasing transparency of prices in the pharmaceutical sector," The Moran Company, Apr. 2017.
[5] "H.R. 1 Medicare Prescription Drug and Modernization Act of 2003 as passed by the House of Representatives on June 27, 2003 and S. 1 Prescription Drug and Medicare Improvement Act of 2003 as passed by the Senate on June 27, 2003, with a modification requested by Senate conferees," Congressional Budget Office Cost Estimate, Jul. 22, 2003.

FTC Says Disclosure Mandates Could Lead to Tacit Collusion

FTC has warned that "whenever competitors know the actual prices charged by other firms, tacit collusion—and thus higher prices—may be more likely."[6] FTC concluded that PBM disclosure mandates could "undermine the ability of some consumers to obtain the pharmaceuticals and health insurance they need at a price they can afford."[7]

Compare PBM Negotiations to Sealed-Bid Auctions

In the current marketplace, contract negotiations between PBMs, manufacturers, and pharmacies are like sealed-bid auctions: manufacturers and pharmacies are encouraged to offer aggressive price concessions since they don't know what's being offered by their competitors. Without confidentiality, economists argue, "disclosure of commercially sensitive contract terms will tend to short-circuit this competitive dynamic" because manufacturers and pharmacies would "know that the granting of any concession will likely lead to pressure for its widespread adoption."[8]

Confidential Plan Sponsor RFP Process Drives Competition Among PBMs

Confidentiality of contract terms is also vital to encourage competition among PBMs as they bid to win contracts with their clients (plan sponsors). Most plan sponsors use sophisticated consultants to prepare requests for proposals (RFPs) that specify their needs and requirements in both price and non-price terms, auditing rights, and guarantees. The RFPs are typically sent out to four to 12 PBMs,[9] with each competing PBM blind to how its competitors will respond.

Plan Sponsors Can Negotiate Full Pass-Through of Manufacturer Rebates

Through the RFP process, plan sponsors can negotiate how manufacturer rebates will be handled and what levels of disclosure and reporting they desire from their PBM. Today, most employers opt to receive 100% of rebates. Less than 10% of clients elect to have PBMs retain a portion of the rebates in order to lower administrative fees. [10]

"With no indication that clients of PBMs lack accurate information on the price and quality of the service that they intend to purchase, it is unclear how requiring PBMs to reveal information related to rebates received from pharmaceutical companies would improve market outcomes," according to FTC.[11] More broadly, FTC has concluded that "allowing competition among PBMs is more likely to yield efficient levels of payment sharing, disclosure, and price than contract terms regulated by government regulation."[12]

---

[6] "Improving health care: a dose of competition," U.S. Federal Trade Commission and the U.S. Department of Justice, Jul. 2004.
[7] Letter from FTC to Rep. Patrick T. McHenry, U.S. Congress, Jul. 15, 2005; Letter from FTC to Assemblyman Greg Aghazarian, California State Assembly, Sept. 3, 2004.
[8] "Declaration of Adam B. Jaffee, Ph.D. in support of plaintiff's motion for preliminary injunction," Pharmaceutical Care Management Association v. G. Steven Rowe, Attorney General of the State of Maine.
[9] Statement of the Federal Trade Commission concerning the proposed acquisition of Medco Health Solutions by Express Scripts, Inc., FTC File No. 111-0210, Apr. 2, 2012.
[10] "2022 economic report on pharmacies and pharmacy benefit managers," Drug Channels Institute, March 2022.
[11] Letter from FTC to Rep. Patrick T. McHenry, U.S. Congress, Jul. 15, 2005.
[12] Letter from FTC to Assemblywoman Nellie Pou, New Jersey General Assembly, Apr. 17, 2007.

B. PBM Fiduciary Mandates

Issue: Fiduciary mandates for PBMs are state proposals to designate PBMs as fiduciaries for their health plan/employer clients.

Cost Impact of Fiduciary Mandates: Fiduciary mandates would reduce savings from many PBM tools, including PA, ST, and a number of other PBM tools. Fiduciary mandates would also increase PBM costs for liability insurance. More specifically, we predict the following impacts:

- Fiduciary mandates would reduce savings from PA, ST, and a number of other PBM tools that improve formulary performance and manage drug utilization. Savings delivered by these PBM tools are significant. Studies have demonstrated that PA can generate savings of up to 50% on drug expenditures for targeted drugs or drug categories, and ST has demonstrated savings of more than 10% for targeted categories. Optimal formulary management tools have demonstrated savings of up to 20% for targeted categories. Other PBM utilization management (UM) tools have demonstrated a reduction of almost 30% in unsafe opioid use.
- Fiduciary mandates would increase liability risks for PBMs and result in more conservative use of PBM tools, which would compress the range of savings achieved in the market. In other words, the PBM clients that are highly conservative in their use of these tools may see little impact, but the majority of clients that make greater use of PBM tools would see compression and reduction of savings. Average savings (across all drug expenditures) would be reduced by an estimated 1 to 2 percentage points for each affected category of PBM tools: PA (2%), ST (1%), and other PBM tools that work to improve formulary performance (2%) and manage drug utilization (2%).
- Fiduciary mandates would also increase PBM costs for additional liability insurance, which would be passed through to PBM clients and would add another 1% to projected drug expenditures.
- Combined, the negative effects of fiduciary mandates would increase projected drug expenditures by an estimated 6.7% over the next 10 years.
- Some PBM clients that currently maximize the use of the affected PBM tools would experience a much greater negative impact than the marketplace average. These clients that are maximizing their savings could see their drug expenditures increase by double the average or 13.4%.

Discussion: In today's marketplace, PBMs serve in administrative and advisory roles for health plans and employer plan sponsors, performing claims processing and other administrative tasks based on negotiated contracts. Proposed state legislation would override these contracts by designating PBMs as fiduciaries for their clients. A fiduciary mandate imposed upon PBMs would entail having discretionary authority over plan assets or making decisions about the scope and design of the benefits being offered by the plan. Today, those responsibilities lie with health insurance plan sponsors, not PBMs. Imposing fiduciary duties on PBMs would raise drug benefit costs by increasing their legal liability and undermining their ability to effectively implement cost management tools for their clients.

PBMs Are Not Fiduciaries According to DOL and Federal Courts

According to the Department of Labor (DOL), Third Party Administrators (TPAs), such as PBMs "who have no power to make any decisions as to plan policy, interpretations, practices or procedures, but who perform [certain] administrative functions for an employee benefit plan…are not fiduciaries of the plan."[13] Likewise, PBMs have no "discretionary authority" over plan assets as defined by DOL, which is an essential threshold requirement for fiduciary status under federal law. Moreover, federal courts have struck down state PBM fiduciary mandates as being preempted by the Employee Retirement Income Security Act (ERISA).[14]

Fiduciary Status Would Create Conflicting Obligations for PBMs

[13] 29 CFR 2509.75-8 - Questions and answers relating to fiduciary responsibility under the Employee Retirement Income Security Act of 1974.
[14] Pharm. Care Mgt Ass'n v. District of Columbia, 613 F.3d 179 (D.C. Cir. 2010).

Imposition of a fiduciary mandate would create a conflict between PBMs' contractual obligations to their clients and the fiduciary duty to act "solely in the interest of plan participants." For example, a PBM's contract may call for the use of PBM tools such as PA and ST that are designed to reduce costs for ALL participants, but which may result in higher costs or less access to a given drug for a particular group of participants. In this case, implementing the contract would conflict with a fiduciary duty. Indeed, such conflicting obligations would likely be common, resulting in second-guessing of every element of the contracts PBMs have negotiated with their clients and requiring substantial and burdensome analysis by both parties to determine if a legally prohibited conflict exists.

Legal Liabilities and Costs Would Increase Under Fiduciary Mandates

Fiduciary mandates would subject PBMs to broader legal liabilities than under current law because they would transform an arm's length contractual relationship into one where one party is responsible for assets that belong to another, such as a trustee relationship. This could result in increased risk for litigation between PBMs and their clients. In addition, consumers could argue they have a private right of action to sue PBMs because they are plan participants protected by ERISA. Increased legal risk could result in PBMs needing to purchase additional liability insurance. The added cost of this insurance would then drive prescription drug benefit costs higher for both PBM clients and the individuals enrolled in their plans.

Fiduciary Mandates Would Decrease the Use of PBM Tools

Increased legal liability and conflicting obligations between fiduciary duties and client contracts could result in PBMs adopting defensive business strategies to mitigate the risk of lawsuits. This could lead to PBMs decreasing their use of formulary compliance and drug UM tools such as PA, ST, and quantity limits. This would raise drug benefit costs for both plan sponsors and their enrollees.

Performance-Based Contracting Would Be Undermined by Fiduciary Mandates

DOL has indicated that certain performance fee arrangements may result in fiduciary self-dealing. This could preclude PBM contracts from containing provisions where some of their fees are contingent on performance. Likewise, creating fiduciary responsibilities for PBMs could limit how they structure manufacturer rebate and pharmacy network contract agreements and negatively impact their bargaining leverage. In addition, the increased reporting requirements that would go hand-in-hand with a fiduciary duty would increase the risk of public disclosure of negotiated price concessions, although we have not explicitly factored that into our modeling.

Fiduciary Mandates Would Increase Administrative Costs

State fiduciary mandates would increase costs as PBMs are forced to develop unique administrative processes and revise contracts with other supply chain entities to comply with a state's new requirements, which would be completely different than other states' and at odds with ERISA's goals of a "uniform administrative scheme" for processing claims and distributing benefits.

C. Limitations on Prior Authorization and Step Therapy

Issue: Some states are considering proposals to limit or prohibit the ability of health plans and their PBMs to implement clinical PA and ST protocols.

Cost Impact of Limitations on PA and ST: Prohibiting the use of PA and ST would eliminate the savings delivered by these PBM tools. Our analysis reveals:

- Studies have demonstrated that PA can generate savings of up to 50% for targeted drugs or drug categories. ST has demonstrated savings of more than 10% in targeted categories.
- PA and ST are widely used by PBM clients to help ensure appropriate and cost-effective use of high-cost and/or high-risk drugs. These tools are becoming increasingly important in managing the rapidly growing use of high-cost specialty pharmaceuticals, so the lost savings associated with restrictions on PA and ST would become greater as specialty drug expenditures grow.
- The loss of savings from PA and ST would increase projected drug expenditures by an estimated 6.75% over the next 10 years.
- Limiting or restricting the use of PA and ST would increase projected drug expenditures by an estimated 2.25%.
- Use of "Gold Card Programs" restricting the use of PA would increase projected drug expenditures by an estimated 0.75%.

PBM clients that currently maximize the use of the affected PBM tools would experience a much greater cost impact, potentially double the increases listed above.

Discussion: Health plans and pharmacy benefit managers utilize independent Pharmacy & Therapeutics Committees, comprised of experts that include physicians, pharmacists, and other medical professionals to develop evidence-based guidelines used in drug management programs—including PA and ST—and to ensure that these management controls do not impair the quality of clinical care.

PA is a requirement that a plan pre-approves a drug before a pharmacy can dispense it to the enrollee as a covered benefit. The major goals of PA are to ensure appropriateness and suitability of the prescribed medication for the specific patient as well as to control costs.

ST requires an enrollee to try a medically appropriate first-line drug, typically a generic alternative to a branded product, when a new therapy is initiated. The prescriber is asked to consider ordering a therapeutic alternative. If that medically appropriate alternative was tried earlier and the patient did not achieve optimal outcome, the brand product is approved and dispensed.

As with other drug benefit management techniques, it is up to each PBM client to decide if and how PA and ST will be applied to its health benefit plan.

PA and ST Used to Help Ensure Prescriptions Are Safe and Appropriate

Many drugs can have harmful side effects or adverse interactions with other medications. Some drugs, such as pain medications or antipsychotics, have a high risk of abuse or overuse so PA is required to help ensure appropriate use. Likewise, specialty medications often have significant side effects and require patient education to be taken effectively, so they also often require PA. Many drugs that commonly appear on PA lists are those that are heavily advertised directly to consumers or have off-label uses not approved by the Food and Drug Administration (FDA).

ST ensures that prescribers consider the medically appropriate available therapeutic alternatives before settling on a course of therapy for a specific patient, which can improve quality of care when that patient is on multiple medications. PA is often used to encourage or require physicians to use ST where they try an appropriate but less expensive medication first before moving the patient to a more expensive option.

FTC Finds Plans Use PA and ST to Lower Costs

According to FTC, "large PBMs and small or insurer-owned PBMs have used step-therapy and prior authorization programs to lower prescription drug costs and increase formulary compliance."[15] FTC also found that "prior authorization often involves a clinical justification for the use of drugs that are prone to misuse or are especially costly."[16] Any limits or prohibitions on PA and ST could thus raise costs.

NASEM Suggests Formulary Controls Keep Premiums Low

According to the National Academy of Sciences, Engineering, and Medicine (NASEM), "Formularies are used to steer patients and prescribing clinicians toward generic substitutes, biosimilars, drugs with similar therapeutic efficacy for the same disease, or other therapeutic options."[17] Without formulary controls, "insurance premiums would rise," notes NASEM.[18] PA and ST are among the most effective formulary controls, thus any state legislation to limit or prohibit their use would likely raise premiums.

NASEM Recommends More, Not Less, Formulary Flexibility

"Some other countries operate formulary systems that provide much greater ability to restrict or exclude drugs from coverage than is the case in the United States," according to NASEM.[19] One of NASEM's recent consensus recommendations to make medicines more affordable was to "Expand flexibility in formulary design to allow the selective exclusion of drugs, such as when less costly drugs provide similar clinical benefit."[20] Since PA and ST are less aggressive formulary controls than outright formulary exclusions, it is reasonable to extrapolate that state proposals limiting or prohibiting their use would be an approach at odds with NASEM's recommendation.

Every Plan Has an Appeals Process

As noted by NASEM, "Every plan, whether Part D or an employer-sponsored pharmacy benefit, has an exception process that permits coverage of a drug not on formulary or reduces out-of-pocket cost if a physician provides information about side effects the patient has experienced from a lower-tiered drug or offers another medical reason for switching."[21] In the case of an appeal, health insurers and PBMs work with the patient and the physician to provide access to non-formulary drugs where medically necessary and/or likely to achieve the best outcome. This process safeguards against the use of PA and ST being too restrictive.

Gold Card Programs

"Gold card" programs allow physicians with high rates of PA approvals over a specified time period to be exempt from PA requirements. While this might appear to beneficially reduce administrative burdens, "gold carding" can create significant challenges, including the following:[22]

- Provider performance tends to slip once the provider has gold card status;
- Performance typically varies across services, so it is difficult to confer gold card status on a provider across all services (i.e., prescriptions, diagnostic tests, etc.)
- Providers within the same clinic or group often perform differently, creating potential confusions;
- Granting gold card status potentially conflicts with state laws that preclude treating enrollees differently;

[15] "Pharmacy benefit managers: ownership of mail-order pharmacies," FTC, Aug. 2005.
[16] Ibid.
[17] "Making medicines affordable: a national imperative," NASEM, Nov. 2017.
[18] Ibid.
[19] Ibid.
[20] Ibid.
[21] Ibid.
[22] Berry K. "Prior Authorization." Presentation to Health Information Technology Advisory Committee Office of the National Coordinator for Health Information Technology. March 2019.

- Prior authorization and claims systems are often not configurable to support different workflows for different providers.

Gold card programs would reduce use of PA and reduce associated savings, as well as increase administrative costs for PBMs and health plans and increase premiums. We estimate the impact on total costs related to this restriction of PA would be approximately half the impact of a fiduciary mandate. Thus, savings from PA would be reduced from a range of 2% to 8% to a range of 2% to 6.5%, and the market average would decrease from 5% to 4.25%. With the reduction of these savings, projected drug expenditures would increase 0.75%.

D. Any Willing Specialty Pharmacy Requirements

Issue: Some states are considering proposals to restrict the ability of health plans and PBMs to selectively contract for the provision of specialty pharmacy services, by imposing any willing pharmacy (AWP) requirements on such contracts.

Cost Impact of Any Willing Specialty Pharmacy Requirements: Any willing specialty pharmacy requirements would reduce savings on specialty drugs achieved through the use of tools such as PA, ST, and other PBM tools that improve formulary performance and manage drug utilization. Our analysis reveals:

- Specialty pharmacy network discounts typically deliver incremental discounts of up to 2 percentage points more than traditional retail networks. In addition, specialty formulary management has demonstrated savings of 20% in a drug category, while drug UM has demonstrated savings of 5% to 10% in targeted categories.
- Any willing specialty pharmacy legislation would effectively eliminate specialty pharmacy network discounts, which are typically 1–2 percentage points greater than baseline retail network discounts.
- Average savings associated with other PBM tools would be compressed and reduced because the effectiveness of the tools is often dependent upon specialized, advanced services delivered by specialty pharmacies in close coordination between the PBM and the specialty pharmacy. Most pharmacies are not prepared to deliver such sophisticated and coordinated services, so the optimal savings would not be as feasible under an AWP scenario. Average savings across all drug expenditures would be reduced by an estimated 1–2 percentage points for each affected category of PBM tools: PA (1%), ST (1%), and other PBM tools that work to improve formulary performance (2%) and manage drug utilization (2%).
- This legislation would affect specialty drug expenditures, which are the fastest growing component of prescription drug expenditures and projected to comprise approximately 50% of total drug expenditures over the next 10 years.
- The overall impact of an any willing specialty pharmacy requirement would be to increase projected drug expenditures (combined specialty and non-specialty) by an estimated 3% over the next 10 years.
- PBM clients that currently maximize the use of the affected PBM tools would experience an even greater cost impact and see their projected drug expenditures increase by 6%.

Discussion: Over the next 10 years, specialty drugs—high cost, often injectable or infusible medications—will likely account for just 1% of prescriptions but roughly 50% of projected drug expenditures.[23] Today, entities known as specialty pharmacies fulfill the complex product handling, clinical support, patient education, and UM requirements associated with specialty drugs. Health plans and PBMs typically contract to include only selected specialty pharmacies in their pharmacy networks to ensure high-quality services for consumers, avoid waste, and ensure appropriate use of high-cost specialty medications. Thus, an AWP requirement could be particularly harmful when applied to specialty pharmacies, resulting in additional costs beyond the already anti-competitive impact associated with AWP requirements more generally.

FTC Says Any Willing Pharmacy Provisions Would Reduce Discounts

According to the FTC, AWP requirements significantly reduce providers' incentive to engage in price competition. If pharmacies know they will automatically be included in a network, they have a reduced incentive to offer plans and PBMs their most competitive terms. FTC has noted that "requiring prescription drug plans to contract with any willing pharmacy would reduce the ability of plans to obtain price discounts based on the prospect of increased patient volume and thus impair the ability of prescription drug plans to negotiate the best prices with pharmacies."[24]

Academic Analysis Finds Any Willing Pharmacy Laws Associated With Higher Costs

[23] Visante estimates.
[24] "Contract year 2015 policy and technical changes to the Medicare advantage and the Medicare prescription drug benefit programs," FTC letter to CMS, Mar. 7, 2014.

An academic analysis of AWP laws concluded that such legislation leads to less competition and higher prices for consumers while providing no compensating benefits with "cost increases of ~5%."[25] Likewise, another academic analysis specific to state AWP laws found that such legislation "is associated with increased pharmaceutical expenditures."[26] Other studies provide additional evidence that any willing provider laws are associated with higher prescription spending.[27]

Low Volume of Specialty Prescriptions Amplifies Impact of Any Willing Pharmacy Legislation

When applied to specialty pharmacies, the consequences of AWP legislation would likely be greater than when simply applied to brick-and-mortar pharmacies. Because specialty drugs are dispensed in such low volumes and target rare conditions, it is infeasible for most retail drugstores to stock these medications and provide the specialized services patients require. Specialty pharmacies can serve an entire region or country using sophisticated information technology and logistics to dispense medications directly to the patient's home or physician's office. This approach allows specialty pharmacies to achieve economies of scale and offer deeper discounts due to a predictable volume of prescriptions flowing through the pharmacy. These economies of scale would not be possible if AWP legislation were to result in drugstores across the country dispensing these medications.

Only Select Pharmacies Typically Meet Specialty Pharmacy Network Requirements

States do not legally differentiate specialty pharmacies from traditional pharmacies, so essentially any licensed pharmacy can market itself as a specialty pharmacy. Some pharmacies that market themselves as specialty pharmacies are actually affiliated with drug manufacturers, which has led to the use of questionable practices to circumvent the benefit design choices of plan sponsors in some cases.[28] PBMs actively work with payers to identify specialty pharmacies that can best serve patient and healthcare provider needs. These payer-aligned specialty pharmacies must meet payers' terms and conditions to be included in preferred pharmacy networks. Terms and conditions focus on quality clinical care, performance, and cost-saving criteria. Qualified specialty pharmacies must also meet payer reimbursement rates to be included in networks.

Payer-Aligned Specialty Pharmacies Provide Unique Clinical and Operational Services

Unlike traditional brick-and-mortar drugstores, payer-aligned specialty pharmacies included in plan networks employ highly trained teams of pharmacists, nurses, and clinicians to work with doctors and patients to ensure that complex specialty medications are administered on time, conveniently, safely, and effectively. The unique clinical services that specialty pharmacies provide include:

- Providing around-the-clock access to specially trained clinicians who offer patients guidance and insight on disease states, as well as the use of specialty drugs;
- Consulting directly with physicians to address patient side effects, adverse drug reactions, non-adherence, and other patient concerns;
- Performing disease- and drug-specific patient care management services;
- Collecting data and tracking outcomes for specific patients;
- Managing patient adherence and persistency of drug regimens; and
- Managing care for manufacturer Risk Evaluation and Mitigation Strategies, including reporting, Phase IV trials, the dispensing of FDA trial drugs under strict protocols, and related clinical and cognitive counseling.

Unique operational services provided by payer-aligned specialty pharmacies in plan networks include:

[25] Klick, Jonathan and Wright, Joshua D., "The Effect of Any Willing Provider and Freedom of Choice Laws on Prescription Drug Expenditures," Am. L. & Econ. Rev. 192 (2015)
[26] Durrance, C., "The impact of pharmacy-specific any-willing-provider legislation on prescription drug expenditures," *Atlantic Economic Journal*, 2009.
[27] Reforming America's Healthcare System Through Choice and Competition, Department of Health and Human Services, 2018, 65.
[28] Chen, C., and Elgin, B., "Philidor said to modify prescriptions to boost Valeant sales," Bloomberg Business, Oct. 29, 2015.

- *Supply chain management:* Adheres to rigorous storage, shipping, and handling standards to meet product label shipping requirements, such as temperature control and the timely delivery of products in optimal conditions.
- *Care coordination:* Offers coordinating services with other healthcare providers, including those providing skilled nursing services, custodial care, infusion administration, and direct-to-physician distribution.
- *Insurance navigation:* Expedites access to therapy by working directly with insurers and navigating their benefits, UM, and PA processes.
- *Patient assistance:* Facilitates eligible patients' enrollment in patient assistance programs and access to charitable resources.
- *Plan optimization:* Aligns economic incentives across medical and pharmacy benefits while helping patients navigate the complexity of these benefit structures.

Physicians Say Not All Pharmacies Capable of Dispensing Specialty Drugs

A 2015 survey of 400 physicians in the cardiology, neurology, gastroenterology, endocrinology, rheumatology, nephrology, infectious disease, oncology, pulmonology, and hematology specialties who prescribe specialty medications showed that two-thirds of those who work with specialty pharmacies think that only some or none of traditional drugstores have the expertise to provide the range of specialty medications to patients.[29]

Accreditation and Credentialing a Key Aspect of Network Requirements

Specialty pharmacy accreditation and credentialing are among the baseline requirements a pharmacy must meet for inclusion in a plan's network. Of the roughly 64,000 pharmacies in the U.S., only about 1570—less than 2.5%—are accredited as specialty pharmacies by the Utilization Review Accreditation Commission.[30] In addition, PBMs utilize credentialing to evaluate a pharmacy's ability to implement plan design, encourage formulary compliance, and meet other contractual obligations.

Impact of Any Willing Pharmacy Legislation on Savings From Specialty Benefit Management

Legislation that prevents PBMs from creating limited networks of specialty pharmacies would likely significantly impact the performance of formulary management, UM, and care management programs for patients using specialty medications. The effective use of these tools has a significant impact on costs. For example, the Pennsylvania Medicaid program's use of specialty pharmacies helped save 21% on overall health expenditures for beneficiaries using specialty drugs, including 16% on specialty drug costs and 56% on inpatient hospital costs.[31] Numerous other studies have demonstrated that specialty pharmacies save 10% to 50% on drug costs and non-drug medical costs.[32,33,34,35,36,37,38,39,40,41,42,43,44]

III. Supporting Evidence and Methods

[29] "Key findings from the survey of New York physicians regarding specialty medications," North Star Opinion Research, Apr. 2015.
[30] 2022 economic report on pharmacies and pharmacy benefit managers, Drug Channels Institute, March 2022.
[31] "Managing Medicaid pharmacy benefits: current issues and options," Kaiser Commission on Medicaid and the Uninsured, Sept. 2011.
[32] Baldini, C., and Culley, E. "Estimated cost savings associated with the transfer of office-administered specialty pharmaceuticals to a specialty pharmacy provider in a medical injectable drug program," *J Managed Care Pharm*. 2011;17(1):51-59.
[33] "Express Scripts' Miller says hepatitis C price war to save billions," Reuters, Jan. 22, 2015.
[34] "Specialty pharmacy: rare disease management," Russek, S., and Szymanski, J., Medco, presented at the PCMA Specialty Pharmacy Symposium, Jun. 2005.
[35] Barlow, J. et al., "Impact of specialty pharmacy on treatment costs for rheumatoid arthritis," *Am J Pharm Benefits*. 2012;4(Special Issue):SP49-SP56.
[36] Dorholt, M., "Advancing drug trend managementt in the medical benefit," *Managed Care,* Jun. 2014.
[37] "Personalizing the specialty business," Miller, S., presentation at the PCMA Specialty Pharmacy Business Forum, Apr. 4, 2012.
[38] Visaria, J., and Frazee, S., "Role of pharmacy channel in adherence to hepatitis C regimens," *Am J Pharm Benefits*. 2013;5(1):17-24.
[39] Mitra, et al., "Treatment patterns and adherence among patients with chronic hepatitis C virus in a US managed care population," *Value Health*. 2010;Jun-Jul;13(4):479-486.
[40] Tan, et al., "Impact of adherence to disease-modifying therapies on clinical and economic outcomes among patients with multiple sclerosis," *Adv Ther*. 2011;28(1):51-61.
[41] Specialty Pharmacy News, Jun. 2013;10(6).
[42] Tschida, et al., "Outcomes of a specialty pharmacy program for oral oncology medications," *Am J Pharm Benefits*. 2012;4(4):165-174.
[43] Tschida, et al., "Managing specialty medication services through a specialty pharmacy program: the case of oral renal transplant immunosuppressant medications," *J Managed Care Pharm*. 2013;19(1):26-41.
[44] Visaria, et al., "Specialty pharmacy improves adherence to imatinib," *Am J Pharm Benefits*. 2013;5(Special Issue):SP33-SP39.

A. Methodology: Impact of Restricting PBM Tools

To assess the cost impact of legislation restricting the use of PBM tools, Visante conducted a comprehensive review of the published evidence on how much PBM tools save as they are currently used in the marketplace. Our evidence comes from a wide range of sources that often use different benchmarks against which to measure savings. While we report on each of these sources using their original benchmarks, it was necessary to then translate and restate this evidence in terms of a common benchmark that we refer to as "projected drug expenditures." These projections are discussed in more detail in Section B below, but it is important to note that our "projected drug expenditures" for the next 10 years are based on the Centers for Medicare & Medicaid Services (CMS) projected national health expenditures and are assumed to reflect the average use of PBM tools.

We use our model to produce estimates that reasonably isolate the impact of individual PBM tools and predict realistic costs and savings under different legislative scenarios that would restrict the use of specific tools. We do this by comparing the savings achieved by the following plans:

1. Plans that use PBM tools to a limited extent or "limited use of PBM tools."
2. Plans that use PBM tools to an average extent or "average use of PBM tools."
3. Plans that optimize the use of PBM tools to their full extent or "best practice use of PBM tools."

In the PBM marketplace, plan sponsors determine the extent to which they use PBM tools based on their resources and objectives. Decisions made by plan sponsors not only guide how actively benefits are managed, but also determine formulary coverage, copayment tiers, UM, and pharmacy channel options. In making choices about the drug benefits being offered to their enrollees, plans' sponsors weigh many factors, including clinical quality, cost, and member satisfaction. The need to control costs is typically weighed against minimizing change for their enrollees, all while ensuring access to needed care.

Government mandates to restrict the use of PBM tools limit the options that plans' sponsors can use to manage their drug benefit costs. Some legislation may prohibit the use of a PBM tool entirely, driving savings to zero. Other legislation may negatively affect the "best practice" use of PBM tools, thereby compressing the range of savings in the marketplace toward the low end. In these cases, we model how the savings from those tools would be reduced and how projected drug expenditures would change over the next 10 years as a result. We have examined savings associated with PBM tools falling into the following categories:

- Manufacturer rebates
- Pharmacy network contract discounts (e.g., retail, preferred, mail-order, specialty)
- PA and ST
- Other PBM tools that improve formulary performance
- Other PBM tools that manage drug utilization

Manufacturer Rebates

Based on Visante estimates and analysis of data from SSR Health and other sources, manufacturer rebates negotiated by PBMs across all branded drugs in the commercial sector now average 33% of Wholesale Acquisition Cost (WAC). This is a sales-weighted average across brand drugs.

Rebates have increased significantly during the past 10 years. Some brands may have rebates of more than 80%, while other brand drugs may have no rebates at all. Visante's estimates, which exclude Medicaid rebates, are roughly consistent with other published estimates.[45,46,] Another report estimates average brand rebates of 30% in Medicare Part D.[47] Our modeling assumes no significant changes to rebates in the future, although there are

[45] "The Use of Medicines in the U.S. 2022, Usage and Spending Trends and Outlook to 2026" IQVIA Institute, March 2022.
[46] "Report to the Congress: Medicare Payment Policy," MedPAC, March 2022.
[47] "2022 economic report on pharmacies and pharmacy benefit managers," Drug Channels Institute, March 2022. Total DIR = 30%, manufacturer rebates 80% of DIR, brands 80% of total spend.

currently proposals that could result in significant changes, such as elimination of the rebate safe harbor in Medicare Part D.

Average rebates for commercial sector payers depend on how fully plan sponsors elect to have their drug benefit managed. It is reasonable to assume that plan sponsors that opt to use the full range of PBM formulary management tools may achieve average brand rebates of up to 5 percentage points greater than the average for the marketplace as a whole, while plans that make limited use of formulary management may achieve rebates averaging 5 percentage points below the marketplace average. Under these assumptions, the average rebate across all brand-name drugs ranges from a high of 38% of WAC to a low of 28% of WAC.

There is wide variation in average rebates for specialty drugs vs traditional (non-specialty brands. We note that many high-cost specialty medications often have less competition and lower (or no) rebates compared with non-specialty medications. However, manufacturer competition is also becoming more important in the specialty area. For example, in late 2014, AbbVie obtained FDA approval to compete against Gilead's market-leading drugs for hepatitis C. PBMs immediately took advantage of the opportunity to obtain discounts of approximately 46%,[48] creating savings estimated at $4 billion in the U.S. for 2015.[49] The weighted average rebate for the 115 top specialty drug products in 2021 was only 21% of WAC, while the weighted average for the top 167 traditional brands was 49%, based on our estimates and analysis of data from SSR Health.[50]

Potential Impact of State Legislation on Rebates: As discussed earlier in this report, FTC and CBO each have concluded that government policies resulting in the disclosure of rebates could lead to tacit collusion among manufacturers and result in higher costs as rebate contracts standardize toward terms more favorable to the drugmakers. We believe that such policies could cause average rebates to cluster toward the lower bound of the current marketplace range of 25% to 35% of WAC. To model this effect, we have assumed that the current 25% to 35% range of average rebates compresses to a new range bounded by the current low of 25% and a new upper bound equal to the current marketplace average of 30%. Assuming a normal distribution, this would result in a new marketplace average rebate of approximately 27% of WAC, a compression of about 3 percentage points from the current marketplace average. This estimated impact is reasonably consistent with a 2017 analysis of disclosure mandates by budget analysts, which suggests that "CBO could reasonably conclude that the effect on branded drug pricing could be greater than 2% over time."[51]

We understand that there are a variety of PBM business models and pricing schemes in the marketplace today, some of which factor "rebate retention" into the overall administrative fee structure for the PBM client. We see this as independent from our analysis. In other words, we are examining the potential impact on the manufacturer rebate contracts themselves. Whether some clients choose to use a portion of their rebate dollars to help reduce their administrative fees is independent from our analysis. That said however, evidence suggests that most employers now receive 100% pass-through of the rebates negotiated by their PBM. [52]

To assess the impact on overall drug expenditures by a reduction in average rebates on brand drug expenditures, we estimate that brand drugs will account for 88% of total drug expenditures over the next 10 years, based on current marketplace dynamics. Therefore, rebates of 28% to 38% of WAC for brand-only drugs would be equivalent to 25% to 34% of total drug expenditures (i.e., brands and generics). Mandatory disclosure would compress the range to the lower end, resulting in a new range of 25% to 28%. The market average would be reduced from 28% to 26.5%. With this decrease in average rebates due to mandatory disclosure requirements, projected drug expenditures would increase an estimated 3.1%. This estimated impact does not include the impact such mandates would have on pharmacy network discounts, as discussed below.

[48] "What Gilead's big hepatitis C discounts mean for biosimilar pricing," Drug Channels, Feb. 5, 2015.
[49] "Express Scripts' Miller says hepatitis C price war to save billions," Reuters, Jan. 22, 2015.
[50] Visante estimates and analysis of non-Medicaid markets based on 2021 data from SSR Health. Further discussion of Visante's methodology for estimating average rebates is available in our June 2017 analysis for PCMA, "Increasing prices set by drugmakers not correlated with rebates."
[51] "Assessing the budgetary implications of increasing transparency of prices in the pharmaceutical sector," The Moran Company, Apr. 2017.
[52] "2022 economic report on pharmacies and pharmacy benefit managers," Drug Channels Institute, March 2022.

Pharmacy Network Contract Discounts (Retail, Specialty, Mail)

Retail Pharmacy Network Discounts: Plan-sponsor survey data indicate that pharmacy network discounts amount to 20-22% of the average wholesale price for brands and 65-70% of the average wholesale price for generics.[53,54] Another report estimates that in 2021, PBMs paid 35% of AWP (i.e., AWP less 65%) ingredient cost reimbursement for a 30-day retail generic prescription, and 29% of AWP for the ingredient cost reimbursement of generic prescriptions filled at a mail pharmacy. Over time, third-party payers have been reimbursing pharmacies at an ever-smaller share of AWP. For instance, pharmacies received AWP-13% in 2000, compared with AWP-19% in 2021.[55]

Cash prices for generic prescriptions varies greatly among pharmacies.[56] [57] One study examined cash prices for 16 brand-name and generic prescriptions at more than 60,000 retail community pharmacies in 2019. Compared with large chain drugstores, cash prices for generic drugs were 151% higher at regional chain drugstores and 161% higher at independent pharmacies. Cash prices were lowest at mass merchants.[58]

Visante analysis of CMS data on prices paid to pharmacies for prescriptions filled by individuals with commercial third-party insurance versus cash-paying customers in 2013 indicated average savings for third-party insurers of 9% to 10% on brands and 20% to 25% on generics.[59] Due to changing market conditions during the past few years, we estimate those savings on brands have changed to 11% to 13% on brands and 15% to 20% on generics. Assuming that brand drugs will be 88% and generics 12% of projected drug expenditures over the next 10 years,[60] we estimate retail network discounts of 12.5% relative to full retail prices charged by pharmacies to cash-paying consumers. We assume 12.5% is a midpoint of a 10% to 15% marketplace range. We consider this range as a baseline network discount achieved through all PBM-managed pharmacy channels, with additional discounts then available from preferred pharmacies, mail-service, and specialty pharmacies, as outlined below.

Preferred and Limited Retail Pharmacy Networks: In the commercial market, half of employer-sponsored plans now offer a preferred network, and about 20% of employer-sponsored plans offer a limited network.[61] Because data on preferred pharmacy network savings are more readily available for Part D plans, we are using Part D data as a proxy for savings in the commercial sector. According to one study, Part D plans that take advantage of preferred pharmacy networks are able to negotiate 1.9% to 2.3% lower prices. And while around 95% of Medicare Part D insurers use preferred pharmacy networks, only half of employers are using narrow or preferred pharmacy networks.[62]

Therefore, we estimate savings for plans with preferred/limited network pharmacies can be approximately 2% relative to plans with baseline retail pharmacy network discounts. The savings could be applied to 50% of the employer/commercial market. Therefore, preferred or limited retail networks may deliver up to 1.0% in additional savings (e.g., 2% × 50% = 1.0%), in addition to baseline retail pharmacy network discounts. Assuming a normal distribution, we estimate an average savings of 0.5% across all plans.

Mail-Service Pharmacy Discounts: A recent report estimates that the median mail-service pharmacy discount on brand drugs is 26% of the average wholesale price, which is 4-7 percentage points better than the discount achieved by retail drugstores.[63] Industry estimates are that 10% to 15% of 30-day equivalent prescriptions are currently filled via mail ("30-day equivalent prescriptions" were adjusted so that one 90-day prescription is normalized to three 30-day prescriptions).[64] Reports published by PBMs indicate that plan sponsors can achieve mail-service penetration of

[53] 2018 Pharmacy Benefit Management Institute, op. cit.
[54] 2022 economic report on pharmacies and pharmacy benefit managers, Drug Channels Institute, March 2022.
[55] Ibid.
[56] Arora, S., The Price May Not Be Right: The Value of Comparison Shopping for Prescription Drugs, The American Journal of Managed Care, July 28, 2017.
[57] Shop Around for Lower Drug Prices, Consumer Reports, April 5, 2018.
[58] Variation in Prescription Drug Prices by Retail Pharmacy Type: A National Cross-Sectional Study. Annals of Internal Medicine, 2019.
[59] Visante analysis of CMS National Average Retail Price (NARP) survey data from 2Q2013. NARP data provided average prescription revenues for more than 4,000 of the most commonly dispensed brand and generic outpatient drugs. The NARP data included: (1) the amounts paid for drug ingredient costs, (2) customer copayments or coinsurance, and (3) dispensing fees. These monthly data were based on 50 million nationwide retail pharmacy claims gathered from independent data suppliers. NARP data reflected prices paid for drugs to retail community pharmacies for individuals with (1) commercial third-party insurance (including Medicaid managed care and Medicare Part D) and with (2) Medicaid fee-for-service, and (3) cash-paying customers. The NARP survey was suspended by CMS in July 2013.
[60] Brand spend inncreased79-84% of total during 2017-21. "The Use of Medicines in the U.S. 2022, Usage and Spending Trends and Outlook to 2026" IQVIA Institute, March 2022.
[61] 2018 Pharmacy Benefit Management Institute, op. cit.
[62] Starc, A., and A. Swanson, Promoting Preferred Pharmacy Networks, 2021.
[63] 2022 economic report on pharmacies and pharmacy benefit managers, Drug Channels Institute, March 2022.
[64] Ibid.

30% or more.[65,66] Approximately 28% of employers report that they require the use of mail-service pharmacies for prescriptions needed on an ongoing basis.[67] Based on this evidence, we estimate savings from mail-service pharmacies range from zero savings for plans with no mail-service pharmacies to up to 1.2% of total expenditures for plans with full use of mail-service. The upper bound 1% estimate is based on a discount of 4-7 percentage points relative to retail, 30% mail-service penetration for non-specialty prescriptions, and 50% of total prescription expenditures being non-specialty.[68] Assuming a savings range with a normal distribution of 0% to 1%, we estimate average mail-service savings of 0.5% on overall drug costs relative to expenditures without mail-service pharmacies. These savings are in addition to "baseline" retail network discounts.

Specialty Pharmacy Discounts: Nearly 80% of employers believe that mail-order specialty pharmacies are the lowest-cost site of service compared with retail community pharmacies and other options.[69] Consequently, the share of large employers with a restricted pharmacy network for specialty drugs has grown, from 36% of employers in 2011 to 68% in 2020.[70] Plan-sponsor survey data indicate that discounts off average wholesale price for specialty pharmacy networks are approximately 2 points better than average network discounts through retail drugstores.[71] To estimate the marketplace impact of specialty pharmacy network discounts, we apply this 2-point discount to expenditures on specialty pharmaceuticals (50% of total drug expenditures), which results in specialty pharmacy network discounts generating savings of approximately 1% relative to drug expenditures without specialty network discounts. Because about a third of the market does not take advantage of specialty pharmacy network discounts, the savings range is estimated to be a normal distribution of 0% to 0.7%, with an average of 0.35%. These savings are in addition to "baseline" retail network discounts.

Potential Impact of State Legislation on Network Discounts

Impact of Disclosure Mandates: Anti-competitive government policies, such as disclosure mandates, would restrict the ability to negotiate pharmacy network discounts, eliminate the largest network discounts, compress the range of discounts toward the low end of the range, and (assuming a normal distribution) thereby reduce the market average discounts to the midpoint of the new range. We predict that retail network discounts would be reduced from a range of 10% to 15% to a new range of 10% to 12.5%, so the average would decrease from 12.5% to 11.25%. Preferred pharmacy savings would be cut from 0% to 1% to a new range of 0% to 0.5%, with the average savings dropping from 0.5% to 0.25%. Mail-service savings would change from 0% to 1% down to 0% to 0.5%, with the average cut from 0.5% to 0.25%. Savings from specialty network discounts would change from 0% to 0.7% down to 0% to 0.35%, and average savings would drop from 0.35% to 0.18%. Again, these savings are all relative to expenditures in the absence of these negotiated discounts. Based on these reductions in average network discounts, projected drug expenditures would increase approximately 2%. This estimated impact is only for lost savings related to pharmacy network discounts and does not include other cost impacts on savings from manufacturer rebates discussed above.

We understand that there are a variety of PBM business models and pricing schemes in the marketplace today, some of which factor pharmacy network discounts and direct and indirect remuneration fees into the overall administrative fee structure for the PBM client. We see this as independent from our analysis. In other words, we are examining the potential impact on the pharmacy contracts themselves. Whether some clients choose to use a portion of their pharmacy savings to help reduce their administrative fees is independent from our analysis.

Impact of Any Willing Specialty Pharmacy Legislation: "Any willing specialty pharmacy" legislation would effectively eliminate specialty pharmacy network discounts. Because specialty drugs account for just 1% of prescription volume, we believe that an any willing pharmacy requirement would spread this small volume across

[65] "Changing rules, changing roles," CVS Caremark Insights, 2011.
[66] "Driving mail service usage reduces pharmacy costs," OptumRx, 2013.
[67] Pharmacy Benefit Management Institute, op. cit.
[68] During the next 10 years (2023-2032), Visante assumes that approximately 50% of drug spending is "traditional drugs" and approximately50% of drug spending is "specialty drugs." This is based on Visante estimates of historical and projected trends in the growth of specialty expenditures.
[69] Trends in Specialty Drug Benefits, PBMI, 2018.
[70] 2022 economic report on pharmacies and pharmacy benefit managers, Drug Channels Institute, March 2022.
[71] Baldini, C., and Culley, E., "Estimated cost savings associated with the transfer of office-administered specialty pharmaceuticals to a specialty pharmacy provider in a medical injectable drug program," *J Manag Care Pharm.* 2011;17(1):51-59.

too many pharmacies and effectively eliminate the ability of any one pharmacy to achieve the economies of scale necessary to offer the level of discounting currently offered by in-network specialty pharmacies. Under this scenario, specialty pharmacy contract discounts would revert to the lower baseline discounts associated with standard retail pharmacies. We estimate this would increase projected drug expenditures (including specialty and non-specialty) by 0.35%. This estimated impact is only for lost network discounts and does not include the additional cost impact that any willing pharmacy legislation would have on savings derived from other PBM tools, which we have modeled separately.

Prior Authorization and Step Therapy

PA: Today, PA is used by 92% of employer plan sponsors to improve clinical safety and decrease inappropriate utilization and waste.[72] PA decreases prescribing rates and reduces drug costs by shifting from non-preferred to preferred drugs.[73] A range of studies demonstrate that PA substantially reduces expenditures in targeted drug categories. For example, one study found that PA for a high-cost antibiotic resulted in 37% lower pharmacy costs and 38% lower total cost of care for patients prescribed the antibiotic.[74] One specialty pharmacy program that used PA to identify inappropriate utilization across six drug categories based on nationally recognized clinical guidelines achieved a 24% cost reduction in targeted categories.[75] A study of 22 state Medicaid programs found that PA lowered total drug expenditures by 0.6% based on its use in just one drug category alone.[76] Other studies have demonstrated that PA for specialty drugs can generate savings of up to 50% for targeted drugs or categories.[77,78] While most plan sponsors use PA, the number of drugs to which it is applied varies widely across plans. We also believe the use of PA is increasing in tandem with the growth of specialty pharmaceuticals. Based on these sources and assumptions, we estimate PA savings to range from 2% to 8%. Assuming a normal distribution, we estimate a market average of 5%, relative to drug expenditures without PA.

Gold Card Programs

"Gold card" programs allow physicians with high rates of PA approvals over a specified period to be exempt from PA requirements. This would seem to be a mutually beneficial approach – health plans meet resource utilization goals and reduce administrative burdens, and physicians following health plan criteria are excused from PA. However, payers and PBM's experience significant challenges with "gold carding," including the following:[79]

- Provider performance tends to slip once the provider has gold card status
- Performance typically varies across services, so it is difficult to confer gold card status on a provider across all services (i.e., prescriptions, diagnostic tests, etc.)
- Providers within the same clinic or group often perform differently
- Granting gold card status potentially conflicts with state laws that preclude treating enrollees differently
- Prior authorization and claims systems are often not configurable to support different workflows for different providers.

Step Therapy (ST): About 82% of employer plan sponsors used ST to some degree in 2017.[80] A number of studies have found that ST generates savings. For example, step therapy has been found to reduce insurer costs by 9% to 11%.[81] One study examined ST applied to three drug classes and found it generated savings of approximately 2.3% relative to *total* drug expenditures without ST (i.e., total expenditures for the plan, not limited to only the three targeted drug classes).[82] Another study evaluated ST for antihypertensive drugs and found that antihypertensive drug

[72] Pharmacy Benefit Management Institute, op. cit.
[73] United States Government Accountability Office. CMS Should Take Actions to Continue Prior Authorization Efforts to Reduce Spending. April 2018.
[74] Starner, et al., "A linezolid prior authorization program: clinical and economic outcomes," *Am J Pharm Benefits*. 2014;6(2):81-88.
[75] "Specialty pharmacy: historical evolution and current market needs," op. cit.
[76] Fischer, et al., "Medicaid prior-authorization programs and the use of cyclooxygenase-2 inhibitors," *N Engl J Med.* 2004;351:2187-2194.
[77] "Specialty utilization management proves effective: ampyra prior authorization improves safety and saves money," Prime Therapeutics, 2011.
[78] "Specialty prior authorizations reduce costs and enhance medication safety," Walgreens Specialty Pharmacy, 2009.
[79] Berry K. "Prior Authorization." Presentation to Health Information Technology Advisory Committee Office of the National Coordinator for Health Information Technology. March 2019.
[80] Pharmacy Benefit Management Institute, op. cit.
[81] United States Government Accountability Office. CMS Should Take Actions to Continue Prior Authorization Efforts to Reduce Spending. April 2018.
[82] Motheral, et al., "Plan-sponsor savings and member experience with point-of-service prescription step therapy," *Am J Manag Care*. 2004;10:457-464.

costs were 13% lower for the patients in the ST intervention group.[83] Another study examined ST for antidepressants and reported average antidepressant drug cost per day decreased by 9% for patients following the protocol.[84] Taken together, the evidence suggests savings from ST of up to 2% to 3% relative to drug expenditures in the absence of ST. Trends indicate that ST is being used by an increasing number of plan sponsors and being applied to an increasing number of therapeutic categories. Thus, we assume the higher savings of up to 3% relative to expenditures without ST. Since nearly 20% of employer plan sponsors are not yet using ST, we assume a range of ST savings in the market of 0% to 3%. Assuming a normal distribution, we estimate a market average savings of 1.5% relative to drug expenditures without ST.

Potential Impact of State Legislation on Prior Authorization and Step Therapy

Impact of Limits on Use of PA and ST: Various limitations on PA and ST have been proposed in different states, including prohibiting the use of these important PBM tools. Such a prohibition would eliminate the savings generated from these tools altogether, eliminating the average PA savings of 5% and ST savings of 1.5% relative to expenditures without these tools, respectively. With the loss of these savings, projected drug expenditures would increase 6.75%.

Impact of Fiduciary Mandate on PA and ST: Government policies, such as fiduciary mandates, would increase liability risks for PBMs and result in more conservative use of PBM tools, including limited use of PA and ST. With scaled back PA and ST, the range of savings would be compressed toward the low end of the range and, assuming a normal distribution, reduce the market average savings to the midpoint of the new range. Thus, savings from PA would be reduced from a range of 2% to 8% to a range of 2% to 5%, and the market average would decrease from 5% to 3.5%. ST savings would be cut from 0% to 3% to 0% to 1.5%, with average savings dropping from 1.5% to 0.75%. Again, these savings ranges are all stated relative to drug expenditures in the absence of PA and ST. Based on these reductions in savings, projected drug expenditures would increase 2.3% as a result of fiduciary mandates limiting the application of PA and ST. Fiduciary mandates would also have other impact savings from formulary and UM programs, which we have modeled separately.

Impact of Gold Card Programs on Use of PA and ST: Gold card programs would reduce use of PA and reduce associated savings, as well as increase administrative costs and increase premiums. We estimate the impact on total costs related to PA would be approximately half the impact of a fiduciary mandate. Thus, savings from PA would be reduced from a range of 2% to 8% to a range of 2% to 6.5%, and the market average would decrease from 5% to 4.25%. With the reduction of these savings, projected drug expenditures would increase 0.75%.

Other PBM Tools That Improve Formulary Performance

In addition to PA and ST, PBMs use a variety of other tools to improve formulary management and promote the use of more cost-effective formulary drugs. These additional tools all work together to improve formulary performance and deliver drug cost savings:

- Formularies and therapeutic substitution
- Copay tiers
- Consumer education

[83] Yokoyama, et al., "Effects of a step therapy program for angiotensin receptor blockers on antihypertensive medication utilization patterns and cost of drug therapy," *J Manag Care Pharm.* 2007;13(3):235-244.

[84] Dunn, J., et al., "Utilization and drug costs outcomes of a step-therapy edit for generic antidepressant in an HMO in an integrated health system," *J Manag Care Pharm*. 2006;12(4):294-302.

Formularies and Therapeutic Substitution: Based on the decisions of plan sponsors, PBMs implement a variety of tools to improve formulary management/compliance and reduce costs. For example, 73% of plan sponsors opt to have PBMs implement formulary exclusions and 58% opt for mandatory generic programs among many other tools and techniques used alone or in combination.[85] CBO examined potential substitution for seven therapeutic classes and concluded that if generics were used in lieu of single-source brand-name prescriptions, prescription drug costs would have fallen by 7%.[86] Several other studies have demonstrated significant cost savings associated with more aggressive approaches to formulary management.[87,88,89,90,91,92,93,94] Some research on PBM therapeutic substitution suggests savings up to 5% relative to drug expenditures without such substitutions.[95] One PBM reported commercial clients that adopted a more highly managed formulary approach saved 8 percentage points more than clients that did not use this approach.[96]

Formulary management savings are available for both traditional and specialty drugs. Specialty drug categories with formulary-preferred brands have most often included growth hormone, multiple sclerosis, rheumatoid arthritis, blood modifiers, and hepatitis C. One plan increased the market share of the formulary-preferred human growth hormone from 27% to 82% within 12 months, generating savings of 20% in this expensive category.[97] As more biosimilars are approved during the next several years—with discounts of up to 50% relative to their brand competitors—these savings will extend to more specialty categories and become increasingly significant for specialty drug expenditures. A recent Rand study predicted that biosimilars will lead to a $54 billion reduction in direct spending on biologic drugs from 2018 to 2027, or about 3% of total biologic spending over the same period.[98]

We estimate that formulary management and therapeutic substitution programs save 2% to 6% on drug expenditures across all therapeutic categories. However, Visante assumes the effectiveness of these three categories of PBM tools (e.g., formularies and therapeutic substitution, copays, consumer education) depend on them being implemented together in an integrated fashion. Therefore, to be conservative and avoid double-counting of savings, we adjust these estimated savings down to a range of 1% to 3%, relative to expenditures without the use of these PBM tools.

Copay Tiers: During the past 20 years, plan sponsors have dramatically increased the use of tiered copay structures to encourage greater use of generics and preferred brands. Benefit designs with three or more tiers have replaced two-tier benefit designs; the difference between the copay tiers has increased from about $10 up to approximately $30.[99] The implementation of tiered copays has created stronger aligned incentives for consumers and helped create more effective formulary management. One study examined the addition of a three-tier copay, with relatively modest copays of $8/$15/$25. Payer costs dropped 17%, with 10% attributed to the absolute increase in copayments and 7% to the utilization of lower-cost drugs.[100] Another study found that changing from a single-tier or two-tier formulary to a three-tier formulary was associated with a decrease in total drug spending of 5% to 15%, depending on the copay structures.[101] Other studies demonstrated that the introduction of a third tier for non-preferred brands induced a shift to lower-tiered drugs and strengthened plans' ability to negotiate price discounts.[102,103] Another study examined the effect of the size of the copay differential and found that each $5 increase in copayment was associated

[85] Pharmacy Benefit Management Institute, op. cit.
[86] "Effects of using generic drugs on Medicare's prescription drug spending," Congressional Budget Office, Sept. 2010.
[87] Shirneshan, et al., "Impact of a transition to more restrictive drug formulary on therapy discontinuation and medication adherence," *J Clin Pharm Ther*. 2016;41(1):64-69.
[88] Parra, et al., "Retrospective evaluation of the conversion of amlodipine to alternative calcium channel blockers," *Pharmacotherapy*. 2000;20(9):1072-1078.
[89] Usher-Smith, et al., "Evaluation of the cost savings and clinical outcomes of switching patients from atorvastatin to simvastatin and losartan to candesartan in a primary care setting," *Int J Clin Pract*. 2007;61(1):15-23.
[90] Good, et al., "Therapeutic substitution of cimetidine for nizatidine was not associated with an increase in healthcare utilization," *Am J Manag Care*. 2000;6(10):1141-1146.
[91] Benedetto, et al., "Impact of interventions designed to increase market share and prescribing of fexofenadine at HMOs," *Am J Health Syst Pharm*. 2000;57(19):1778-1785.
[92] Meissner, et al., "Drug and medical cost effects of a drug formulary change with therapeutic interchange for statin drugs in a multistate managed Medicaid organization," *J Manag Care Pharm*. 2006;12(4):331-340.
[93] McKinley, et al., "Intraocular pressure control among patients transitioned from latanoprost to travoprost at a Veterans Affairs Medical Center Eye Clinic," *J Ocul Pharmacol Ther*. 2009;25(2):153-157.
[94] Schneeweiss, et al., "A therapeutic substitution policy for proton pump inhibitors: clinical and economic consequences," *Clin Pharmacol Ther*. 2006;79(4):379-388.
[95] Kaiser Family Foundation, op. cit.
[96] "Mid-year drug trend: prime held spending increases to 0.8% for commercial clients, generated negative trend for government program clients," Prime Therapeutics, Oct. 2017.
[97] "Specialty pharmacy: historical evolution and current market needs," presented at PCMA Specialty Pharmacy Symposium, May 5, 2008.
[98] Mulcahy, et al., "Biosimilar cost savings in the United States," The Rand Corporation, Oct. 2017.
[99] "Employer Health Benefits Survey," Kaiser Family Foundation Sept. 2022.
[100] Motheral, et al., "Effect of three-tier prescription copay on pharmaceutical and other medical utilization," *Med Care.* Dec. 2001;39(12):1293-1304.
[101] Landon, et al., "Incentive formularies and changes in prescription drug spending," *Am J Manag Care.* Jun. 2007;13(part 2):360-369.
[102] Joyce, et al, op. cit.
[103] Huskamp, et al., "The impact of a three-tier formulary on demand response for prescription drugs," *J Econ Manag Strategy.* Jul. 2005;14(3):729-753.

with decreased rates of switching to a relatively more expensive drug and an increased rate of switching to drugs of equal or lesser cost.[104]

Our savings model examines combined drug expenditures for both payers and consumers, so reallocating costs from payers to consumers is not counted as savings. That said, there is uncertainty about what the "optimal amount of consumer cost sharing" should be. According to one literature review, 85% of studies that examined changes in patient cost sharing revealed that increasing cost sharing had a negative effect on adherence.[105] Cost-related non-adherence has prompted some employers to reevaluate their cost-sharing policies. Some plan sponsors have reduced or eliminated copayments for selected medications in accordance with value-based insurance designs and demonstrated improvements in adherence as a result.[106,107]

Based on the published evidence, we estimate a range of savings of 2% to 10% associated with more advanced approaches to copay tiers. Again, we count only savings associated with the use of lower-cost drugs. Any shift in the distribution of costs from plan sponsors to consumers is not counted as savings. However, as stated above, Visante assumes the effectiveness of these three categories of PBM tools (e.g., formularies and therapeutic substitution, copays, consumer education) depends on these tools being used in an integrated fashion. Therefore, in order to be conservative and avoid double-counting of savings, we adjust these estimated savings down to 1% to 5%. In other words, moving from a one- or two-tiered copay to more advanced copay tiers may promote use of lower-cost drugs, creating savings of 1% to 5%. Assuming a normal distribution, we estimate average savings of 3%, relative to expenditures with rudimentary copay structures.

Consumer Education: PBMs use a variety of educational programs to increase consumer understanding of their pharmacy benefit. For example, a recent survey revealed that 71% of employer clients provide online tools and mobile apps, 57% provide clinical support and counseling, and 42% provide personalized health information.[108] In addition to stand-alone consumer education programs, PBMs may include incentives in their pharmacy network contracts to achieve improved formulary compliance and use of generic alternatives. For example, one PBM study estimated that consumer education can save up to 4% by combining generic incentives with consumer education.[109] While some plans and PBMs may save up to 4%, other plans invest little time or money in consumer education.

Therefore, we estimate a range of savings of approximately 0% to 4% associated with consumer education. However, as stated above, Visante assumes the effectiveness of these three categories of PBM tools (e.g., formularies and therapeutic substitution, copays, consumer education) depend on working together in an integrated fashion. To be conservative and avoid double-counting of savings, we adjust these estimated savings down to a savings range of 0% to 2%. Assuming a normal distribution, we estimate average savings of 1%, achieved relative to drug expenditures by plans with no consumer education programs.

Other PBM Tools That Manage Drug Utilization

Prior authorization is often used as a UM tool, but PBMs offer their clients other UM tools as well, including drug utilization review (DUR), refill-too-soon checks, and quantity limits.

DUR: DUR programs improve quality and safety by preventing drug duplication, drug interactions, and polypharmacy. Such programs also reduce dangerous over-utilization of prescription drugs. Some DUR programs occur while the prescription is being filled in the pharmacy and the prescription claim is processing through the PBM. These checks include drug-drug interactions, drug duplications, and potential overuse. In addition to these concurrent checks during the claims processing, many employers also use retrospective DUR programs that occur after the prescription has been filled. Approximately 50% of employer plan sponsors now use retrospective DUR services, and 30% use prescriber profiling. More than 75% of employers use DUR programs focused on opioids and

[104] Saito, et al., "Copayment level and drug switching: findings for type 2 diabetes," *Am J Pharm Benefits*. 2010;2(6):412-420.
[105] Eaddy, et al., "How patient cost-sharing trends affect adherence and outcomes—a literature review," *Pharm Ther*. Jan. 2012;37(1):45-55.
[106] Chernew, et al., "Impact of decreasing copayments on medication adherence within a disease management environment," *Health Aff (Millwood)*. 2008;27(1):103-112.
[107] Maciejewski, et al., "Copayment reductions generate greater medication adherence in targeted patients." *Health Aff (Millwood)*. 2010;29(11):2002-2008.
[108] Pharmacy Benefit Management Institute, op. cit.
[109] Visante analysis of PBM Drug Trend Reports.

other controlled substances, while more than 80% of employers use specialty care management programs that include DUR activities.[110] Numerous studies have documented drug cost savings associated with DUR programs. One study examined DUR programs and found average savings of 6.9% relative to total drug expenditures without DUR programs (i.e., total expenditures under the plan, not limited to only drug categories targeted by the DUR programs).[111] An opioid DUR program demonstrated a 28% reduction in potentially unsafe opioid use.[112] DUR savings apply to both traditional (i.e., non-specialty) and specialty drug expenditures. Specialty pharmacies also use DUR to reduce product waste. One specialty pharmacy demonstrated that hemophilia assay management and waste reduction using DUR reduced targeted expenditures by 7.7%, that dose optimization using DUR saved 6.6% on a targeted medication, and that a waste reduction program using DUR reduced drug expenditures on targeted therapy by 1%.[113] Based on this evidence, we estimate a range of DUR savings in the marketplace of 3% to 7%. Assuming a normal distribution, we estimate a market average savings of 5% relative to drug expenditures without DUR.

Refill-Too-Soon Checks: About 92% of employer health plan sponsors use refill-too-soon checks in the claims processing system.[114] A refill-too-soon alert is sent to the pharmacy if, say, a pharmacy dispenses a 30-day supply of medication and the patient tries to refill it 10 days later. We estimate that virtually all plan sponsors obtain savings of 1% based on refill-too-soon checks (savings relative to expenditures without refill-too-soon checks).

Quantity Limits: More than 90% of employers report using quantity limits for top drug categories.[115] Research suggests that specific drug limits and general limitations can save up to 1% of drug expenditures.[116] PBMs publish their standard lists of drugs and quantity limits, which are all very similar.[117] We estimate that virtually all plan sponsors obtain savings of 1% (savings relative to drug expenditures without the use of quantity limits).

Potential Impact of State Legislation on Other Formulary and Utilization Management Programs

Impact of Fiduciary Mandate: Government policies such as fiduciary mandates would increase liability risks for PBMs and result in more limited use of formulary and UM programs. As these programs are scaled back, the range of savings would be compressed toward the low end of the current marketplace range, and thereby reduce the average. We predict that the range of formulary management savings would compress from 2% to 10% to 2% to 6%, with market average savings dropping from 6% to 4%. Savings from DUR programs would decrease from 3% to 7% to 3% to 5%, with the average savings cut from 5% to 4%. Again, these savings are all relative to drug expenditures in the absence of these PBM tools. Based on these reductions in average savings, projected drug expenditures would increase 3%. This estimated impact is only for lost savings related to formulary and UM, and does not include other cost impacts on savings from PA and ST discussed above.

Impact of Any Willing Specialty Pharmacy Legislation: The effectiveness of PA, ST, formulary management, and UM programs in managing specialty drug expenditures often hinges on active participation by specialty pharmacies. Specialty pharmacies have highly trained teams of pharmacists, nurses, and other experts to deliver advanced patient care services, customized for individual patients and individual drug therapies. Specialty pharmacy operations may be coordinated with a PBM's PA, ST, formulary, and UM programs, including special training, staff, and information systems. Any willing specialty pharmacy legislation would bring in specialty pharmacies that do not have specialized resources and expertise and are not coordinated with PBM programs. Therefore, the effectiveness of these PBM programs would be hampered. Without active participation by specialty pharmacies, the range of savings would be compressed toward the low end of the range and, assuming a normal distribution, thereby reduce the market average savings. The range of formulary management savings would decrease from 2% to 10% to 2% to 6%, with the market average savings dropping from 6% to 4%. Savings from DUR programs would decrease from a range of 3% to 7% to a range of 3% to 5%, with the average savings dropping from 5% to 4%. Again, these savings

[110] Pharmacy Benefit Management Institute, op. cit.
[111] Moore, et al., "Systemwide effects of Medicaid retrospective drug utilization review programs," *J Health Polit Policy Law.* Aug. 2000;25(4):653-688.
[112] Qureshi, et al., "Effectiveness of a retrospective drug utilization review on potentially unsafe opioid and central nervous system combination therapy," *J Manag Care Spec Pharm.* Oct. 2015;21(10):938-944.
[113] "Specialty Pharmacy: Historical Evolution and Current Market Needs," op. cit.
[114] Pharmacy Benefit Management Institute, op. cit.
[115] Ibid.
[116] Visante analysis of PBM Drug Trend Reports.
[117] Visante analysis of PBM published quantity limits.

are all relative to drug expenditures in the absence of these PBM tools. This negative impact on PBM savings would be limited to specialty drug expenditures, which are expected to represent approximately 50% of projected drug expenditures during the next 10 years. Based on these reductions in average savings on specialty drug costs, overall projected drug expenditures (i.e., specialty and non-specialty) would increase 2.9%. This estimated impact is only for lost savings related to formulary and UM and does not include other negative impacts on savings from other PBM tools discussed above (e.g., specialty pharmacy, network discounts, PA, and ST).

Potential Impact of Fiduciary Mandates: Additional Costs of Liability Insurance

Requiring PBMs to owe a fiduciary duty to covered entities would expose PBMs to increased legal risk that may result in the need to adopt defensive business and operating strategies to avoid the threat of litigation. The added cost of increased insurance exposure could drive pharmaceutical costs higher. Operationally, we believe that an important impact of the legislation is to expose PBMs to legal liability for the drug benefits that they manage. PBMs would have to boost their liability insurance and might limit the use of utilization techniques to avoid potential lawsuits.

The most reliable data on medical liability insurance costs were published in 2010.[118] These data suggested that total liability insurance costs for doctors and hospitals were approximately 1% of total U.S. expenditures for doctors and hospitals. We estimate that PBMs would be forced to purchase liability insurance that might be priced in a similar manner. Therefore, we apply the same ratio to PBMs and drug expenditures (i.e., additional PBM liability insurance costs will be approximately 1% of covered drug expenditures). In other words, projected drug expenditures would increase 1%. This estimated impact is only for the additional cost of liability insurance and does not include other cost impacts on savings from other PBM tools discussed above.

We interviewed a number of legal experts who believe that this methodology is reasonable. However, given the limited information available, it probably understates the potential cost of additional insurance, particularly since this would be a new type of insurance coverage and thus carry additional risk and additional price premiums from liability insurers.

In addition, fiduciary mandates would result in additional costs from administering benefits under a patchwork of varying legal requirements across states. Additional costs and risks could result from private actions for damages by a client or a consumer, as a result of a "fiduciary" label. All those costs would be passed back inevitably to the plan sponsors, but we are unable to specifically estimate these potential costs. Therefore, we believe our estimates for both insurance and other costs associated with fiduciary requirements are conservative and understated.

Summary: Potential Impact of State Legislation on PBM Tools and Savings

The table below summarizes which PBM tools would be negatively affected by four types of state legislation.

PBM Tools/Impact	Disclosure Mandate	Fiduciary Mandate	Prohibit PA and ST	Any Willing Specialty Pharmacy
Manufacturer rebates	✓			
Pharmacy network contract discounts	✓			✓
PA and ST		✓	✓	✓
Other PBM tools that improve formulary performance		✓		✓
Other PBM tools that manage utilization		✓		✓
Additional liability insurance		✓		
Increase in projected drug expenditures	**5.2%**	**6.7%**	**6.75%**	**3.0%**

[118] Mello, et al., "National costs of the medical liability system," *Health Aff (Millwood).* 2010;29(9):1569-1577.

B. Projected Drug Expenditures (2023 to 2032) and State-by-State Breakdowns

To derive baseline drug expenditures managed using PBM tools, Visante began with CMS National Health Expenditure (NHE) projections for outpatient prescription drug expenditures from 2021 to 2030. These expenditures do not include drugs administered in hospitals or physician offices. Visante extrapolated these projections to 2031 and 2032. By these estimates, spending on outpatient prescription drugs will grow from $398 billion in 2023 to $623 billion in 2032, for a total of more than $5 trillion over the 10-year period.[119]

The projections reflect CMS assumptions concerning the impact of health reform, manufacturer price inflation, patent expirations, new drug introductions, follow-on biologics, and other factors. Our model incorporates these assumptions to the extent that they are incorporated into the NHE projections.

CMS outpatient drug expenditure projections reflect net costs to payers, including plan sponsors and consumers. Manufacturer and pharmacy discounts are reflected in CMS figures. CMS segments outpatient prescription drug expenditures by payer, including private insurance, Medicare, Medicaid, and other government programs. Visante assumes that nearly all commercial/private insurer expenditures are associated with the use of PBM tools. Visante also estimated the share of consumer out-of-pocket expenditures arising from copayments/cost sharing for prescriptions associated with PBMs and PBM tools, based on survey data for commercial plan sponsors.[120,121]

After these calculations, we estimate that outpatient prescription drug expenditures for the commercial market (associated with average use of PBM tools, including plan sponsor and consumer payments) will be approximately $187 billion in 2023 and $2.2 trillion over the 10-year period 2023 to 2032. Drug expenditures for the fully insured portion of the commercial market will be $90 billion in 2023 and more than $1 trillion over the 10-year period from 2023 to 2032.

As discussed, CMS's 10-year projections reflect many assumptions regarding marketplace trends. We believe that CMS estimates reasonably capture these trends and reflect the current savings that PBMs achieve in the marketplace. For example, CMS estimates that drug manufacturer rebates to pharmacy benefit managers have increased sharply in the past few years and have dampened prescription drug spending growth. However, CMS does not publish the detailed factors underlying its model, so we estimated the factor inputs necessary to model PBM savings and then applied them to baseline expenditures derived from CMS data. Our modeling assumes no significant changes to rebates in the future, although there are currently proposals that could result in significant changes, such as elimination of the rebate safe harbor in Medicare Part D,

We assume that over the 10-year projection period:

- Expenditures for traditional prescription drugs will show low growth or no growth during the next 10 years, while specialty drug spending will continue to grow rapidly.[122] The generic dispensing rate was 92% in 2021[123] and will grow slowly.[124] We assume that these trends are captured in the CMS projections.
- Specialty medications will continue to be the dominant force driving growth in prescription drug expenditures. One report estimates total specialty drug revenues increasing from 28% of total in 2011 to 55% in 2021.[125] We estimate the total specialty share of drug expenditures under the pharmacy benefit growing from 47% in 2023 to 61% in 2032. Our estimates do not include specialty drug expenditures covered under the medical benefit and administered in hospitals, clinics, and physician offices, which are not included in CMS projected outpatient drug expenditures and not included in our analysis.
- While more PBMs are playing a management role in physician-administered specialty injectable drugs

[119] National Health Expenditure Data, CMS.
[120] "Employer health benefits survey," Kaiser Family Foundation, Sept. 2022.
[121] Pharmacy Benefit Management Institute, op. cit.
[122] Drug Trend Reports from CVS Health, Express Scripts, and Prime Therapeutics.
[123] IQVIA Institute, op. cit.
[124] IQVIA and PBM Drug Trend Reports.
[125] IQVIA Institute, "specialty as % of BOTH OP pharmacy and medical benefit drug spend," op. cit.

covered by medical benefits, our projected drug expenditures and PBM savings estimates do not reflect such activity.

We created a state-by-state breakdown for the national projected drug expenditures for various health insurance markets. Projected national outpatient drug expenditures were then calculated for each state based on Visante's state-by-state enrollment estimates, including state-by-state enrollment estimates for commercial fully insured, commercial self-insured, Medicare, and Medicaid based on a number of published references. [126,127,128,129,130,131,132,133,134]

Our methodology results in state-by-state estimates that capture many—but not all—of the factors that may characterize the prescription drug market in individual states. Any unusual circumstances that would not be captured by enrollment patterns would not be reflected in our estimates. Finally, some states may have already enacted laws related to the legislative areas included in our economic model. To the extent that such laws have already raised costs, those costs would be included in the estimates presented in the report.

[126] US Census, State Population Totals.
[127] US Census - Health Insurance in the United States: Number and Percentage of People Without Health Insurance Coverage by State
[128] Kaiser Family Foundation, Share of Private-Sector Enrollees Enrolled in Self-Insured Plans
[129] More than 98% of covered workers in employer-sponsored plans have a specialty prescription drug benefit. "Employer health benefits survey," Kaiser Family Foundation, Sept. 2022.
[130] Marketplace Enrollment, Kaiser Family Foundation.
[131] Dual Eligibles as a Percent of Total Medicare Beneficiaries, Kaiser Family Foundation.
[132] Medicaid Enrollment: Monthly Medicaid and CHIP Application, Eligibility Determination, and Enrollment Reports, from Medicaid.gov.
[133] Medicare Advantage/Part D Contract and Enrollment Data - Monthly Enrollment By State.
[134] Medicaid Gross Spending for Drugs by Delivery System and Brand or Generic Status, macpac.gov

Appendix: Ten-Year Cost of Proposals Impacting PBM Tools by State, 2023-2032

Fully Insured Commercial Sector Only		**Potential PBM Savings Lost** *(millions, 2023-2032)*			
State	**Beneficiaries in Fully Insured Plans**	**Cost of Disclosure Mandate**	**Cost of Fiduciary Mandate**	**Cost of Prohibition on PA & ST**	**Cost of Any Willing Specialty Pharmacy**
Alabama	1,092,455	$782	$1,006	$1,018	$481
Alaska	112,234	$80	$103	$105	$49
Arizona	1,540,484	$1,102	$1,419	$1,436	$678
Arkansas	621,343	$444	$572	$579	$273
California	11,000,887	$7,870	$10,133	$10,255	$4,839
Colorado	1,533,228	$1,097	$1,412	$1,429	$674
Connecticut	804,532	$576	$741	$750	$354
Delaware	221,203	$158	$204	$206	$97
District of Columbia	184,091	$132	$170	$172	$81
Florida	5,661,652	$4,050	$5,215	$5,278	$2,490
Georgia	2,073,953	$1,484	$1,910	$1,933	$912
Hawaii	467,694	$335	$431	$436	$206
Idaho	459,809	$329	$424	$429	$202
Illinois	2,961,571	$2,119	$2,728	$2,761	$1,303
Indiana	1,152,892	$825	$1,062	$1,075	$507
Iowa	700,662	$501	$645	$653	$308
Kansas	793,845	$568	$731	$740	$349
Kentucky	721,909	$516	$665	$673	$318
Louisiana	835,720	$598	$770	$779	$368
Maine	334,326	$239	$308	$312	$147
Maryland	1,399,848	$1,001	$1,289	$1,305	$616
Massachusetts	1,885,023	$1,348	$1,736	$1,757	$829
Michigan	2,041,463	$1,460	$1,880	$1,903	$898
Minnesota	1,224,258	$876	$1,128	$1,141	$538
Mississippi	613,759	$439	$565	$572	$270
Missouri	1,539,379	$1,101	$1,418	$1,435	$677
Montana	238,063	$170	$219	$222	$105
Nebraska	357,525	$256	$329	$333	$157
Nevada	746,469	$534	$688	$696	$328
New Hampshire	391,496	$280	$361	$365	$172
New Jersey	1,981,755	$1,418	$1,825	$1,847	$872
New Mexico	296,722	$212	$273	$277	$131
New York	4,317,695	$3,089	$3,977	$4,025	$1,899
North Carolina	2,386,096	$1,707	$2,198	$2,224	$1,050
North Dakota	248,618	$178	$229	$232	$109
Ohio	2,465,141	$1,763	$2,271	$2,298	$1,084
Oklahoma	828,984	$593	$764	$773	$365
Oregon	1,033,144	$739	$952	$963	$454
Pennsylvania	3,093,272	$2,213	$2,849	$2,884	$1,361
Rhode Island	266,571	$191	$246	$248	$117
South Carolina	1,149,919	$823	$1,059	$1,072	$506
South Dakota	243,905	$174	$225	$227	$107
Tennessee	1,627,547	$1,164	$1,499	$1,517	$716
Texas	6,440,037	$4,607	$5,932	$6,003	$2,833
Utah	1,157,322	$828	$1,066	$1,079	$509
Vermont	131,583	$94	$121	$123	$58
Virginia	1,708,642	$1,222	$1,574	$1,593	$752
Washington	1,828,957	$1,308	$1,685	$1,705	$804
West Virginia	302,879	$217	$279	$282	$133
Wisconsin	1,512,453	$1,082	$1,393	$1,410	$665
Wyoming	173,890	$124	$160	$162	$76

HB0357_Amended_MVP_Wienner_FAV.pdf
Uploaded by: Stephen Wienner
Position: FAV

Mt. Vernon Pharmacy

900 Cathedral St. * Baltimore, Maryland 21201 * Phone: 410-539-8030 * Fax: 410-539-8115
Prescription and Over the Counter Medications * Prescription Counseling * Diabetes Supplies * Vaccinations

IN SUPPORT OF:
HB0357 – Pharmacy Benefits Managers – Definitions of Carrier, ERISA, and Purchaser

SENATE FINANCE COMMITTEE
Hearing: 3/29/2023 at 1:00 PM

Mt. Vernon Pharmacy offers its **SUPPORT of HB0357 – Pharmacy Benefits Managers – Definitions of Carrier, ERISA, and Purchaser, as amended in the House, without further amendments.**

Pharmacy bills and laws take may years to pass involving many, many compromises. When those initial bills were passed can you guess what the PBMs and PCMA argued. Each and every piece of PBM legislation in every state has historically had two opposing arguments by PCMA, the trade group for PBMs.

Argument 1: What you want to legislate is "plan design" and your laws don't affect self-insured payers. Everything is plan design. Every dotted "I" and crossed "t" is plan design. And though independent pharmacy argued against such nonsense, PCMA cluing to the plan design argument. If self-insured plans were blind-sided by the Supreme Court Rutledge decision that said PBM legislation is absolutely not plan design and subject to state legislation, it is the fault of bad advice by consultants, lobbyists, and attorneys that acted as parakeets for what the self-insured payers wanted to hear.

Argument 2: What you want to legislate will raise prices for payers and plans. There has not been one piece of current legislation, past or present, where PCMA has not claimed the sky will fall because of increased expense to payers. Some notable pieces of already passed legislation that were supposed to bankrupt payers:

- Maryland original Pharmacy Audit laws passed in 2008
- Language mandating that pharmacies be paid by ACH rather than paper checks.
- Pharmacy MAC appeal language giving pharmacies a way to appeal payments under the pharmacy's cost for generic drug reimbursement.
- Laws mandating PBM's give timely notice of contract changes to pharmacies
- Laws removing gag clauses by PBM's: allowing pharmacies to disclose to a patient aless expensive alternative to what was originally prescribed or what might be preferred on a PBM formulary
- Laws removing gag clause by PBM's that were used to charge patients high copays at the pharmacy counter and then the PBM would claw those funds back from the patient by recouping those inflated copays back from the pharmacy.

The fiscal note lists the areas of Maryland Law that will be affected by this bill. I challenge any of the opponents to identify what specifically will raise costs for plans, and to quantify that increase by showing how the laws originally raised cost when originally enacted.

The PBM industry has been for the most part unregulated in this country, and that industry has abused that lack of regulation. The three largest PBMs' are number 4,5 and 12 on the Fortune 100 list. It is very profitable to not be regulated. A quick google search of state and federal lawsuits against PBMs will display that abuse.

While on Google, do a search for, "What are the causes of increased prescription costs for payers/ insurers." I challenge you to find any listing that says the source of rising drug costs are the result of pro pharmacy PBM legislation.

And sure, I could certainly fill prescriptions cheaper without any pharmacy regulation. Dispensing prescription drugs without a pharmacist on staff in my pharmacy would save a boat load of money. But that is not a valid excuse and does not make it right. This same holds true for regulating these entities that have such a profound impact on the lives of your constituents and patients.

I thank the Committee for all the effort you have expended in working through PBM legislation in the past and **respectfully ask your favorable support on HB0357, as amended in the House, without further amendments**.

Should the Committee require any additional information, please contact me or Dennis F. Rasmussen, **dfr@rasmussengrp.net** or 410-821-4445.

Respectfully,

Steve Wienner, RPh
EPIC Legislative Committee
Mt. Vernon Pharmacy and Mt. Vernon Pharmacy at Fallsway
mtvernonpharmacy@gmail.com – 410-207-3052

hb0357 testomony .pdf
Uploaded by: Tom Wieland
Position: FAV

Tom Wieland bill HB0357 in favor of

3/28/23

2464 Symphony lane, Gambrills, Md. 21054

Ritchie Pharmacy, 5507 Ritchie Hwy, Brooklyn Park, Md. 21225

My store is located next to Second Chance. Second Chance is a facility that deals with people trying to get their life straight and also off drugs. While they are at Second Chance, they are required to have their medicine held by Second Chance technicians. When they need meds new or refilled, the techs there just walk over to my store and get them. However, many have United Health Care, a MCO that does not allow us to fill their meds. This includes meds for high blood pressure, diabetes, and other meds. Since Second Chance, doesn't know which meds these patients will be needing before being admitted there, the patients are stuck without their meds. We (Ritchie Pharmacy) is not the only pharmacy excluded from this MCO and is making very difficult for people in need to get their meds in a convenient time and way.

Tom Wieland

Tom Wieland

RPh

HB 357_MDCC_Pharmacy Benefits Managers - Definitio
Uploaded by: Andrew Griffin
Position: UNF

MARYLAND
Chamber of Commerce

LEGISLATIVE POSITION:
Unfavorable
House Bill 357 – Pharmacy Benefits Managers - Definition of Purchaser and Alteration of Application of Law
Senate Finance Committee
Wednesday, March 29, 2023

Dear Chairwoman Griffith and Members of the Committee:

Founded in 1968, the Maryland Chamber of Commerce is the leading voice for business in Maryland. We are a statewide coalition of more than 6,400 members and federated partners working to develop and promote strong public policy that ensures sustained economic health and growth for Maryland businesses, employees, and families.

House Bill 357 amends current state law governing pharmacy benefit managers by repealing the previous definitions of "carrier" and "ERISA" and altering the definition of "purchaser." As a result, the bill seeks to broadly expand the state regulations governing pharmacy benefit managers to additional entities providing prescription drug coverage or benefits in the state, including programs subject to the federal Employee Retirement Income Security Act of 1974 (ERISA).

This legislation will have major impacts on both employers and employees throughout the state. With the majority of private sector employees participating in healthcare plans that are covered under ERISA protections, the Chamber urges the committee to avoid any legislative action that could increase healthcare costs for Marylanders and negatively impact the ability of health plan providers to design affordable products for the Maryland healthcare market. While we understand that the *Rutledge* Supreme Court decision has opened the door to new and additional state regulation, the Chamber is very concerned that further state regulation of ERISA protected health plans will result in worse outcomes for both employers and employees.

HB 357 would strip away the very ERISA protections and benefits that have allowed employers to provide healthcare and prescription drug benefits at affordable prices for thousands of hard-working Marylanders. **By removing these policies, protections, and benefits that allow employers to keep benefit premiums as low as possible, Maryland employers and employees stand to incur significant increases in co-pays, co-insurance rates, and prescription drug prices.** The increased costs will flow downhill to employees who want and need these benefits and the employers who strive to offer them.

In 2019, Maryland became the first state to establish a Prescription Drug Affordability Board. The law requires the board to review both state and commercial health plans' use of prescription drugs and make recommendations to state officials on ways to make them more affordable for residents. By December 1, 2023, the board is required to submit a report to the General Assembly that recommends whether legislation should be passed to expand the authority of the

board to set upper payment limits to all purchases and payor reimbursements of prescription drug products in the state. HB 357 should not be implemented until the report has been submitted and reviewed.

Healthcare coverage must remain affordable so that employers can continue to offer these benefits that employees both want and cherish. Given the far-reaching and negative impacts of this legislation, the Maryland Chamber of Commerce respectfully requests an **Unfavorable Report** on H**B 357.**

HB 357 - UNF - MML.pdf
Uploaded by: Angelica Bailey Thupari
Position: UNF

Maryland Municipal League

The Association of Maryland's Cities and Towns

TESTIMONY

March 29, 2023

Committee: Senate Finance

Bill: HB 357 – Pharmacy Benefits Managers - Definition of Purchaser and Alteration of Application of Law

Position: Oppose

Reason for Position:

The Maryland Municipal League strongly opposes HB 357, which effectively limits the tools Pharmacy Benefits Managers (PBMs) can use to negotiate pharmaceutical prices on behalf of their clients, including local governments.

By restricting the ability to design all aspects of benefits plans, to have full management over contracting with vendors to provide benefits, and to create the checks and balances employers deem necessary to protect staff and their financial contributions to the plan, this legislation increases the cost of co-pays and overall plans, infringing on an employer's ability to offer affordable benefits.

Our 157 towns and cities employ thousands of Maryland residents across the State. Most municipalities cannot afford to pay the salaries offered in the private sector; providing comprehensive and affordable benefits is one of the few tools we have to attract and retain staff and thereby provide quality services to our residents. Increasing the cost of providing those benefits will be detrimental to our members and their employees.

For these reasons, the League joins the Maryland Association of Counties (MACo) and respectfully requests that this committee provide HB 357 with an unfavorable report.

FOR MORE INFORMATION CONTACT:

Theresa Kuhns	Chief Executive Officer
Angelica Bailey Thupari, Esq.	Director, Advocacy & Public Affairs
Bill Jorch	Director, Public Policy
Justin Fiore	Deputy Director, Advocacy & Public Affairs

1212 West Street, Annapolis, Maryland 21401

410-268-5514 | 800-492-7121 | FAX: 410-268-7004 | www.mdmunicipal.org

HB 357 Oppose.pdf
Uploaded by: Balfour Albacarys
Position: UNF

INTERNATIONAL BROTHERHOOD OF ELECTRICAL WORKERS - LOCAL UNION No. 24

AFFILIATED WITH:
Baltimore-D.C. Metro Building Trades Council — AFL-CIO
Baltimore Port Council
Baltimore Metro Council — AFL-CIO
Central MD Labor Council — AFL-CIO
Del-Mar-Va Labor Council — AFL-CIO
Maryland State - D.C. — AFL-CIO
National Safety Council

AFL-CIO-CLC
BALTIMORE, MARYLAND 21230

C. SAMUEL CURRERI, President
DAVID W. SPRINGHAM, JR., Recording Secretary
JEROME T. MILLER, Financial Secretary
MICHAEL J. McHALE, Business Manager

OFFICE:
2701 W. PATAPSCO AVE
SUITE 200

Phone: 410-247-5511
FAX: 410-536-4338

Written Testimony Of

Rico Albacarys, Assistant Business Agent, IBEW Local 24

Before the Senate Finance Committee On

HB 357 Pharmacy Benefits Managers – Definition of Purchaser and Alteration of Application of Law

OPPOSE

March 28, 2023

Madame Chair Griffith and Members of the Senate Finance Committee,

Thank you for the opportunity to submit testimony in **opposition of HB 357**.

My name is Rico Albacarys and I am a member and employee of IBEW Local 24, in Baltimore. I represent over 2,000 working men and women in the State of Maryland and roughly 6,000 individuals when including spouses and dependents. Excluding certain groups and benefits managers will have an adverse impact on prescription costs for many Marylanders. Increasing prescription costs at a time when inflation is already placing an economic burden on families does not seem like sound policy.

We are being told this legislation will increase prescription costs for our members, somewhere between 5%-10%.

For this reason, we ask that you vote **unfavorably on HB 357**.

Sincerely,

Rico Albacarys

Assistant Business Manager, IBEW 24

NAIFAhb3572023.pdf
Uploaded by: Brett Lininger
Position: UNF

House Bill 357

Pharmacy Benefits Managers – Definition of Carrier, ERISA, and Purchaser

Position: Unfavorable

Dear Chair Griffith, Vice Chair Klausmeier and Members of the Senate Finance Committee.

NAIFA-MD ("The National Association of Insurance and Financial Advisors – Maryland Chapter") appreciates the opportunity to submit written testimony on House Bill 357. NAIFA-MD is made up of insurance agents and advisors, financial advisors and financial planners, investment advisors, broker/dealers, multiline agents, health insurance and employee benefits specialists, and more. We are the closest to the consumer and employers by helping them navigate the complex arena of health benefits.

NAIFA-MD opposes House Bill 357[1] as it broadly expands Maryland's regulation of pharmacy benefit managers working on behalf of self-funded large employers, counties, municipalities, unions and their respective employees. For nearly 50 years, ERISA has prevented state legislators from preempting federal laws governing self-funded plans. This means employers with self-funded plans could expect consistency across state lines. However, a 2020 U.S. Supreme Court decision in Rutledge v. PCMA has jeopardized those federal protections. The Rutledge decision upheld an Arkansas law that required PBMs to reimburse pharmacists at certain levels. The decision has emboldened a wave of state-level activism, such as this legislation, driven by stakeholders who are looking to increase their profits.

To understand the potential impact of this legislation, which is being opposed by employers in the State, including unions, counties, municipalities, and private employers, it is important to understand what legislation has been introduced previously in Maryland and around the country.

- Statutorily set reimbursement rates and dispensing fees
- prohibition on preferred mail order
- dismantling of specialty networks

Additionally, it was thought network design was part of benefit design but the MIA's interpretation that §15-1611.1 is not plan design makes key decisions self-funded plans make to manage cost by tailoring their networks fair game. Passing this legislation means guaranteeing profits for a small number of pharmacies over keeping benefits affordable and available for employees across the State.

[1] As introduced and as amended and passed out of the House.

As the State looks to lower prescription drug costs through the Prescription Drug Affordability Board ("PDAB"), the legislature should also be thoughtful and intentional about not driving up the cost of prescription drug benefits through bills such as this.

We urge an unfavorable report.

HB357_MAC0_OPP
Uploaded by: Brianna January
Position: UNF

MARYLAND Association of COUNTIES

House Bill 357

Pharmacy Benefits Managers - Definition of Purchaser and Alteration of Application of Law

MACo Position: **OPPOSE**

To: Finance Committee

Date: March 29, 2023

From: Brianna January

The Maryland Association of Counties (MACo) **OPPOSES** HB 357. This bill seeks to limit the tools Pharmacy Benefits Managers (PBMs) can use to negotiate pharmaceutical prices on behalf of their clients, including county governments. In doing so, it would greatly disrupt counties' ability to provide our staff with the best and most fiscally responsible benefits for their public service.

The bill would do so in several ways, including by restricting the abilities to design all aspects of benefits plans, to have full management over contracting with vendors to provide benefits, and to create the checks and balances employers deem necessary to protect staff and their financial contributions to the plan. In practice, HB 357 would substantially limit, if not negate, PBMs' ability to leverage certain cost-saving tools critical to negotiating the best and fairest prescription drug prices for counties and our staff, like requiring 90-day supplies of certain drugs or requiring mail orders to fill certain prescriptions.

Counties employ and fund thousands of workers across the state as county staff, first responders, correctional employees, and school staff. Providing benefits for large numbers of employees is something counties take very seriously. We accomplish this through well-established negotiations, consultants, benefit managers, RFPs and more. The State has not been a part of this work and should not be, however, under HB 357, the State would do just that, with detrimental financial impacts to counties and the thousands they employ.

Ultimately, HB 357 would not only restrain counties' ability to provide comprehensive health benefits, but it would also increase the co-pays and overall plan costs of our staff – everyday Marylanders serving their communities. It is no secret that local governments cannot compete with the salaries offered by the private sector. However, counties can, and do, offer excellent benefits at low or no-cost to staff. By meddling with the abilities of PBMs to negotiate fair prices on behalf of employers, HB 357 would greatly undermine counties' ability to continue to do so. For these reasons, MACo **OPPOSES** HB 357 and urges an **UNFAVORABLE** report.

HB 357_MAHU_UNF.pdf
Uploaded by: Bryson Popham
Position: UNF

March 27, 2023

The Honorable Melony Griffith
Chair, Senate Finance Committee
3 East, Miller Senate Office Building
Annapolis, MD 21401

RE: House Bill 357 - Pharmacy Benefits Managers - Definition of Purchaser and Alteration of Application of Law - UNFAVORABLE

Dear Chair Griffith and Members of the Senate Finance Committee,

On behalf of the Maryland Association of Health Underwriters (MAHU), I wish to express our opposition to House Bill 357.

MAHU is a trade association comprised of several hundred licensed health insurance producers in Maryland who represent both businesses and individuals in analyzing their need for health insurance and advising clients on health insurance coverage and benefits. MAHU members have traditionally served as the representatives for small and medium-sized businesses in the negotiation of health benefit plans for the employees of those businesses.

An important part of the services provided by MAHU members is assisting employer clients in evaluating the cost of benefits and coverages. One area where both the cost and benefit design offer employers a number of options is in the area of pharmacy benefits. MAHU members typically use the services of pharmacy benefits managers (PBMs) to provide these services, and PBMs compete vigorously for this business.

Traditionally, PBMs have not been subject to State law requirements because they have operated under the federal law known as ERISA. Senate Bill 357 would remove this exemption, and subject pharmacy benefit plans to more restrictive State law requirements. This will have the effect of removing options currently available to these employers, and for that reason MAHU opposes the provisions of House Bill 357.

MAHU does not see a consumer benefit that would be achieved by the passage of this legislation. We are aware of no serious complaints by either employers or persons covered under employer-based health plans who use PBM services. For these reasons, we respectfully request an unfavorable report on House Bill 357.

Very truly yours,

Jon S. Frank
301-502-8522

cc: Bryson F. Popham
Nancy Colaianne, President MAHU

2023-03-16 PBM Primer - PCMA2.pdf
Uploaded by: Camille Fesche
Position: UNF

Pharmacy Benefit Companies 101: A Primer

March 16, 2023

- Rx Research Corner

Given all the recent attention around pharmacy benefit companies and prescription drug costs, I thought it would be helpful to create a primer of what exactly a pharmacy benefit company is and does. A lot of people aren't too sure what roles pharmacy benefit companies play in the drug supply chain, and I'm hoping to clear some of that ambiguity up with a Q&A.

What is a pharmacy benefit company?

A pharmacy benefit company is an entity that is responsible for pharmacy benefits – the way you gain access to your prescription drugs – function well for more than 275 million people nationwide, allowing us all to access our drugs easily. Pharmacy benefit companies help the entire healthcare system by driving down drug costs, saving money for patients and health plan sponsors – those that hire pharmacy benefit companies, including public and private sector employers, government programs like Medicare and Medicaid, health insurers, and labor unions.

Pharmacy benefit companies save health plan sponsors and patients $1,040 per person per year, adding up to $1 trillion over the next ten years.

How do pharmacy benefit companies save money for health plan sponsors and patients?

According to research, pharmacy benefit companies save health plan sponsors and patients $1,040 per person per year, adding up to $1 trillion over the next ten years. Much of this direct savings comes from the rebates and discounts that pharmacy benefit companies negotiate from drug companies and pass back to plan sponsors, who can choose to use the savings to make benefits more affordable or lower patient out-of-pocket costs. Rebates function, in effect, as volume-based discounts that can best be negotiated when there is competition among drug companies. The use of the savings is fully at the discretion of the employer or plan sponsor. But pharmacy benefit companies do far more than just negotiate rebates. Pharmacy benefit companies provide at least $148 billion in value for the healthcare system every year. In addition to negotiating drug company rebates, pharmacy benefit companies also reduce costs and improve health by negotiating lower costs and higher quality from pharmacies, facilitating convenient mail delivery of prescriptions, promoting the use of less costly yet

equally effective generic drugs, and helping patients stay on their drugs, thereby avoiding serious and costly medical events.

What are pharmacy benefit companies doing to help patients afford their medications?

Pharmacy benefit companies provide affordable access to prescription drugs for 275 million people every year, which means helping patients, clinicians, and pharmacists navigate more than 3.6 billion prescriptions filled annually. Without pharmacy benefit companies, the savings they negotiate, and prescription drug coverage, patients could be forced to pay drug companies' list prices – sometimes incredibly high list prices – for their prescriptions. Pharmacy benefit companies have programs to help patients who face high cost sharing (i.e., out-of-pocket costs), including those patients who are in their deductible phase of coverage. This program covers a wide range of drugs used to treat chronic conditions like diabetes, asthma, and heart disease. For example, many pharmacy benefit companies cap the cost of insulin at $25 for a 30-day supply.

How do pharmacies negotiate with pharmacy benefit companies?

Pharmacies of all sizes work with pharmacy benefit companies and contract with pharmacy benefit companies for agreed-upon reimbursement rates for prescription drugs. These rates are based on drug acquisition costs, taxes, and other fees charged by the pharmacy. While independent pharmacists can choose to negotiate their contracts directly with pharmacy benefit companies, the vast majority choose to join a pharmacy services administrative organization (PSAO), which has scale and collective bargaining power. The PSAO marketplace is dominated by the big three wholesalers: AmerisourceBergen, Cardinal Health, and McKesson. Over 75% of independent and small-chain pharmacies contract with a PSAO owned by one of these wholesalers. PSAOs are powerful corporate entities, operating with virtually no state or federal regulation or oversight.

Why do pharmacy benefit companies use pharmacy networks?

Pharmacy benefit companies build pharmacy networks to allow patients access their prescriptions at discounted rates. Pharmacies negotiate to be in networks, offering discounts in exchange for network status to attract customers. They also are held to performance metrics that enable a high-quality experience for patients; for example, encouraging generic drug dispensing and patient medication adherence. Keeping pharmacies accountable for providing lower-cost drugs and high-quality service is an important tool pharmacy benefit companies use to keep the rising costs of prescription drugs down for patients and taxpayers. In Medicare Part D, where the use of pharmacy

networks is extremely common, pharmacy benefit companies are able to negotiate 1.9% to 2.3% lower drug prices.

Do pharmacy benefit companies force independent pharmacies to close?

Pharmacies are important partners with pharmacy benefit companies, who help make drugs accessible and affordable for patients. Rather than being in decline, the independent pharmacy market is stable and profitable. According to National Council for Prescription Drug Programs' (NCPDP) data, over the last ten years, the number of independent retail pharmacies nationwide increased by 1,638 stores or 7.5%. Over the last five years, the number of independent pharmacies has increased 0.5%, indicating a stable marketplace. In fact, this is not just NCPDP's data showing this; the National Community Pharmacy Association (NCPA), the lobbying group for independent pharmacists, agrees. In their annual 2022 Digest Report, they report that the number of independent pharmacies increased by 0.4% in the last year, stating that the "independent pharmacy category was essentially flat."

Additionally, independent pharmacies' financials have also been stable. From 2016 to 2020, the average per prescription gross profit margin for independent pharmacies ranged from 20.8% to 21.1%, showing little fluctuation. This market's strength and stability allows pharmacy benefit companies more opportunities to partner with independent pharmacies to achieve our shared objectives of increasing access to affordable medications and helping patients stay on their prescribed medications.

How competitive is the pharmacy benefit marketplace?

The pharmacy benefit marketplace is highly competitive, with 70 full service pharmacy benefit companies operating in 2021. And this number is increasing, with nearly 10% more pharmacy benefit companies in 2021 than in 2019. Pharmacy benefit companies differentiate themselves through product innovation and client services. For example, they can offer employers and health plan sponsors the ability to include medication adherence programs, patient support programs, and customized low or zero cost sharing in the prescription drug benefits they offer to their employees and plan members.

Do pharmacy benefit companies support transparency?

Pharmacy benefit companies are strongly in favor of transparency that provides usable information for plan sponsors, prescribers, and patients. Technology like real time benefit tools (RTBT), electronic prior authorization (ePA), and electronic prescribing (eRx) reduce burdens and provide actionable information. Pharmacy benefit companies also provide plan sponsors with financial data on savings they've secured on

prescription drugs, fees and payments, aggregate data on drug utilization and plan enrollees, and details about how much will be paid for each drug filled under the plan. This information helps plan sponsors make the best plan choices for them and the people they enroll in prescription benefit coverage. Pharmacy benefit companies also submit to regular, contractually required, plan-sponsor audits. Misguided "transparency" proposals that require disclosure of proprietary information would encourage drug companies to offer fewer price concessions once they realized competitors weren't discounting as deeply. This tacit collusion by drug companies would result in higher drug costs.

How are pharmacy benefit companies paid?

In addition to making final decisions on benefit design and coverage, employers, and health plan sponsors (i.e., payers) also choose how they would like to pay for the services and programs pharmacy benefit companies deliver to them. There are two main choices that employers and health plans make when hiring a pharmacy benefit company:

Risk Mitigation Contracting

- The employer or health plan pays their pharmacy benefit company a set reimbursement amount for each drug, regardless of where the patient fills the prescription. If the patient's pharmacy charges the pharmacy benefit company more than that set reimbursement rate, the pharmacy benefit company takes a loss. If the patient's pharmacy charges less than the set reimbursement rate, the pharmacy benefit company earns a margin (i.e., the spread). Smaller employers often choose what are referred to as "spread contracts" because of the pricing predictability and savings they derive.
- Alternatively, the employer or health plan may choose to pay the pharmacy benefit company a fee to administer the claims and pay the pharmacy benefit company whatever the pharmacy charges (based on the pharmacy/pharmacy benefit company contract). Many large employers prefer this compensation model over a risk mitigation (spread) model because they have the scale to absorb reimbursement variability.

Rebate Contracting

- Employers and health plan sponsors may also choose to allow the pharmacy benefit companies to keep a small portion of the drug company's rebates, or discounts, as a way to incentivize pharmacy benefit companies to negotiate

deeper discounts. While this aligns incentives toward deriving cost savings, it is a less common payment model.

- Alternatively, employers and health plan sponsors may choose to keep 100 percent of the rebates and pay the PBM fees for negotiating rebates and setting up a formulary.

What happens to drug company rebates?

For brand drugs for which there is therapeutic competition, pharmacy benefit companies negotiate rebates, which are price concessions on drug company list prices, from drug companies in exchange for placement on drug formularies. Once rebates are negotiated, they are usually "passed through" from the pharmacy benefit company to the health plan sponsor. According to the Government Accountability Office (GAO), 99.6% of rebates in Medicare Part D are passed through to plan sponsors. In the commercial market, 91% of rebates are passed to plan sponsors. Plan sponsors choose what to do with those rebate dollars, which typically includes lowering premiums and cost sharing and enhancing benefits.

For Information: Mike Johansen, mjohansen@rwllaw.com 410.591.6014

Camille Fesche, cfesche@rwllaw.com 410.935.7721

BDCBT HB 357 Pharmacy Benefits Manager - Definitio

Uploaded by: Jeffry Guido

Position: UNF

Electrical Workers
Insulators
Boilermakers
United Association
Roofers
Cement Masons
Teamsters
Laborers
Bricklayers
Ironworkers
Sheet Metal Workers
Elevator Constructors
Painters
Operating Engineers
Carpenters

Maryland Senate - Finance Committee

Chair: Melony Griffith
Vice Chair: Katherine Klausmeier

HB 357 Pharmacy Benefits Managers - Definitions of Carrier, ERISA, and Purchaser

Position: Oppose

The Baltimore DC Building Trades and its affiliated local Unions oppose House Bills HB 357. We are a multi employer ERISA medical health insurer. The Building Trades Council with 25 local unions and our signatory contractors provide health insurance as a major part of our benefit package. This legislation was not sought by, requested or been supported by the Building Trades or our employers. The premiums for our insurance is negotiated as part of a total wage package and the more we have to pay for health insurance the less we have earned in the envelope as wages. Our insurance plans cover our members and their dependents without any medical exclusions. If you have a spouse or child with an illness they are covered. Regardless of the condition; chronic, terminal or otherwise.

We urge the Committee for an unfavorable report. Thank you.

Sincerely,

Jeffry Guido

(E) consultingbyjlg@gmail.com (C) 240-687-5195

2023.03.29 MD HB 357 HB 374 Testimony.pdf
Uploaded by: Michael Johansen
Position: UNF

Heather R. Cascone
Assistant VP, State Affairs
(202) 744-8416
hcascone@pcmanet.org

March 28, 2023

Chairwoman Melony Griffith
Senate Finance Committee Members
Miller Senate Office Building, 3 East
Annapolis, Maryland 21401

OPPOSE - HB 357 – Altering the Definition of Purchaser & HB 374 – Pharmacy Audits

Dear Chairwoman Griffith, Vice Chair Klausmeier, and Members of the Senate Finance Committee:

On behalf of the Pharmaceutical Care Management Association (PCMA), I appreciate the opportunity to comment on HB 357, a bill to amend the statutory definition of purchaser in various sections of the Insurance Statute (15-1601 through 15-1633), as well as HB 374 which give the state authority to regulate ERISA and self-funded plans as they conduct audits of network pharmacies. PCMA respectfully requests an unfavorable report on this bill.

PCMA is the national trade association representing America's Pharmacy Benefit Managers (PBMs), which administer outpatient prescription drug plans for more than 266 million Americans with health coverage provided through Fortune 500 large and small employers, labor unions and government programs. PBMs are projected to save payers over $34.7 billion through the next decade -- $962 per patient per year – due to tools such as negotiating price discounts with drug manufacturers and establishing and managing pharmacy networks, in addition to disease management and adherence programs for patients.

HB 357 and HB 374 expand the state's authority over ERISA and self-funded plans to the detriment of employer health benefit plan sponsors.

In 2020, the US Supreme Court "Rutledge" case examined whether an Arkansas law regarding reimbursements to pharmacies was preempted by federal ERISA statute, or in other words, whether ERISA plans were exempt from the state's authority. Ultimately, while the court held that Arkansas had the authority for rate regulation, the Court also acknowledged that the law in question could raise costs for ERISA plans and that those plans could pay more for prescription benefits in Arkansas compared to other states. Additionally, the Court implied that states are still not allowed to force employer plans to structure benefits in a specific way that would increase costs so much for employers that the employer would be forced to restructure its benefits because that may run afoul with federal law.

HB 357 & HB 374 will prevent the ability of governments, employers, and labor unions to provide affordable and accessible prescription drug coverage for their employees and their families by limiting the tools used by PBMs to control healthcare costs. There is not one payor entity asking for the state to have this level of oversight over its plan.

Finally, while PCMA appreciates the work of the House committee by amending HB 374 (Audit), the bill still inappropriately extends the state's authority over how self-funded plans conduct audits.

It is with these considerations for government plans, employers, and labor unions in mind that we respectfully oppose HB 357 and HB 374. I appreciate the opportunity to voice our concerns and am happy to address any questions you may have.

Sincerely,

Heather R. Cascone

AHIP Comments_MD ERISA HB357_3.28.23.pdf
Uploaded by: Mollie Gelburd
Position: UNF

601 Pennsylvania Avenue, NW
South Building, Suite 500
Washington, D.C. 20004

T 202.778.3200
F 202.331.7487
ahip.org

March 28, 2023

The Honorable Melony Griffith
Chair, Senate Finance Committee
Maryland General Assembly
Miller Senate Office Building
Annapolis, MD 21401

RE: AHIP Opposition – HB 357 / SB 898 in relation to ERISA

Dear Senator Griffith;

I write today on behalf of AHIP to respectfully oppose HB 357, legislation regulating pharmacy benefits managers (PBM). Our concern focuses on the bill's extension to ERISA policies. This legislation will jeopardize the single, cost-saving standard your state's self-insured employers rely upon to provide uniform and affordable health insurance coverage to Marylanders.

Health insurance should be simple, effective, and affordable. Patients and employers should not have to navigate complex regulations to get the care they need at a cost they can afford. AHIP supports a single, cost-saving national standard of regulation for self-funded employer-provided coverage, ensuring more affordable coverage for all, that is easier to understand. A 50-state patchwork of complicated and inconsistent mandates for employer-provided coverage will cause more confusion and make coverage more expensive for Maryland's employers and employees.

HB 357 will increase health care costs by subjecting Maryland's self-insured employers to new state requirements. Self-funded employer-provided health plans are currently regulated by the Employee Retirement Income Security Act (ERISA), which sets standards and creates uniformity for employers managing benefits across multiple state lines under its preemption provision. HB 357 changes the term "purchaser", which under current law acts to exclude self-funded ERISA plans from being subjected to state laws. This definitional change will subject Maryland self-insured employers to new state pharmacy coverage requirements.

ERISA's preemption provision was recently upheld in the Supreme Court case *Rutledge v. PCMA*. This case affirmed the long-standing precedent that state laws are preempted by ERISA when they impact a core function of health plan administration or directly relate to the health plan. The *Rutledge* Court clarified a very narrow set of activities that states could regulate; it did not create a new category of permissive state regulation, which HB 357 attempts to accomplish.

- We have attached **an analysis from ERISA experts at The Groom Law Group that outlines which HB 357 (as introduced) provisions exceed the scope of the *Rutledge v. PCMA* decision** and thus should be preempted.

March 28, 2023

Thank you for your consideration of AHIP's concern and opposition to HB 137. We stand ready to partner together in making health care more affordable and accessible for the citizens of Maryland.

Sincerely,

Kris Hathaway
Vice President, State Affairs
khathaway@ahip.org, 202.870.4468
AHIP

AHIP is the national association whose members provide health care coverage, services, and solutions to hundreds of millions of Americans every day. We are committed to market-based solutions and public-private partnerships that make health care better and coverage more affordable and accessible for everyone. Visit www.ahip.org to learn how working together, we are Guiding Greater Health.

ERISA Preemption of MD HB 357

ERISA preempts any state law that "relates to" an ERISA-covered employee benefit plan. ERISA § 514(a). As recognized by the Supreme Court of the United States, a central purpose of ERISA's broad preemption provision is to allow for the uniform administration of ERISA plans. *See, e.g., Egelhoff v. Egelhoff*, 432 U.S. 141, 148 (2001) (holding that ERISA preempted a state statute governing beneficiaries under an ERISA plan). A state law "relates to" a plan, and implicates preemption, when it has a "connection with or reference to" an ERISA plan. *Id*. at 147.

The Supreme Court in *Gobeille v. Liberty Mut. Ins. Co*. determined that a state law has an impermissible reference to an ERISA plan and is preempted "[w]here a State's law acts immediately and exclusively upon ERISA plans . . . or where the existence of ERISA plans is essential to the law's operation." 577 U.S. 312, 319–20 (2016) (internal quotations omitted). Additionally, "ERISA pre-empts a state law that has an impermissible connection with ERISA plans, meaning a state law that governs . . . a central matter of plan administration or interferes with nationally uniform plan administration." *Id.* (internal quotations and citations omitted). The *Gobeille* decision was cited approvingly by the most-recent Supreme Court decision on ERISA preemption, *Rutledge v. Pharm. Care Mgmt. Ass'n*, 141 S. Ct. 474 (2020). That said, *Rutledge* did expand the scope of permissible state regulation over pharmacy benefit managers in their contractual relationships with pharmacies, which has an indirect financial impact on ERISA-covered plans.

In *Rutledge v. PCMA*, the Supreme Court held that an Arkansas rate-setting statute that set rates with respect to PBMs did not have an impermissible reference to or connection with ERISA-covered plans. It found that any economic impact of the state's rate setting on plans was indirect and did not bind plans' benefit design choices. The Court, in *Rutledge*, did however affirm that preemption should apply where acute, (even if indirect) economic effects effectively bind the benefit choices of plan sponsors under ERISA. The Court's decision also affirmed long-standing precedent that state laws are preempted by ERISA when they impact a core function of plan administration, mandate a certain scheme of benefits coverage, or directly refer to the plan.

Since *Rutledge*, one district court has held that Oklahoma's PBM regulation that directly impacts ERISA-covered plans benefit designs was not preempted by ERISA relying on *Rutledge*. *PMCA v. Mulready*, 598 F. Supp. 3d 1200, 1208 (W.D. Okla. 2022). The court, however, did not provide a thorough analysis of the impact of the state statute on ERISA-covered plans. Rather, the court's conclusory decision relies entirely on the fact that the statute regulates contracts between the PBM and the pharmacy (notwithstanding the direct economic and benefit design impacts of those contractual regulations on ERISA-covered plans). That case is currently on appeal to the Tenth Circuit Court of Appeals which has requested the Department of Labor's views on ERISA's preemptive effect on the Oklahoma law. Accordingly, this is a highly unsettled area of the law and the District Court opinion in *Mulready* does not represent the final determination of the extent to which states may regulate PBMs with respect to their ERISA-covered business.

With respect to Maryland HB 357, the legislation seeks to impose the state's insurance laws governing PBMs directly to ERISA-covered health plans. HB 357 accomplishes this by eliminating the specific exclusion of ERISA plans from the statute and including a much broader concept of "purchasers" of PBM services. Despite the contentions of the legislators, if this statutory change is adopted a number of these provisions should be preempted by ERISA based on existing Supreme Court jurisprudence, including *Rutledge*. In the following chart, we identify the specific bill provision, provide a description of the provision, and include the basis for federal law preemption.

Provision	***Description***	***Reason for Federal Law Preemption***
Md. Code Ann., Ins. § 15-1611.1(a)	Prohibits PBMs from requiring the use of pharmacies affiliated with the PBM.	This provision limits the ability of ERISA-covered plans to determine the scope of their pharmacy networks, which is inherent in the plan's benefit design. Thus, the provision should be preempted because it requires a specific benefit design choice by the plan sponsor.
Md. Code Ann., Ins. § 15-1612(b)	Prohibits a PBM from reimbursing a non-affiliated pharmacy less than the PBM reimburses affiliated pharmacies.	This provision limits the ability of ERISA-covered plans to contract for high-value pharmacy networks, which is inherent in the plan's benefit design. Thus, the provision should be preempted because it requires a specific benefit design choice by the plan sponsor.
Md. Code Ann., Ins. § 15-1629	Proscribes the manner in which PBMs may audit pharmacies and recover overpayments.	This provision could impose acute *and* direct economic burden on plans because it limits recovery of plan assets. Moreover, it could directly conflict with ERISA's fiduciary duty to act solely in the interest of the plan. As a result, the provision should be preempted.

HB 357 Before Senate Finance Victoria Leonard LIUN
Uploaded by: Victoria Leonard
Position: UNF

March 28, 2023

The Honorable Melony Griffith, Chair
The Honorable Katherine Klausmeier, Vice Chair
Finance Committee
2 West, Miller Senate Office Building
Annapolis, Maryland 21401

Testimony of Victoria Leonard
on HB 357: Pharmacy Benefits Managers – Definition of Carrier, ERISA, and Purchaser
Position: UNFAVORABLE

Chair Griffith, Vice Chair Klausmeier, and Members of the Senate Finance Committee,

LiUNA appreciates the opportunity to offer testimony on HB 357.

My name is Victoria Leonard. I am the Political and Legislative Director for the Baltimore Washington Laborers' District Council (BWLDC), an affiliate of the Laborers' International Union of North America, or LiUNA for short. The BWLDC represents more than 7,500 members across Maryland, Virginia, and the District of Columbia. Our members are proudly employed on many infrastructure construction projects across the region. More than half of our members are Maryland residents.

LiUNA opposes Senate Bill 898 and its cross-file, HB 357 as they broadly expand Maryland's regulation of pharmacy benefit managers working on behalf of self-funded large employers, counties, municipalities, unions and their respective employees.

One of the most important fringe benefits a LiUNA member receives is health insurance coverage. This legislation, SB 898, has the potential to adversely impact the cost and type of coverage our members are provided.

HB 357 would upend a long body of case law and a long legislative history of the State not regulating self-funded or ERISA health insurance plans. HB 357 has been supported by pharmacies for the sole purpose of increasing their remuneration at the expense of union members. The proponents incorrectly assert that this legislation is constitutional under the 2020 Supreme Court decision in Rutledge v. PCMA.

If passed this legislation would result in employers and unions with self-funded plans would have inconsistent rules across state lines. SB 898 would result in additional costs for employers and or union members. The increased costs will be borne directly by the employer or our union members in the forms of decreased benefits or increased co-pays for prescription drugs.

Specifically, HB 357 may change current negotiated health care plans and coverages in the following manner:

1) Increasing prescription dispensing fees;
2) Altering the terms and costs of mail order pharmacy dispensing;
3) Altering current networks; and
4) Eliminating protections from price gouging for specialty drugs.

We urge this committee to protect our current benefits and allow our plans to be treated consistently nationwide. We strongly oppose the legislation and respectfully ask for an unfavorable report. Should the committee have any questions please reach out to our legislative counsel, Bill Kress.

HB 357 MICUA_LOI.pdf
Uploaded by: Matt Power
Position: INFO

MICUA Maryland Independent College and University Association

140 South Street, Annapolis, MD 21401

CAPITOL Technology University
GOUCHER college
HOOD COLLEGE
JOHNS HOPKINS UNIVERSITY
LOYOLA UNIVERSITY MARYLAND
MICA MARYLAND INSTITUTE COLLEGE OF ART
McDANIEL COLLEGE
MOUNT ST. MARY'S UNIVERSITY
NOTRE DAME OF MARYLAND UNIVERSITY
ST JOHN'S College
STEVENSON UNIVERSITY
WASHINGTON ADVENTIST UNIVERSITY
WASHINGTON COLLEGE

AFFILIATES

Ner Israel Rabbinical College
St. Mary's Seminary & University

Letter of Information

Finance Committee
HB 357 Pharmacy Benefits Manager – Definition of Purchaser and Alteration of Application of Law

Matt Power, President
mpower@micua.org
March 29, 2023

On behalf of the member institutions of the Maryland Independent College and University Association (MICUA) and the 56,000 students we serve, I thank you for the opportunity to provide this letter of information regarding *HB 357 Pharmacy Benefits Manager – Definition of Purchaser and Alteration of Application of Law*.

HB 357 would change the existing landscape of Maryland's self-funded plans. The State's longstanding policy has been to follow ERISA laws that prohibit state legislatures from overriding federal preemption of self-funded plans. Several MICUA institutions offer self-funded plans, and this change in practice would impact their operations and capability to offer reasonably priced employee benefits packages.

The catalyst of the bill is the 2020 U.S. Supreme Court decision in *Ruthledge v. PCMA* that upheld an Arkansas law requiring Pharmacy Benefits Managers (PBMs) to reimburse pharmacists at certain levels. There has been a misinterpretation of the decision, and thus, across many states, it has ignited a flurry of bill introductions by pharmacists seeking increased profits. Employers with self-insured plans would see passed-through fees from PBMs if this legislation were to advance. MICUA schools could foresee some challenges with offering affordable plans to their employees on an already stretched budget. The current inflation levels have tremendously impacted many budget items at an institution of higher education, and there are concerns HB 357 could overburden some MICUA members. Institutions of higher education aim to attract highly qualified individuals to their campuses to educate students who will enter the workforce. Employee benefits are used as a recruiting tool to recruit skilled academic and administrative personnel, and this legislation could interfere with these efforts.

Thank you for the opportunity to provide this information related to House Bill 357 on behalf of our member institutions. If you have any questions or would like additional information contact Irnande Altema, Associate Vice President for Government and Business Affairs, ialtema@micua.org.