25.1281.02002 Title. Prepared by the Legislative Council staff for Representative Kasper March 13, 2025

Sixty-ninth Legislative Assembly of North Dakota

PROPOSED AMENDMENTS TO FIRST ENGROSSMENT

ENGROSSED HOUSE BILL NO. 1584

Introduced by

Representatives Kasper, Koppelman, Lefor, Steiner, Vigesaa, Warrey Senators Barta, Boehm, Boschee, Hogue, Klein

- 1 A BILL for an Act to create and enact two new sections to chapter 26.1-27.1 of the North Dakota
- 2 Century Code, relating to pharmacy benefits managers; to amend and reenact sections
- 3 26.1-01-07.1, 26.1-27.1-01, 26.1-27.1-02, 26.1-27.1-04, 26.1-27.1-06, and 26.1-27.1-07 of the
- 4 North Dakota Century Code, relating to the insurance regulatory trust fund and pharmacy
- 5 benefits managers; to provide a penalty; to provide for a transfer; to provide an exemption; and
- 6 to declare an emergency.

7 BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

8 SECTION 1. AMENDMENT. Section 26.1-01-07.1 of the North Dakota Century Code is 9 amended and reenacted as follows: 10 26.1-01-07.1. Insurance regulatory trust fund established. 11 There is hereby created a trust fund designated as the "insurance regulatory trust 12 fund". The following amounts must be deposited in the insurance regulatory trust fund: 13 All sums received under section 26.1-01-07. 14 b. All sums received under section 26.1-01-07.2 from the insurance regulatory trust 15 fund investments. 16 All retaliatory fees imposed upon persons by the insurance department as 17 authorized by law. 18 All administrative penalties, fines, and fees collected by the commissioner from d. 19 any person subject to this title. 20 Any other amounts provided by legislative appropriation.

- 2. The moneys so-received and deposited in the insurance regulatory trust fund are reserved for use by the insurance department to defray the expenses of the department in the discharge of its administrative and regulatory powers and duties as prescribed by law subject to the applicable laws relating to the appropriations of state funds and to the deposit and expenditure of state moneys. The insurance department is responsible for the proper expenditure of these moneys as provided by law.
- 3. Except as otherwise provided by law, after the fiscal year has been closed and all expenses relating to the fiscal year have been accounted for, the office of management and budget shall transfer any fund balance remaining in the insurance regulatory trust fund that exceeds one million three million dollars to the general fund.

SECTION 2. AMENDMENT. Section 26.1-27.1-01 of the North Dakota Century Code is amended and reenacted as follows:

26.1-27.1-01. Definitions.

In this chapter, unless the context otherwise requires:

- 1. "Covered entity" means a nonprofit hospital or a medical service corporation; a health insurer; a health benefit plan; a health maintenance organization; a health program administered by the state in the capacity of provider of health coverage; or an employer, a labor union, or other entity organized in the state which provides health coverage to covered individuals who are employed or reside in the state. The term does not include a self-funded plan that is exempt from state regulation pursuant to the Employee Retirement Income Security Act of 1974 [Pub. L. 93-406; 88 Stat. 829; 29 U.S.C. 1001 et seq.]; a plan issued for coverage for federal employees; or a health plan that provides coverage only for accidental injury, specified disease, hospital indemnity, Medicare supplement, disability income, long-term care, or other limited-benefit health insurance policypolicies or contracts that do not include prescription drug coverage.
- "Covered individual" means a member, a participant, an enrollee, a contractholder, a
 policyholder, or a beneficiary of a covered entity who is provided health coverage by
 the covered entity. The term includes a dependent or other individual provided health
 coverage through a policy, contract, or plan for a covered individual.

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1	3.	"De	e-identified information" means information from which the name, address,
2		tele	phone number, and other variables have been removed in accordance with
3		req	uirements of title 45, Code of Federal Regulations, part 164, section 512,
4		sub	esections (a) or (b).
5	4.	"Ge	eneric drug" means a drug that is chemically equivalent to a brand name drug for
6		whi	ch the patent has expired.
7	5.	"La	beler" means a person that has been assigned a labeler code by the federal food
8		and drug administration under title 21, Code of Federal Regulations, part 207,	
9		sec	tion 20, and that receives prescription drugs from a manufacturer or wholesaler
10		and	repackages those drugs for later retail sale.
11	6. 5.	"Pa	yment received by the pharmacy benefits manager" means the aggregate amount
12		of t	he following types of payments:
13		a.	A rebate collected by the pharmacy benefits manager or a rebate aggregator
14			which is allocated to a covered entity, or retained by the pharmacy benefits
15			manager;
16		b.	An administrative fee collected from the manufacturer in consideration of an
17			administrative service provided by the pharmacy benefits manager to the
18			manufacturer;
19		c.	A pharmacy network fee; pharmacy price concessions, and any other financial
20			payment made by a pharmacy to a pharmacy benefits manager; and
21		d.	Any other fee or amount collected by the pharmacy benefits manager from a
22			manufacturer or labeler for a drug switch program, formulary management
23			program, mail service pharmacy, educational support, data sales related to a
24			covered individual, or any other administrative function.
25	7. 6.	"Ph	armacy benefits management" means the procurement of prescription drugs at a
26		negotiated rate for dispensation within this state to covered individuals; the	
27		administration or management of prescription drug benefits provided by a covered	
28		entity for the benefit of covered individuals; or the providing of any of the following	
29		services with regard to the administration of the following pharmacy benefits:	
30		a.	Claims processing, retailpharmacy network management, and payment of claims
31			to a pharmacy for prescription drugs dispensed to a covered individual;

1		b.	Clinical formulary development and management services; or	
2		c.	Rebate contracting and administration.	
3	8. 7.	"Pharmacy benefits manager" means a person thatwho performs pharmacy benefits		
4		mar	nagement <u>, as a third party, under a contract or other fincancialfinancial</u>	
5		arrangement with a covered entity. The term includes does not include a person actir		
6		for a health benefit plan that manages or directs its own pharmacy benefits manager		
7		a contractual or employment relationship in the performance of pharmacy benefits-		
8		management for a covered entity. The term does not include a public self-funded pool		
9		or a	private single-employer self-funded plan that provides benefits or services directly	
10		to it	s beneficiaries. The term does not include a health carrier licensed under title 26.1-	
11		if th	e health carrier is providing pharmacy benefits management to its insureds.	
12	9. 8.	"Re	bate" means a retrospective reimbursement of a monetary amount by a	
13		mar	nufacturer under a manufacturer's discount program with a pharmacy benefits	
14		mar	nager for drugs dispensed to a covered individual.	
15	10. 9.	"Util	lization information" means de-identified information regarding the quantity of drug	
16		pres	scriptions dispensed to members of a health plan during a specified time period.	
17	SEC	TION 3. AMENDMENT. Section 26.1-27.1-02 of the North Dakota Century Code is		
18	amende	d and	reenacted as follows:	
19	26.1	-27.1	-02. Licensing - Terms and fee - Application.	
20	1.	A pe	erson may not perform<u>establish</u> or actoperate as a pharmacy benefits manager in	
21	r	this	state unless that person holdswithout first obtaining a certificate of	
22		registrationlicense as an administrator under chapter 26.1-27 from the the		
23		com	missioner under to this section. A person violating this subsection is guilty of a	
24		<u>clas</u>	s C felony.	
25	<u>2.</u>	<u>A pe</u>	erson applying for a pharmacy benefits manager license shall submit an application	
26	ı	to the commissioner. The commissioner shall make an application form available on its		
27		<u>web</u>	site that which includes a request for the following information:	
28		<u>a.</u>	The identity, address, and telephone number of the applicant;	
29		<u>b.</u>	The name, business address, and telephone number of the contact person for	
30			the applicant:	
31		<u>c.</u>	If applicable, the federal employer identification number for the applicant; and	

	d. Any other information the commissioner considers necessary and appropriate to
	establish the qualifications to receive a license as a pharmacy benefits manager
Î	to complete the licensure process.
3.	The term of licensure is one year, from April thirtieth through March thirty-first.
<u>4.</u>	The pharmacy benefits manager shall pay an annual renewal fee no later than April
	thirtieth.
<u>5.</u>	The commissioner shall determine the amount of the initial application fee, which may
	not exceed two hundred fifty dollars. The commissioner shall determine the amount of
	the renewal application fee for the registration, which may not exceed one hundred
	dollars. The applicant shall submit the fee with an application for registration. An initial
	application fee is nonrefundable. The commissioner shall return a renewal application
	fee if the renewal of registration is not granted.
<u>6.</u>	Each application for a license, and subsequent renewal for a license, must be
	accompanied by evidence of financial responsibility in an amount of one million
	<u>dollars.</u>
<u>7.</u>	Upon receipt of a completed application, evidence of financial responsibility, and fee,
	the commissioner shall review each applicantapplication and issue a license if the
	applicant is qualified in accordance with the provisions of this section and the rules
	promulgated by the commissioner under this section. The commissioner may require
	additional information or submissions from an applicant and may obtain any
	documents or information reasonably necessary to verify the information contained in
	the application.
<u>8.</u>	The license may be in paper or electronic form. The license is nontransferable, and
	must prominently list the expiration date.
SEC	TION 4. AMENDMENT. Section 26.1-27.1-04 of the North Dakota Century Code is
amended	and reenacted as follows:
26.1	27.1-04. Prohibited practices.
1.	A pharmacy benefits manager shall comply with chapter 19-02.1 regarding the-
	substitution of one prescription drug for another.
2.	A pharmacy benefits manager may not require a pharmacist or pharmacy to
	participate in one contract in order to participate in another contract. The pharmacy
	4. 5. 5. 8. SEC amended 26.1- 1.

1		benefits manager may not exclude an otherwise qualified pharmacist or pharmacy	
2		from participation in a particular network if the pharmacist or pharmacy accepts the	
3		terms, conditions, and reimbursement rates of the pharmacy benefits manager's	
4		contract.	
5	<u>3.</u>	A pharmacy benefits manager shall offer pharmacy contracts that are opt-in contracts	
6	ii.	with at least thirty days to respond and signatures must be obtained from the	
7		pharmacy or entities an entity contracting on behalf of pharmacies the pharmacy.	
8	4.	A pharmacy must be allowed tomay opt-out of a pharmacy benefits managers contract	
9		by providing at least a ninety-day notice.	
10	SEC	CTION 5. AMENDMENT. Section 26.1-27.1-06 of the North Dakota Century Code is	
11		d and reenacted as follows:	
12	26.1	-27.1-06. Examination of insurer-covered entity.	
13	1.	During an examination of a covered entity as provided for in chapter 26.1-03, 26.1-17,	
14		or 26.1-18.1, the commissioner shall examine any contract between the covered entity	
15		and a pharmacy benefits manager and any related record to determine if the payment	
16		received by the pharmacy benefits manager which the covered entity received from	
17		the pharmacy benefits manager has been applied toward reducing the covered entity's	
18		rates or has been distributed to covered individuals.	
19	2.	To facilitate the examination, the covered entity shall disclose annually to the	
20	8	commissioner the benefits of the payment received by the pharmacy benefits manager	
21		received under any contract with a pharmacy benefits manager and shall describe the	
22		manner in which the payment received by the pharmacy benefits manager is applied	
23		toward reducing rates or is distributed to covered individuals.	
24	3.	Any information disclosed to the commissioner under this section is considered a trade	
25		secret under chapter 47-25.1. This section does not prevent the disclosure of a final	
26		order issued against a pharmacy benefits manager. Such order is an open record.	
27	SEC	TION 6. AMENDMENT. Section 26.1-27.1-07 of the North Dakota Century Code is	
28	25		
29			
30		commissioner shall adopt rules as necessary before for implementation of to implement	
31			

1	SECTION 7. A new section to chapter 26.1-27.1 of the North Dakota Century Code is			
2	created and enacted as follows:			
3	Enforcement.			
4	<u>1.</u>	All powers granted to the commissioner under title 26.1 and chapter 28-32 are		
5		available in enforcing chapter 26.1-27.1, including subpoena power.		
6	<u>2.</u>	This section does not limit the attorney general from investigating and prosecuting		
7		violations of the law.		
8	<u>3.</u>	This section does not prohibit the commissioner, state board of pharmacy, or		
9		department of health and human services from collaborating through joint exercise of		
10		common powers agreements.		
11	SECTION 8. A new section to chapter 26.1-27.1 of the North Dakota Century Code is			
12	created and enacted as follows:			
13	Administrative penalties.			
14	<u>1.</u>	A pharmacy benefits manager found to be in violation of this chapter or any rules		
15		adopted under this chapter is subject to:		
16		a. A monetary penalty of up to ten thousand dollars per violation:		
17		b. Suspension or revocation of license; and		
18		c. A civil penalty of up to fifty thousand dollars for a second or subsequent violation.		
19	<u>2.</u>	The commissioner may require a pharmacy benefits manager to provide restitution to		
20		affected covered entities, pharmacies, or individuals for losses incurred as a result of		
21		the violation.		
22	<u>3.</u>	A pharmacy benefits manager subject to penalties under this section is entitled to a		
23		hearing conducted in accordance with chapter 28-32.		
24	SEC	TION 9. TRANSFER - DRUG PRICING FUND TO INSURANCE REGULATORY		
25	TRUST	FUND. On the effective date of this Act, the office of management and budget shall		
26	transfer a	any moneys in the drug pricing fund to the insurance regulatory trust fund for the		
27	purpose	of enforcing the provisions of chapter 26.1-27.1.		
28	SEC	TION 10. EXEMPTION - FULL-TIME EQUIVALENT POSITION ADJUSTMENTS -		
29	REPORT. Notwithstanding any other provision of law, the insurance commissioner may			
30	increase or decrease authorized full-time equivalent positions, subject to the availability of			
31	funds, during the biennium beginning July 1, 2025, and ending June 30, 2027, for the purpose			

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- of enforcing the provisions of chapter 26.1-27.1. The insurance commissioner shall report to the
- 2 office of management and budget and legislative council any adjustments made pursuant to this
- 3 section.
- 4 SECTION 11. EMERGENCY. This Act is declared to be an emergency measure.

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/ Prescription Benefits Manager Optum Rx Refuses to Provide Requested Data to State Auditor's Office

Prescription Benefits Manager Optum Rx Refuses to Provide Requested Data to State Auditor's Office

<< All News

Thursday, February 2, 2023 - 02:50pm

Categories: News Releases

On April 30, 2021, state lawmakers passed House Bill 1004 which required the State Auditor's Office to hire a third-party contractor to conduct a performance audit on the prescription drug coverage of NDPERS. The third-party contractor hired was Myers and Stauffer. The reason why a third-party contractor would be required for this audit was because of the complex and specialized nature of the report.

NDPERS is the organization that administers benefits e employees. One of those benefits is

healthcare. Sanford Health is the entity that provides healthcare to state employees. Sanford contracts with a third-party prescription benefits manager, called Optum Rx to manage pharmacy benefits for state employees. Their main responsibility is processing and paying prescription drug claims. They also negotiate discounts and rebates with drug manufacturers, contract with pharmacies, and maintain drug formularies.

In the audit, there were five different areas of opportunity to improve upon. These are called "findings" by auditors. All of the findings related to Optum Rx refusing to provide the information necessary to complete the audit. In the NDPERS contract with Sanford – as well as two sections of state law (N.D.C.C. 54-52.1-04.16, and N.D.C.C. 54-10-19) – both Sanford and Optum Rx are required to provide information and data upon request to complete this audit.

The number of people who fall under the NDPERS health plan totals over 49,000. This number includes state employees, retirees, and their dependents.

"The fact that an organization thinks it's big enough to refuse to give information necessary for an audit is offensive." Said State Auditor Joshua Gallion. "It's offensive to the lawmakers, it's offensive to state employees, and it's offensive to North Dakota taxpayers who deserve to know how their money is being spent."



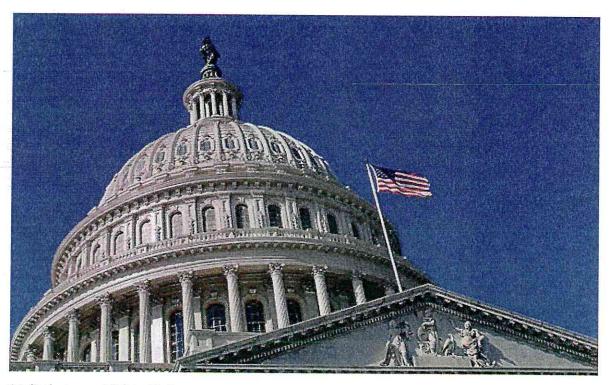
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House members roll out bipartisan PBM drug price transparency bill

A pharmacy benefit manager that fails to give employer plans detailed information could face a steep fine of \$100,000 per violation.

By Allison Bell | March 28, 2025 at 11:09 AM



Credit: doganmesut/Adobe Stock

Two Republicans and two Democrats joined together Thursday to introduce a bill that could create extensive new reporting requirements for pharmacy benefit managers that serve employer plans.

The new Prescription Drug Transparency and Affordability Act bill would apply to PBMs that serve both employers with self-insured plans and employers with fully insured group health coverage.

Rep. Kristen McDonald Rivet, D-Mich., is the lead sponsor. The original cosponsors are Rep. Buddy Carter, R-Ga.; Rep. Robert Menendez, D-N.J.; and Rep. John James,

R-Mich.

"With this bill, we're bringing much-needed transparency to how drugs are priced in this country," McDonald Rivet said.

The bill is under the jurisdiction of the House Energy and Commerce Committee, the House Education and the Workforce Committee and the House Ways and Means Committee.

The backdrop: PBMs help insurers, employers and other payers run prescription benefits programs.

Pharmaceutical manufacturers, pharmacies and other prescription drug markets have argued that large PBMs that own their own pharmacies are making deals that end up increasing their own revenue, rather than passing any savings negotiated on to the payers or the patients.

The PBMs contend that the other players are <u>angry about</u> their successful efforts to hold down increases in prescription costs and squeeze excessive profits out of drug costs.

The new PBM bill is based on PBM reporting provisions included in the Further Continuing Appropriations and Disaster Relief Supplemental Appropriations Act, 2025, a 1,547-page legislative package that was designed to keep the government running and get many popular bills through Congress.

Related: New 'must pass' House package includes employer plan PBM section

Congress scrapped that version and passed a much shorter bill, without any PBM provisions, after Elon Musk, a presidential advisor, objected to passing the original version.

Bill provisions: The new PBM bill is similar in some ways to the <u>Hidden Fees</u> Disclosure Act bill, which was reintroduced earlier this month.

One important difference involves the enforcement mechanism. The Hidden Fees bill includes no explicit penalty provision.

The new bill imposes a penalty of up to \$100,000 for failures to provide the required information or cases in which PBMs knowingly provide false information.

"Applicable entities," such as group purchasing organizations, drug manufacturers, wholesalers and rebate aggregators, would have to provide the information PBMs need to create the reports.

PBMs would have to provide reports in a way that provides only summary information, not protected health information, such as specific patients' names and prescription use.

The PBM reports would have to provide information such as the contracted compensation paid by the plan for each covered drug; the contracted compensation paid to the pharmacy; whether each prescription was provided through a retail, mail-order or specialty pharmacy; the wholesale cost of each drug prescribed; the net price for a treatment after taking all remuneration and discounts into effect; and patients' total out-of-pocket spending.

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For Release

FTC Sues Prescription Drug Middlemen for Artificially Inflating Insulin Drug Prices

Caremark, Express Scripts, Optum, and their affiliates created a broken rebate system that inflated insulin drug prices, boosting PBM profits at the expense of vulnerable patients, the FTC alleges

September 20, 2024 | (7) X (1)



Tags: Competition | Bureau of Competition | Nonmerger | Pharmacy Benefits Managers (PBM) Health Care | Prescription Drugs

Today, the Federal Trade Commission brought action against the three largest prescription drug benefit managers (PBMs)—Caremark Rx, Express Scripts (ESI), and OptumRx—and their affiliated group purchasing organizations (GPOs) for engaging in anticompetitive and unfair rebating practices that have artificially inflated the list price of insulin drugs, impaired patients' access to lower list price products, and shifted the cost of high insulin list prices to vulnerable patients.

The FTC's administrative complaint alleges that CVS Health's Caremark, Cigna's ESI, and United Health Group's Optum, and their respective GPOs—Zinc Health Services, Ascent Health Services, and Emisar Pharma Services—have abused their economic power by rigging pharmaceutical supply chain competition in their favor, forcing patients to pay more for life-saving medication. According to the complaint, these PBMs, known as the Big Three, together administer about 80% of all prescriptions in the United States.

The FTC alleges that the three PBMs created a perverse drug rebate system that prioritizes high rebates from drug manufacturers, leading to artificially inflated insulin list prices. The complaint charges that even when lower list price insulins became available that could have been more affordable for vulnerable patients, the PBMs systemically excluded them in favor of high list price, highly rebated insulin products. These strategies have allowed the PBMs and GPOs to line their pockets while certain patients are forced to pay higher out-of-pocket costs for insulin medication, the FTC's complaint alleges.

"Millions of Americans with diabetes need insulin to survive, yet for many of these vulnerable patients, their insulin drug costs have skyrocketed over the past decade thanks in part to powerful PBMs and their greed," said Rahul Rao, Deputy Director of the FTC's Bureau of Competition. "Caremark, ESI, and Optum—as medication gatekeepers—have extracted millions of dollars off the backs of patients who need life-saving medications. The FTC's administrative action seeks to put an end to the Big Three PBMs' exploitative conduct and marks an important step in fixing a broken system—a fix that could ripple beyond the insulin market and restore healthy competition to drive down drug prices for consumers."

Insulin medications used to be affordable. In 1999, the average list price of Humalog—a brand-name insulin medication manufactured by Eli Lilly—was only \$21. However, the complaint alleges that the PBMs' chase-the-rebate strategy has led to skyrocketing list prices of insulin medications. By 2017, the list price of Humalog soared to more than \$274—a staggering increase of over 1,200%. While PBM respondents collected billions in rebates and associated fees according to the complaint, by 2019 one out of every four insulin patients was unable to afford their medication.

The FTC's Bureau of Competition makes clear <u>in a statement issued today</u> that the PBMs are not the only potentially culpable actors – the Bureau also remains deeply troubled by the role drug manufacturers like Eli Lilly, Novo Nordisk, and Sanofi play in driving up list prices of life-saving medications like insulin. Indeed, all drug manufacturers should be on notice that their participation in the type of conduct challenged here raises serious concerns, and that the Bureau of Competition may recommend suing drug manufacturers in any future enforcement actions.

The PBMs Benefit from Higher List Prices

The PBMs' financial incentives are tied to a drug's list price, also known as the wholesale acquisition cost. PBMs generate a portion of their revenue through drug rebates and fees, which are based on a percentage of a drug's list price. PBMs, through their GPOs, negotiate rebate and fee rates with drug manufacturers. As the complaint alleges, insulin products with higher list prices generate higher rebates and fees for the PBMs and GPOs, even though the PBMs and GPOs do not provide drug manufacturers with any additional services in exchange.

The complaint further alleges that PBMs keep hundreds of millions of dollars in rebates and fees each year and use rebates to attract clients. PBMs' clients are payers, such as employers, labor unions, and health insurers. Payers contract with PBMs for pharmacy benefit management services, including creating and administering drug formularies—lists of prescription drugs covered by a health plan.

The PBMs' Chase-the-Rebate Strategy Reduced Patients' Access to Lower List Priced Insulins, the FTC Alleges

Insulin list prices started rising in 2012 with the PBMs' creation of exclusionary drug formularies, the FTC's complaint alleges. Before 2012, formularies used to be more open, covering many drugs. According to the complaint, that changed when the PBMs, leveraging their size, began threatening to exclude certain drugs from the formulary to extract higher rebates from drug manufacturers in exchange for favorable formulary placement. Securing formulary coverage was critical for drug manufacturers to access patients with commercial health insurance, the FTC alleges.

Competition usually leads to lower prices as sellers try to win business. But in the upside-down insulin market, manufacturers—driven by the Big Three PBMs' hunger for rebates—increased list prices to provide the larger rebates and fees necessary to compete for formulary access, the FTC's complaint alleges. According to the complaint, one Novo Nordisk Vice President said that PBMs were "addicted to rebates." While PBMs' rebate pressures continued, insulin list prices soared. For example, the list price of Novolog U-100, an insulin medication manufactured by Novo Nordisk, more than doubled from \$122.59 in 2012 to \$289.36 in 2018.

The complaint alleges that even when low list price insulins became available, the PBMs systematically excluded them in favor of identical high list price, highly rebated versions. As described in the complaint, one PBM Vice President acknowledged that this strategy allowed the Big Three to continue to "drink down the tasty ... rebates" on high list price, highly rebated insulins.

The PBMs Caused the Burden of High Insulin List Prices to Shift to Vulnerable Patients, the FTC Alleges

According to the complaint, as insulin list prices escalated, the PBMs collected rebates that, in principle, should have significantly reduced the cost of insulin drugs for patients at the pharmacy counter. Certain vulnerable patients, such as patients with deductibles and coinsurance, often must pay the unrebated higher list price and do not benefit from rebates at the point of sale. Indeed, they

may pay more out-of-pocket for their insulin drugs than the entire net cost of the drug to the commercial payer. Caremark, ESI, and Optum knew that escalating insulin list prices and exclusion of low list price insulins from formularies hurt vulnerable patients—yet continued to pursue and incentivize strategies that shifted the burden of high list prices to patients, the FTC's complaint alleges.

Caremark, ESI, and Optum and their respective GPOs engaged in unfair methods of competition and unfair acts or practices under Section 5 of the FTC Act by incentivizing manufacturers to inflate insulin list prices, restricting patients' access to more affordable insulins on drug formularies, and shifting the cost of high list price insulins to vulnerable patient populations, the FTC's complaint alleges.

The Commission vote to file an administrative complaint was 3-0-2, with Commissioners Melissa Holyoak and Andrew N. Ferguson recused.

NOTE: The Commission issues an administrative complaint when it has "reason to believe" that the law has been or is being violated, and it appears to the Commission that a proceeding is in the public interest. The issuance of the administrative complaint marks the beginning of a proceeding in which the allegations will be tried in a formal hearing before an administrative law judge.

The Health Care Division of the FTC's Bureau of Competition was responsible for this matter.

The Federal Trade Commission works to <u>promote competition</u>, and protect and educate consumers. The FTC will never demand money, make threats, tell you to transfer money, or promise you a prize. You can learn more about <u>how competition benefits consumers</u> or <u>file an antitrust complaint</u>. For the latest news and resources, <u>follow the FTC on social media</u>, <u>subscribe to press releases</u> and <u>read our blog</u>.

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Medicaid Managed Care Reform

States must reform their Medicaid managed care prescription drug benefits to protect Medicaid beneficiaries, taxpayers, and local community pharmacy businesses. Too much control over the Medicaid drug benefit has been ceded to managed care organizations (MCOs) and their pharmacy benefit managers (PBMs), who have been <u>found</u> to "employ controversial utilization and management tools to generate revenue for themselves in a way that is detrimental to health plan sponsors, patients, and pharmacies."

MCOs and PBMs work for their own best interests, instead of the beneficiaries' or taxpayers' best interests. They engage in spread pricing, which "is inflating prescription drug costs that are borne by beneficiaries and by taxpayers." In Ohio and Kentucky, spread pricing allowed PBMs to pocket \$224.8 million and \$123.5 million respectively in one year. They create drug formularies and negotiate rebates that lead to the greatest value for themselves, instead of the state, leading New York to unnecessarily pay \$605 million to its MCOs and PBMs over a four-year period. State investigations into MCO and PBM practices have led one MCO to set aside \$1.1 billion to settle lawsuits alleging mismanagement of public funds paid to administer the Medicaid managed care prescription drug benefit.

The Solution: Increase PBM Transparency/Accountability and Ensure State Oversight of Medicaid Prescription Drug Benefits

1. Carve pharmacy benefits out of the Medicaid managed care program and administer the benefits through the fee-for service program

California, Missouri, New York, North Dakota, Tennessee, West Virginia, and Wisconsin have carved their pharmacy benefits out of the Medicaid managed care program. This move helped West Virginia save over \$54.4 million and North Dakota save \$17 million in one year by carving out of the managed care program. California estimates that the carveout will save at least \$150 million a year. New York budgeted nearly \$1 billion of savings in the first two years of its NYRx transition.

2. Require MCOs and PBMs to reimburse at the transparent fee-for-service rates

Fee-for-service Medicaid programs reimbursement rates are transparent and evidence-based. Recognizing the value to taxpayers of requiring transparent reimbursements in their Medicaid managed care programs, Arkansas, Georgia, Iowa, Kansas, Kentucky, Louisiana, Michigan, Mississippi, Nebraska (independents only), New Mexico (independents only) North Carolina, and Ohio (dispensing fees vary based on volume) require MCOs and PBMs to reimburse pharmacies at the same rates established under the fee-for-service program. If such transparent reimbursement methodologies were adopted nationwide, federal Medicaid spending would drop by almost \$1 billion over 10 years.

3. Increase regulatory oversight over PBMs in the Medicaid managed care program

Some states have passed legislation giving Medicaid officials greater oversight over the PBM Medicaid managed care contracts.

- Single PBM: Kentucky, Louisiana, Mississippi, and Ohio now contract with a single PBM to administer their Medicaid managed care prescription drug benefits, allowing greater authority to oversee the administration of benefits. Kentucky saved \$282.7 million in 2021-2022.
- Single PDL: Michigan, Ohio, and South Carolina adopted single preferred drug lists (PDL) to ensure that MCOs and their PBMs establish formularies that create the most value for taxpayers.

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 Pass-through pricing models: Alaska, Arkansas, Colorado, Delaware, Florida, Iowa, Idaho, Louisiana, Michigan, Oklahoma, Pennsylvania, Vermont, Virginia, and Washington incentivize pass-through pricing models by curtailing or prohibiting spread pricing. Approximately half of states prohibit spread pricing in their Medicaid managed care programs.

States have found that an excessive amount of taxpayer dollars remain with pharmacy benefit managers (PBMs).

The Centers for Medicare and Medicaid Services is concerned that PBMs' use of "spread pricing is inflating prescription drug costs that are borne by beneficiaries and by taxpayers," and CBO estimates that moving to transparent pharmacy reimbursement and eliminating spread pricing will save \$2 billion over 10 years.

- <u>Pennsylvania</u>: Between 2013 and 2017, the amount that taxpayers paid to PBMs for Medicaid enrollees more than doubled from \$1.41 billion to \$2.86 billion.
- <u>Ohio</u>: the state Auditor found that, of the \$2.5 billion that's spent annually through PBMs on Medicaid prescription drugs, PBMs pocketed \$224.8 million through the spread alone during a one-year period.
- <u>Kentucky</u>: In response to a state report that found state PBMs keep \$123.5 million in spread annually, the Attorney General has launched an investigation into allegations that the PBMs have overcharged the state and discriminated against independent pharmacies.
- Louisiana: PBMs retained \$42 million that was incorrectly listed as "medical costs."
- New York: An <u>audit</u> found the state unnecessarily paid \$605 million to Medicaid managed care organizations and their PBMs over a four-year period, because "MCOs typically work with their PBMs to conduct their own clinical reviews to identify drugs that provide the greatest value to <u>THEM</u> and therefore should be placed on the drug formulary."
- Michigan: Drug price manipulation allowed PBMs to overcharge Michigan Medicaid by at least \$64 million.
- <u>Virginia</u>: A state-commissioned report on Medicaid found PBMs pocket \$29 million in spread pricing alone.
- Maryland: A state Medicaid report found PBMs pocket \$72 million annually in spread pricing alone.
- Florida: A report found PBMs steer patients to PBM-affiliated pharmacies, and "when it comes to dispensing brand name drugs, MCO/PBM-affiliated pharmacies are making 18x to 109x more profit over the cost of the drugs than the typical community pharmacy."
- <u>Arkansas</u>: A state-commissioned report found that PBMs in the Medicaid program reimbursed national chain pharmacies more (defined as greater than 5% difference) than regional chain and independent pharmacies for the same drug.¹
- <u>Illinois</u>: an audit found \$200 million of spread pricing in 2021-2022, revealing no monitoring of contracts, including reimbursement rates or rebates, and non-compliance with many statutory requirements.
- Oregon: a 2023 audit found insufficient transparency and compliance with highly inconsistent reimbursement, including twice as much reimbursement to PBM-owned pharmacies than to independent pharmacies for selected drugs.

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