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PBMs lower most drug costs for most people, encourage innovation in pharmaceutical pricing, production

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Skyrocketing costs for prescription drugs has put scrutiny on the role pharmacy benefit managers, or PBMs, play in negotiating pharmaceutical prices with manufacturers on behalf of insurers who provide health policies for nearly 300 million Americans.

Drawing heat from the Trump Administration, Congress and state lawmakers around the nation is the opaque PBM practice of securing rebates – or clawbacks – from drug-makers and imposing rules that forbid pharmacists from discussing prescription drug prices with customers.

U.S. Food and Drug Administration Commissioner Scott Gottlieb and Health and Human Services Secretary Alex Azar have both recently suggested eliminating rebates negotiated by PBMs will lower drug prices.

In May, Azar called for federal legislation banning the pharmacist gag rule.

"Right now, some pharmacy benefit managers are telling pharmacists, 'You're not allowed to tell the patient that if they paid cash for this generic drug it would be cheaper for you than if you run it through your insurance,'" he said in a White House news conference. "We think it is unconscionable."

According to the Centers for Medicare and Medicaid Services, PBMs collected more than $130 billion in clawbacks, or Direct and Indirect remuneration (DIR) fees, between 2012 and 2016.

PBMs maintain these rebates are returned to insurance providers in the form of lower group prices for prescription drugs, but most have resisted attempts to reveal what DIRs they receive and how they are distributed.

At least four bills addressing transparency in disclosing pharmaceutical pricing practices, clawbacks and so-called "gag orders" have been introduced in Congress since 2017, including The Patient Right to Know Drug Prices Act, sponsored in March by Sen. Susan Collins, R-Maine.

Some 40 state legislatures have considered prohibiting clawbacks and "gag orders" with 23 enacting laws since 2016, according to the National Conference of State Legislatures (NCSL).

Among states that banned PBM-imposed "gag orders" on pharmacists in 2018 is Colorado (House Bill 1284), Florida (HB 351), Louisiana (SB 241), Ohio (SF 3656) and Virginia (HB 1177).

Similar bills are pending in Michigan and Pennsylvania. Minnesota's bill (SF 2836) passed the Senate, but was not adopted by the House before the session adjourned in mid-June.

Louisiana lawmakers took PBM scrutiny a step further with the adoption of SB 282, becoming the first state to pass a "Share The Rebate" bill that requires consumers to receive up to 50 percent of DIRs offered for certain prescription medications.

But in the fervor to appear responsive to concerns over healthcare costs, Congressional and state lawmakers are targeting PBMs as "a scapegoat of convenience," Cato Institute fellow Ike Bannon told Watchdog.org.

"Blaming the system of rebates for high drug prices completely misdiagnoses the prescription drug market, and eliminating them would accomplish nothing," Bannon said.

In fact, he said, imposing a blanket ban on DIRs would undo decades of progress that is only now beginning to bear results for consumers in lowering prescription drug prices and "throw the baby out with the bathwater."

PBMs Lower Prescription Drug Costs

Brannon, president of Capital Policy Analytics, a consulting firm in Washington D.C., recently co-authored a study with Tony Lo Sasso of the University of Illinois at Chicago, that maintains "tying the hands of PBMs could very well raise drug prices."

Bannon said that PBMs maximize the purchasing power for large groups of patients, resulting in a price reduction for their prescriptions and medications. PBMs leverage volume buying power to secure rebates and discounts from pharmaceutical drug manufacturers, he said.

Conceding the rebate system "might appear somewhat convoluted," Bannon said that PBMs have fostered "a robust system of price negotiation and bargaining" that not only lowers costs for consumers, but does so in a way that can be "profitably accommodated."

PBMs negotiate prices for on-patent drugs and encourage competition in the drug market, he said.

While prices for new prescription medications are often expensive, Bannon said insurance companies rarely pay the full freight for producing them because PBMs frequently negotiate discounts in the form of rebates that, in turn, allows insurance companies to keep premiums lower.

He said the development of "me too" drugs, which duplicate existing pharmaceuticals at second- and later-generation price reductions, was spurred by pressure from PBMs who have steered doctors into prescribing generic equivalents or other substitutes when available.

As an example, Bannon cites Gilead Science's 2013 release of Sovaldi, a "remarkable cure" for Hepatitis C, with a list price of $84,000 for a 12-week course of treatment.

However, he said, that list price was "not anywhere near what insurance companies paid" for Sovaldi because pressure from PBMs encouraged other drug-makers to introduce their own Hepatitis C drugs, which dramatically reduced costs across-the-board, not only for insurance policyholders.

Gilead "was vilified for the price" but PBMs induced a copycat that forced costs down, he said, noting the negative publicity about Sovaldi's costs obscured how "PBMs quickly drew pricing down to something reasonable."

PBMs Do Not Lower Prescription Drug Costs

A range of consumer groups, pharmacists and lobbyists for the insurance industry insist rebates negotiated by PBMs do not translate into lower costs and point to "opaque proprietary financial arrangements" with manufacturers as evidence of deceit.

"Very little, if any, of that money, goes to the patients whose prescriptions make the rebate revenue happen," Robert Goldberg, vice president of the Center for Medicine in the Public Interest wrote in a February 2017 op-ed in The Hill.

Goldberg said that PBMs do not negotiate for lower prices but for higher rebates that they simply keep.

"PBMs set up the drug benefit to maximize these rebates. That is, it will cover drugs that generate more rebates and discourage patients from taking others that produce less profit," he wrote. "That's a big reason why many sick people must fail on one or more drugs before being able to get a drug that works covered."

"Unethical PBM tactics" under-compensate pharmacies "with little to no recourse" and increase drug prices, limit formularies (list of medicines that may be prescribed for a particular ailment) and restrict pharmacy access for patients, Brittany Hoffman-Eubanks of the Illinois Pharmacists Association wrote in a February Pharmacy Times op-ed.

PBMs "have successfully leveraged their 'middle-man' status to maximize profits while simultaneously harming American pharmacies and increasing costs to patients," Hoffman-Eubanks said.

Senior Care Pharmacy Coalition (SCPC) President Alan Rosenbloom wrote in a September 2017 op-ed in The Hill that a CMS report found that while drug companies and pharmacies are paying larger rebates, PBMs "simply keep the money rather than translating it into lower costs."

According to the CMS, DIR fees increased from $31 billion in 2012 to $50 billion in 2015.

"At a time when transparency in the marketplace, in government and within society at-large is a driving force for positive change benefitting every American, the PBM industry's reliance upon hiding facts, and making secret deals behind closed doors, will and should be a target for lawmaker, regulator and media scrutiny alike," Rosenbloom writes.

Goldberg maintains variations in preferential pricing and rebates negotiated by PBMs have nothing to do with an "objective review of medical literature."

"What drives this variance is the (agreements) made between PBMs and pharmaceutical companies," he writes. "These rigged arrangements explain why most PBMs charge patients with cancer, multiple sclerosis, autoimmune diseases, HIV up to 50 percent of the list price of their medicines."

Different Prices For Different People

Bannon told Watchdog.org that the anger directed toward PBMs as the "cause du jour of high healthcare costs" is misdirected.

"There are plenty of reasons why healthcare inflation continues to plague the United States, but the drug rebate system is not the villain," he said.

Differentials in pricing for various prescription drugs for different constituencies is an example of how the system saves most consumers money, Bannon said.

The pharmaceutical market is complex, he said, noting "almost all people don't pay list prices" for prescription medications because of differences in preferential pricing negotiated by PBMs.

"Different prices for different people" is, essentially "cost-sharing" based on need and affordability, he said.

The expansion of insurance coverage and higher healthcare costs "disconnect consumers from actual costs," Bannon said.

"As insurance coverage rates increased, fewer people were exposed to the prices charged by providers as the third-party payers, the insurers, picked up the tab," he and Lo Sasso wrote in their study. "With many more insured consumers not bearing the marginal cost of healthcare services, and absent a mechanism for insurers to negotiate, charges were effectively unbounded, because they were disconnected from market forces. The provider could simply set its prices wherever it desired and expect to be paid at that rate."

The advent of the PBM industry beginning in the 1960s ensures that doesn't happen, Bannon said.

"The true cost is assessed those who can afford it and on other products to subsidize innovation and fairness in distribution," Bannon said. "Airlines do it. Hotels do it. It is not a bad thing."

The model may be good, but the way PBMs implement it is "a bad thing," according to Goldberg.

"PBMs charge the sickest patients an average of 40 percent of the list price of medicines," he wrote.

Goldberg said the "sickest" 1 percent of patients – about 2.9 million Americans – annually generate $50 billion in rebates and another $10 billion from consumers paying list price of the drug.

"Of course, that money also goes to the PBMs" and is not recouped by consumers in the form of lower prices for prescription drugs, he wrote.

Transparency and PBM Mergers

Hoffman-Eubanks wrote that to secure lower costs, employer plan sponsors and federal and state governments "need to demand complete transparency from PBMs for all health plans."

Complete transparency, she said, would include "all indirect and direct revenue streams that PBMs acquire as a result of administering prescription benefit plans."

Bannon said criticism — and legislation — requiring more transparency in how PBMs negotiate rebates must be carefully crafted or it could result in higher prices and in stifling innovation within the pharmaceutical industry.

“It may not be the rebates, per se, that are objectionable to most people, but rather that lack of transparency regarding their nature and amount,” he said. “There does need to be more transparency.”

Because consumers are usually not informed of the amount of the rebate or how it is applied, “the rebate system is somewhat opaque,” Bannon said.

There are reasons for this lack of transparency, he said.

“First and foremost being that the outcome of negotiations are essentially trade secrets,” Bannon said.

In their study, Bannon and Lo Sasso compared PBMs’ contracts with drug makers with the details of a long-term contract between a restaurant and a food distributor.

The details of the agreements “are not relevant to consumers, yet the end result of such negotiations is lower prices and better food options,” they wrote. “Similarly, PBMs that negotiate the hardest to strike the best deals with drug companies will be able to achieve better prices for drugs for enrollees” or they would not be in business.

“The irony should not be lost on the public that these byzantine efforts are often necessary in response to even more byzantine and obtuse government regulation,” Bannon and Lo Sossa wrote. “The key observation is that consumers benefit from this process.”

Bannon said PBMs originated in the 1960s and evolved with the growth of managed care. Since then, mergers among PBMs have resulted in three entities now dominating the industry.

According to HealthCare Consultants Pharmacy Staffing, the three largest, or "Super PBMs," are Express Scripts, CVS Health (formerly CVS Caremark) and United Health, also referred to as OptumRx & Catamaran.

Rosenbloom said domination by the three has created, “for all intent and purpose, a PBM oligopoly, controlling more than 80 percent of prescription medications dispensed to patients in long-term care facilities” and, overall, for more than 200 million Americans with health insurance.

Lisa Bair, CEO of Quantuvis, a healthcare IT company, told Pharmaceutical Processing that “PBM mergers have been a strong trend for some time now” and with the consolidation comes less incentive to compete.

PBMs have said with growth comes increased leverage in negotiating better prices for their clients. While declining comment, Express Scripts and CVS Health referred to statements they had issued in response to criticism.

“By taking on tough challenges, we helped employers save $32 billion on their prescription drug bill in 2017 alone,” Express Scripts said. “Express Scripts stands up to drug companies and drug stores to make sure everyone – patients, employers, health plans, unions, and government entities – get a fair deal for the money they spend.”

“As a pharmacy benefit manager, CVS Health negotiates the lowest possible net price from drug manufacturers for clients, which are health plans, employers, unions, government programs like Medicare Part D and Medicaid, and ultimately for the millions of Americans who pick up their prescriptions at pharmacy counters every day,” CVS Health said.

CVS Health said it returns “approximately 95 percent of discounts and other price concessions like rebates to commercial clients and their members, while at the same time keeping drug price growth at a minimal 0.2 percent, the lowest level in five years, despite manufacturer brand list price increases on drugs near 10 percent.”

PBM Alternates Emerging

HHS Secretary Azar has proposed completely eliminating rebates and instead using a flat pricing model.

“What if instead we said no rebates, flat price, fixed price in the contracts,” he said in May at the White House. “Take away the whole gross-to-net spread that makes people indifferent to the list price in that system, and take away incentives where the pharmacy benefit manager makes more money from high list prices.”

Azar proposed moving to a fiduciary model where a PBM works for the payer or patient “and is only compensated by that party.”

Hoffman-Eubanks said as an alternative to traditional PBMs, some plan sponsors have terminated the use of PBMs and, essentially, formed their own prescription drug pricing negotiating units

She cites the Health Transformation Alliance (HTA) as an example. HTA was formed in 2016 by 20 large employers, including Coca-Cola and Marriott Hotels, that now includes 40 major corporations, covers more than 6 million people and has an “annual spend” of $25 billion.

“Many businesses, however, may not have the means to form these PBM alternative organizations but can seek out other resources such as transparent PBMs and pharmacy benefit administrators (PBAs),” Hoffman-Eubanks wrote.

Transparent PBMs do not profit from rebates, spreads, “or other secret incentives” and charge a flat administrative fee for each prescription, she wrote.

Goldberg said there is no need for more laws or regulation.

“Because all the rebate money comes from drug companies, they have the power to make a simple change in who benefits from the value new medicines generate,” he said.

Bannon said entrusting the pharmaceutical industry to somehow set more affordable prices is “such a naive idea” that demonstrates little understanding of the market.

“Letting pharmaceutical companies earn more money is not the route to constraining health care costs,” he said.

“You can legislate what you want. It doesn’t mean you will get a satisfactory result,” he said, noting eliminating rebates may sound good but those now profiting from the system “will figure out another way to do it.”

The best solution is “a robust market” that encourages innovation, not only in developing products but in pricing, and “rewards them for innovation,” Bannon said. “Ultimately, those who come up with innovation will be rewarded to some degree and it seems, to me, most innovation is in the pharmaceutical manufacturing field now. What we don’t want to do is throw the baby out with the bathwater.”