Doctors: Decisions by PBMs make vital drugs unaffordable for many patients

Darrel Rowland
The Columbus Dispatch

Dr. Stephanie Ott's eyes tell the story of Americans' frustrating struggles to obtain essential prescription drugs.

They moisten above her multi-hued mask almost to the point of tears as she describes a patient with crippling rheumatoid arthritis taking her first steps in years after successful drug treatment.

Health care consolidation: Rules block patients from counting thousands in drug discounts toward health insurance deductible

"I'll never forget. She was sitting in an (examination) room one against the wall and I didn't see a wheelchair. I thought, 'Well, I guess somebody took it out, right?'" Ott recalls.

"She says 'I want to give you a hug.' And I said, 'OK, I'll come right over.'

"And she says, 'Oh no, I'm coming to you.' And she got up and she walked across the room …

"To this day, I get chills when I think about it. She's like, 'I can hold my grandkids!' She was so proud to tell me how she had swept her front porch."

But the doctor's eyes fill with anger as she relates how a Lupus patient was denied insurance coverage for a drug Ott prescribed, wound up in the hospital and remains on dialysis to this day.

Switched out? Find out if the drugs you take are still covered by insurance

And the Lancaster physician's visage hardens even more while diagnosing the cause of this mess: Multibillion-dollar pharmacy benefit managers and health insurers making decisions about which drugs should be covered by insurance based on what she says is corporate greed rather than medical need.

“It’s not that (a drug) didn’t work. It’s just that somebody’s profits got in the way. That's what I call practicing profit medicine instead of real medicine, because I’m trained to practice evidence-based medicine,” said Ott, who has been president of the Ohio Association of Rheumatology since 2011.

She is talking about a rapidly growing practice by pharmacy benefit managers, often known as PBMs, and health insurers to use something called "formulary exclusions." That sounds complicated, but it’s actually quite simple.

Formulary is a fancy name for the list of prescription drugs that a PBM says should be covered by health insurers. However, in the past several years, PBMs have come up with a separate list of drugs they say should *not* be covered by health insurance. Thus, they are excluded from the formulary, and known collectively as formulary exclusions.

'The perfect lose-lose for patients'

Because America’s health-care system is increasingly consolidated, the formulary decisions of just three pharmacy benefit managers essentially dictate the entire U.S. market, since they handle nearly 80% of the country's prescription drugs. All three PBMs also are corporately joined with major health insurers, magnifying the consolidation.

Since 2014, the number of drugs excluded from the trio's' formularies has skyrocketed tenfold, to more than 1,300.

What the jargon means: Glossary of terms in the formulary exclusion debate

Representatives of trade associations for the PBMs and health-insurance companies say the new maneuver is an attempt to stem the rising cost of prescription drugs for U.S. consumers.

"PBMs develop prescription-drug formularies with pharmacy and therapeutic committees that are composed of primary care and specialty physicians, pharmacists, and other clinical professionals," said a statement from the Pharmaceutical Care Management Association, the national group representing America's pharmacy benefit managers.

Those committees "evaluate available clinical evidence to select the best drugs for various conditions. This review focuses only on clinical considerations, including medical literature, Food and Drug Administration-approved prescribing information and safety data, and current therapeutic use guidelines – not economic or cost considerations."

Kristine Grow, senior vice president of communication for a national group that includes health insurers, AHIP, criticized drug makers for setting high prices while showing little transparency into their much-touted research and development costs.

However, Robin Feldman, associate professor at the University of California's Hastings College of the Law in San Francisco, says the problem with formulary exclusions reflects the truism at the heart of most discussions about excessive drug prices: The system is set up so that all involved benefit from higher prices — except those who pay those high prices.

"The core of the incentive problem lies with the PBM system. These middle players, who establish the drug formularies and negotiate between drug companies and the insurance plans, have evolved in a manner that creates upward pressure on prices," she said in an article for the Harvard Journal on Legislation.

"In short, it is the perfect lose-lose for patients. Manufacturers raise the price, the consumer pays the higher price, the extra goes to the PBM. And in exchange, the PBM creates competition-free zones for the drug company's drug. In the short term, the patient pays more in the form of higher prices. In the long term, the patient pays more in the form of fewer competitors to offer lower-priced drugs."

How formulary exclusions can raise your prescription drug prices

Here's how experts say formulary exclusions work:

The key lies in the big value of gaining a spot on the PBM-developed formularies, especially for expensive, brand-name drugs that pharmaceutical companies have spent millions to develop. For drug makers, getting their products onto the list of recommended drugs used by health insurers nationwide is critical.

Thus PBMs wield immense power with their decisions about which drugs make the cut and which don't. Adding to the complexity: Tiers placed within the formulary by PBMs greatly affect how much patients can be charged for each drug – and thus how valuable they are to drug companies.

"Pharmaceutical manufacturers compete fiercely for formulary placement," noted an investigation released in January by the U.S. Senate Finance Committee.

"These negotiations can be of such great financial importance to pharmaceutical companies that senior executives up to and including the chief executive officer are often personally involved in the process."

Two spokeswomen for Pharmaceutical Research and Manufacturers of America – Pamela N. Roberto and Ashley Czin, respectively vice president and deputy vice president of policy and research – backed up this depiction of high-stakes negotiations.

“Being on the formulary is crucial for patients to have access to a drug. It points to the market power of the PBMs, the fact that they have so much negotiating power, because they can say, ‘If you don't do X, Y, or Z, we will exclude you from the formulary,'” said Roberto, vice president of policy and research for the trade group of U.S. drug makers.

She and Czin also confirmed the most controversial part of the process: Drug companies pay large sums to PBMs to win spots on the formulary.

Those payments come primarily in the form of rebates off PhRMA's list price for drugs. But here's the crucial point: A portion of those rebates winds up in the PBMs' coffers. Therefore, the higher the rebates to PBMs, the more likely a drug maker will land a spot on the coveted formulary, experts say.

And here's the rub for consumers and patients: Since rebates and other incentives represent a percentage of the list price of a drug, the main way for a drug maker to increase the size of its rebate is to increase the drug's price.

"What is important to understand about these rebates is that they are not discounts for patients," said Andre Barlow of the Coalition to Protect Patient Choice at a hearing on health-market competitiveness in March 2020 by the Federal Drug Administration and Federal Trade Commission.

"Because the rebates go to PBMs and (health insurance) plans rather than to consumers, payers have perverse incentives to negotiate higher list prices so they can secure higher rebates without regard to patient well-being or patient cost. These rebates actually increase patients' cost, because the patient's coinsurance is based on the inflated list price of the branded drug."

Americans' net prescription drug spending is projected to rise from $359 billion in 2020 to as much as $400 billion in 2025, a report in late May from the IQVIA Institute for Human Data Science showed. Total out-of-pocket costs for all patients — including retail prescriptions and non-retail medicines — increased $1 billion in 2020 to a record $77 billion.

PBMs say increasing drug rebates aren't 'padding their bottom line'

Professor Feldman obtained groundbreaking results on the relationship between rebates and prices by studying 1 million Medicare Part D patients from 2006 to 2017. Her main finding: "Although rebates rose, prices rose faster, far outstripping the effects of the rebates."

The average price per dosage-unit of brand-name drugs after rebates rose 313% during the 12-year study, from $38 to $157 – far outstripping the 22% inflation rate for the period, a finding she called shocking. At the same time, the average price for generic drugs increased from $3 to $4.

As these deals become more sophisticated, they often involve not just a single drug but an entire portfolio of medications that a drug company uses during its high-stakes negotiations with PBMs over rebates and other financial incentives.

Further, the constant push for higher rebates to PBMs and increased market share lessens the incentive for drug makers to lower their prices.

"This investigation found several instances where manufacturers increased their rebate offers significantly following the threat of exclusion" from a PBM's formulary, the Senate Finance panel said.

"In some cases, manufacturers appear to have been concerned that decreasing ... prices would be viewed negatively by PBMs, since PBMs capture a portion of rebate revenue and are also paid administrative fees based on a percentage" of the list price.

Janssen Pharmaceutical, part of Johnson & Johnson, is the rare drug maker that details its rebate payments. In its "transparency report" for 2020, the Belgium-based company said its rebates to commercial payers more than quadrupled in the four years from 2016 to 2020, from $1.7 billion to $6.9 billion. The company also said that the radical increase in rebates to PBMs has not led to lower prices for consumers.

Indeed, a study released in early May showed that for the 57% of patients whose health insurance policies required coinsurance or deductibles, the average 15% increase in their out-of-pocket costs correlated with drug companies' list price increases of 16.7% for 79 popular brand-name drugs from 2015-17.

However, the patients' costs were not affected by the drug makers' elevated rebate amounts. The research performed by three doctors was posted on JAMA Network Open, an open access medical journal published by the American Medical Association.

Roberto, the PhRMA vice president, said, “The incentives are upside down in the existing system. The way in which rebates are being used by the plans and the PBMs has led to this situation where you have the sick subsidizing the healthy, which is the exact opposite of what we think of when we think of insurance.”

Any woes experienced by the pharmaceutical industry certainly don't stem from a lack of clout in Washington. Drug companies spent a record $92 million to lobby the federal government in just the first three months of 2021, said the Center for Responsive Politics.

The industry’s spending in that time period represents a 6.3% increase over the same period last year, putting drug companies on track to break their combined all-time spending record for the second year in a row. Private manufacturers of pharmaceuticals and health products typically far outspend other industries to lobby Washington. In 2021, the industry already has spent more than double the sum spent by the second highest-spending industry.

The PBMs' trade group discounted the notion that rebates "are padding their bottom line." Instead, the organization said in a statement, "PBM-negotiated rebates are a key tool to reduce prescription-drug costs for consumers" and allow health insurers "to maintain more affordable premiums for those enrolled in a health plan."

Most of the studies the group provided to back up their assertions were produced by PBM-related entities.

Rebate walls or 'rebate traps' keep cheaper alternatives locked out

Sometimes, just making it onto the PBM's formulary isn't good enough for drug makers. They not only desire a prime position for their own products, but they also want their competitors' drugs walled off from the formulary itself. And they're willing to pay the PBM even more for these so-called rebate walls, sometimes dubbed rebate traps because many patients suddenly have no way to get the drugs they need.

"In return for all of these attractive payments and incentives, drug companies want an exclusive or more favorable position for their drug," Feldman said. "In other words, they want to make sure that cheaper alternatives are locked out. And that's what happens over and over again."

Robin Feldman on Drugs, Money, and Secret Handshakes - Econlib

PhRMA leaders say that's not what they want, even if individual drug makers do.

"Because we are a trade association, we can't speak about specific companies or products. As an advocacy organization, we believe patients should have access to the medicines that they and their doctors determine are the best course of therapy," Roberto said.

Prescription Drug Rebates, Explained

On occasion, a drug maker won't seek a complete blockage of a rival's drug. But the company will demand that before insurance covers that competing drug, the patient must go through "fail first" procedures in which the preferred drug must be proven not to work.

Another frequent requirement is step therapy, in which cheaper drugs must be tried before the patient can "step" into the rival's product – a process that studies have shown can lower the chances a patient will get better.

Almost always, patients with more complex medical needs must obtain prior authorization, sometimes called preauthorization, from their health insurer before they receive coverage for the expensive specialized drugs their doctor says are necessary.

High-ranking officials oppose use of prescription drug rebates, to no avail

The use of rebate walls persists despite widespread condemnation. President Donald Trump's Health and Human Services Secretary Alex Azar proposed regulations to reduce them. Trump's Food and Drug Administration Commissioner Scott Gottlieb called for an end to protection of rebates from the federal anti-kickbacks statute.

In a Gallup Poll taken shortly after President Joe Biden took office in January, 70% of U.S. adults said lowering health insurance premiums should be a high priority for the new administration, while 66% said the same about lowering drug costs.

Xavier Becerra, Biden's HHS secretary, spoke out against rebate walls while he was California attorney general. But asked about the issue several times during his confirmation hearing Feb. 24, he responded only with generalities, such as "I am committed to reducing drug prices and ensuring Americans have access to the drugs that they need."

In response to a lawsuit from PBMs, a federal court put on hold until at least until 2023 aTrump administration rule to end the kickback protections for drug rebates under Medicare that was to start in 2022. The PBMs and health plans contended that removing the rebates would lead to higher prices for consumers. It is not yet clear what the Biden administration will do about rebates long term.

A Federal Trade Commission report in late May concluded that rebate walls "may give payers strong incentives to block patient access to lower-priced medicines, whereas absent rebates a lower-priced equally effective product would tend to take sales from the higher

priced incumbent product. In this way, some rebates can operate to increase overall drug spending."

Minnesota Sen. Amy Klobuchar has been outspoken in the battle over rebate walls.

“Rebates can help to lower prescription drug prices, but complex ‘rebate trap’ schemes used by some drug makers can make it difficult for more affordable drugs to compete in the market," the Democrat said in a statement to The Dispatch.

"These rebate traps can be used by Big Pharma to suppress competition, limit patient access to new treatments, and keep drug prices high in the long run."

She was among a group of senators in June 2020 calling for the Government Accountability Office to delve into the issue.

“The coronavirus pandemic puts into sharp focus the urgent imperative to ensure that critical medications are actually available to patients in need,” Klobuchar and the other senators told the GAO. Her staff is pressing the agency to complete its probe.

A conservative Ohio think tank stands in accord with the liberal senator on this issue.

Rea S. Hederman Jr., executive director of the Economic Research Center at The Buckeye Institute, said one of the complications of the heavily consolidated U.S. health-care industry is twisted incentives leading to lower competition and higher prices – exemplified by such practices as rebate walls.

“You’re using a rebate to game market share that’s not going to a consumer and pocketing the difference,” Hederman said. "Sicker people are paying more, and healthy people are paying less, the opposite of the intent of insurance."

He pointed to a December 2020 study by the Pacific Research Institute saying that "when rebate walls successfully block competition, they are imposing excessive and unjustifiable costs on patients."

Hederman called for Ohio lawmakers to investigate the practice: "Rebate walls are one of the murkiest, least-transparent practices in health care – and perhaps it is time for a routine check-up."

Physicians say money, not medicine is behind PBM, health insurer decisions

Critics say this black box of determining whether a particular drug winds up on a PBM formulary, and which tier it occupies, is primarily based on financial considerations, not which medication will help patients the most.

"Clinical and cost-effectiveness does not correlate with a drug's excluded or recommended status," Joshua Cohen, an independent health-care analyst, found. "It suggests exclusions are more a function of horse trading and rebating, rather than being evidence- and value-based."

Professor Feldman said it boils down to this: "PBMs and drug companies have figured out how to monetize health-plan tiering in a way that's not in the patient's interest."

Or, as Dr. Madelaine "Maddie" Feldman put it: "The entire formulary construction paradigm in the U.S. is geared toward one thing only, and that is profits."

Madelaine Feldman, president of the Coalition of State Rheumatology Organizations and a clinical assistant professor of medicine at Tulane University School of Medicine in New Orleans, said the problem is simple: PBMs and health insurers are excluding drugs that help her patients get better. That forces her to try unproven ones.

However, changing medications can be detrimental. She notes that, on average, it takes 18 months of treatment to get a rheumatoid arthritis patient adjusted to the drug.

"If throwing the dice was sufficient to determine which drug was best for my patients – hey, this system would work," Feldman said.

"Non-medical switching" is what doctors call the practice of removing coverage for a drug that's working and essentially forcing a patient to change to another drug that the PBM has decreed as the only one covered by insurance. In other words, a patient is forced to switch drugs for non-medical reasons.

Ohio lawmakers currently are considering a proposal to limit the gambit. The measure was temporarily made part of the state budget bill but removed when the House approved the spending measure April 20.

Non-medical switching "is a financially motivated change that becomes a needless additional burden to patients and the mental health professionals trying to provide the best possible care to them," testified Dr. Brian Evans, president of the Ohio Psychiatric Physicians Association, during a hearing in late May of the House Insurance Committee.

"If a patient is stable on a specific medication and it is helpful to their condition, it is devastating if their insurance company or PBM suddenly makes a mid-year formulary change that makes the medication unaffordable, stops covering the medication entirely, or introduces other barriers that a patient must find a way around in order to continue to obtain their medication. By forcing patients to switch from a current medication to one that costs the health plan or PBM less, the health plan issuer causes avoidable suffering to the patient and can ultimately negate much of the potential savings."

Frustrated doctor says appeals of non-medical switching are almost useless

Back at her office next to Fairfield Medical Center, Dr. Ott laments for her patients caught in the middle when PBMs change their formulary, such as the almost annual switch between blockbuster drugs Enbrel (third most sales in America, at $8.1 billion, in 2019) and Humira (top-selling drug in the U.S., at $21.4 billion).

“It's who's the better negotiator, right? ... They’re getting a better rebate, they’re getting a better incentive to have their patients switched, let’s just say, from Humira to Enbrel," said Ott, director of rheumatology for Fairfield Healthcare Professionals.

Although both laboratory-created products are designed to treat rheumatoid arthritis and plaque psoriasis, "they are not the same, so these drugs are not interchangeable. We've got plenty of research to show that if (the patients) are doing well, you shouldn't be doing non-medical switching."

She especially feels for those who picked out health coverage specifically because that plan covered the medication they take – only to have the insurer remove the drug from its formulary after the patients' open enrollment period ends.

"This could be, you know, your momma with diabetes who's doing well on (hypothetical) insulin 'A.' And they say, OK, well, we're not going to cover that anymore," Ott said.

She sometimes pursues an appeal all the way up to what is supposed to be a "peer-to-peer" conversation with another physician representing the insurance company about why the patient needs the prescribed drug. But Ott said it's usually fruitless – and sometimes downright insulting.

"I had a conversation about trying to get Rituxan (used to decrease joint pain and swelling) for a patient and I was doing a peer-to-peer, and the 'peer' comes on the phone. It was an emergency room physician who said, 'I'm just covering for so & so that you were supposed to talk to. I really haven't had a chance to review everything, but I looked up the drug and you can't have it.'

"Well, the red in my hair's real. And my temper may have flared. We did not have the kindest conversation at that point. Here I've got this ER doc that's covering for somebody else that basically read the PDF on this and thought that they knew my patient and what was right for them."

That unpleasant incident illustrates the problem of PBMs and insurers essentially replacing the role of doctors in deciding what medications their patients should receive, she said.

“I spent nine years in my life training to be a rheumatologist: four in medical school, three as an internal medicine and then two in rheumatology. So it's been nine years training to do this.

"But I don't get to practice medicine, because these insurers tell me how long I can spend with a patient, how much time I can have in a room, what tests they'll pay for, and then what medicines I can use.

"So I'm not kidding you when I tell you, I don't know what I'm here for."

A grant from the nonpartisan, nonprofit National Institute for Health Care Management helped pay for research for this story, but the organization had no input on its content.

drowland@dispatch.com

@darreldrowland