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Prospect of lower fees for prescription drugs could be dashed by new maneuver from PBMs

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A few months ago, proposed federal action to reduce fees on prescription drugs used by millions of older Americans was hailed as a "real game-changer" that would save consumers billions.

But powerful middlemen in the tangled web of U.S. drug purchases already have moved to counteract much of the proposed savings and preserve profits.

Explaining how those fees are calculated is difficult. But pharmacists and industry observers say there's no mistaking the intent of the middlemen's changes: They want the ability to unilaterally set new fees to offset any losses they may suffer from the federal revamp.

The impact of this latest money-making tactic by pharmacy benefit managers will cause higher prices and more pharmacies to close, a severe problem for people who need potentially life-saving prescriptions to battle cancer, said Ted Okon, executive director of the Community Oncology Alliance, a Washington-based nonprofit group that advocates for community oncology practices nationwide.

"This will end up creating pharmacy deserts for patients," he said. "This causes all types of treatment delays and even denials."

Local pharmacies charged fees by drug distribution middlemen

U.S. Sen. Sherrod Brown, an Ohio Democrat whose October request helped spark the proposed changes by the U.S. Centers for Medicare & Medicaid Services (CMS), is trying to stop the PBMs' maneuver.

"Pharmacy benefit managers are once again finding ways to make it hard for local pharmacies to serve their communities by enforcing contracts with unnecessary fees," his office said.

Brown is asking the federal Office of Management and Budget to make sure the proposed revamp "includes the comprehensive reform and transparency requirements necessary for CMS to address any remaining anti-competitive tactics employed by supply chain middlemen that could threaten beneficiary access to care."

Nearly 50 million are enrolled in Medicare Part D, the federal prescription drug program for those 65 and older.

What are DIR fees?

At the heart of the controversy lies a little-known assessment on pharmacies called Direct and Indirect Remuneration fees. These DIR fees skyrocketed by 91,500% between 2010 and 2019, CMS calculated. The fees now total $11.2 billion a year, up from $200 million in 2013.

Calculating DIR fees often varies from PBM to PBM, and from contract to contract. Many stem from quality metrics for pharmacies that numerous experts and members of Congress deem irrelevant. Some are based on drug ingredient costs.

If an expensive specialty drug is involved, a percentage may be charged. Sometimes rebates from drugmakers are considered. Often multiple contracts are rolled together and a PBM determines what "effective rate" it wants to hit.

The one common thread: The precise methodology to determine how much a PBM is owed remains a mystery to virtually all pharmacists. And, the Pharmacy Times says, "There is no evidence that the (DIR fee) obtained from the pharmacy is ever credited back to the patient."

CMS Administrator Chiquita Brooks-LaSure called the huge fee increases "troubling" when she announced the prospective federal rule change in December. The agency says its proposal would save Medicare recipients $21.3 billion over 10 years, a 2% cost savings.

A study of one large health plan by 3 Axis Advisors identified a rate increase of 51% for generic drugs used by Medicare recipients during a 30-month period ending in mid-2021. During the same time, the national average pharmacy acquisition costs for generic drugs actually decreased by 8.7%.

3 Axis is a drug analytics firm is headed by Antonio Ciaccia, formerly of the Ohio Pharmacists Association.

In theory, DIR fees are used by PBMs to make sure pharmacies not only dispense drugs to Medicare recipients but are carrying out follow-up measures as well, such as calling patients to make sure they are actually taking the drugs.

However, critics say that in recent years, the PBMs' justification for the fees has deviated far from its origin.

Perhaps the biggest complaint from pharmacists: They have no way of telling how much they must pay, and the bill doesn't come until weeks or often months after a prescription is filled. Repeated mystery charges assessed retroactively make it difficult to difficulty to run a pharmacy, they say.

With just three PBMs — all part of Fortune 15 companies — controlling about 80% of the market, pharmacies have little negotiating power.

What do newly revealed documents show about PBM tactics?

The heavily consolidated segment of the U.S. health-care marketplace helps the PBMs dodge the impact of potential new federal restrictions.

For example, CVS Caremark included an "escalator clause" in its new pacts last year that essentially allows the PBM to simply increase its fees to offset any changes in DIR fees. In a March update viewed by The Dispatch, Caremark gives itself the power to unilaterally change the contract "in order to preserve the relative economics" of all parties existing before any CMS intervention.

Currently, Express Scripts Inc. is doing much the same, giving pharmacies notice of contract changes that would kick in if CMS acts.

The new language, contained in a confidential seven-page document obtained by The Dispatch, includes sweeping language giving the PBM broad powers. For example, the contract revisions say that "ESI, in its sole discretion, may apply different rates and fees."

Neither CVS nor Express Scripts responded to Dispatch requests Monday for comment.

PBM pushback: The federal changes actually would increase drug prices

The PBMs say the DIR fees are needed to keep costs down for consumers.

“CMS has stated that the intent of the pharmacy DIR rule is to make discounts on drugs available at the pharmacy counter, rather than lower premiums, as pharmacy DIR is used now," said Greg Lopes, assistant vice president for strategic communications for the PBMs' trade group, Pharmaceutical Care Management Association.

"It should not be a surprise that PBMs will negotiate with pharmacies to achieve the same level of savings for Medicare beneficiaries.”

As part of 31 pages of comments filed on the CMS measure, Melissa Schulman, senior vice president of government & public affairs for CVS Health, said the proposed change would "increase beneficiary premiums and eliminate an important tool plans use to incentive higher quality and better performance. This policy will also increase costs to the federal government and provide a windfall to (drug) manufacturers."

But many of the 4,300-plus comments filed on the proposal came from pharmacy owners begging for relief to stay in business.

"Fruth Pharmacy has seen our DIR fees grow from a few thousand dollars to over $5 million dollars a year," said Lynn Fruth, president and chairman of the family-owned company that operates a chain of small-town pharmacies in southern Ohio, West Virginia and Kentucky.

"As a result, in the past three years, we have reduced store hours at every store in our chain, and we have reduced from nearly 700 employees to less than 500. We have closed four stores, and we must actively consider closing others."

"Quite frankly the PBM performance measures have been a sham. The PBMs, under the guise of raising outcomes, has taken over $5 million dollars a year from us while Fruth can only earn back under $100,000 for great performance. The metric has been stacked in favor of PBMs taking credit for all performance improvements while starving retail pharmacies that are doing the heavy lifting."

More than 200 pharmacies and other organizations — including Costco, Kroger, Meijer, Walgreens, Walmart and the Ohio Council of Retail Merchants — said in a letter last month

to Health and Human Services Secretary Xavier Becerra that the CMS changes "would meaningfully promote beneficiary access to needed medications."

"As it stands now, the inconsistent and opaque nature in which these retroactive fees are applied makes it difficult for pharmacies to continue operating, and many pharmacies have closed, which negatively impacts patient access to care."

Warnings over drug middlemen's maneuver

Some groups, such as Okon's Community Oncology Alliance, anticipated that the PBMs would attempt to dodge the new regulations. Regulators who have attempted to rein in PBMs over the years often voice frustrations that they are playing Whac-a-Mole, because when they clamp down on one area, the PBMs simply pop up in new place with a different profit-making technique.

"PBMs will simply abuse loopholes to blunt the positive impact of the proposal, shifting to other fees and tactics that will continue to artificially raise drug costs for Medicare beneficiaries, forcing pharmacy providers out of business in the process," the alliance warned.

Monique Whitney, executive director of Pharmacists United for Truth and Transparency, told CMS to clearly define the new rule "to include all price concessions negotiated by PBMs, otherwise pharmacies may be subjected to the current practice of PBMs restructuring 'negotiated price' to include revenue for themselves."

She added: “DIRs are revenue ploys for the largest PBMs, whose first allegiance is to shareholders, not patients.”

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