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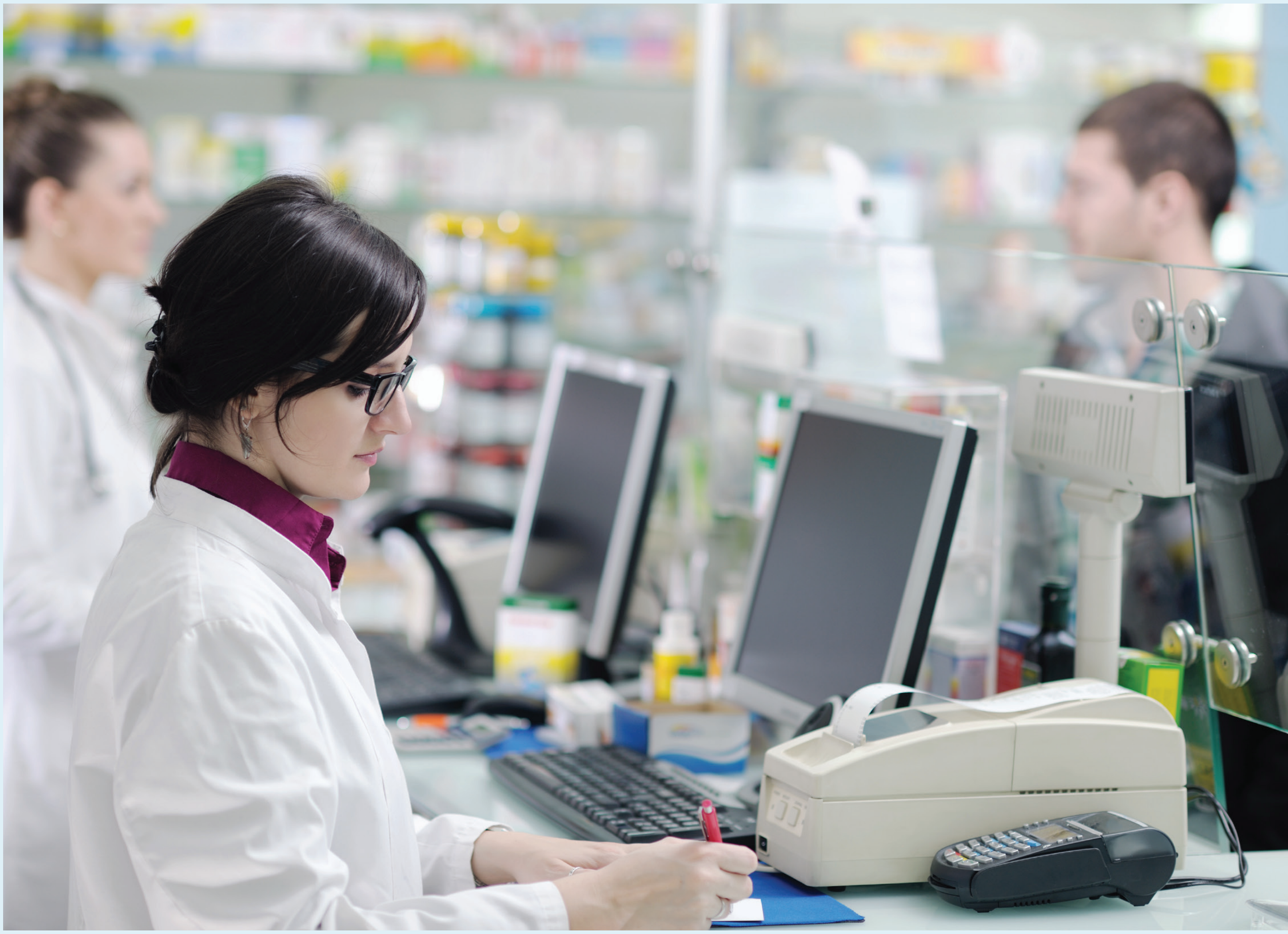
How DIR Fees Impact the Independent Pharmacy Industry

DIR fees were intended to provide transparency and lower patient costs, but they have become a serious financial burden for pharmacy owners. What's next, and how can a PSAO help?



By the numbers:

Pharmacy DIR in 2017:

1.5%

of retail prescription revenues

$4 billion total

$63,000

per retail pharmacy location

-Drug Channels Institute

DIR Fees: A Growing Challenge

Direct and indirect remuneration (DIR) fees are a growing challenge for independent pharmacies. The lack of clarity on these retroactive fees – and the struggle to correctly anticipate them – have created financial strains for many independent pharmacies and are increasingly leading to higher prices for patients at the point of sale.

This runs counter to the original vision for DIR, which was developed with the goal of bringing clarity to prescription drug pricing and passing along savings, ultimately lowering costs for patients. But, as DIR fees have multiplied, they have developed into an industry-wide pain point that is compromising the accuracy of the reconciliation process and threatening the stability of many independent pharmacies. Despite recent proposals to account for DIR at the point of sale, the issues remain mostly unsolved for now.

What is on the horizon for the community pharmacy industry regarding the effects of DIR fees? In the next few pages, we will discuss what DIR fees have come to mean since their implementation, how they are currently affecting the industry, and how partnering with a Pharmacy Services Administrative Organization (PSAO) can help minimize the financial difficulties these fees impose on independent pharmacy owners.

The History and Evolution of DIR Fees

DIR fees originated in 2006 when Medicare Part D launched. The intent of DIR, as defined by the Centers for Medicare and Medicaid Services (CMS), was to provide transparency and account for any additional compensation, such as rebate dollars, received by pharmaceutical companies or pharmacy benefit managers (PBMs) after the point of sale.

Originally, DIR fees were a result of the reconciliation process between the claim and the "negotiated drug price" – i.e., the insurers and the pharmaceutical manufacturers. When DIR fees were created, they did not exist in the pharmacy world as they do today. In 2014, CMS changed the definition of a "negotiated price" to include all pharmacy price concessions – which opened the door for PBMs to create DIR fees for pharmacies.

The new definition of negotiated price took effect in 2016, and CMS directed that DIR fees could be charged to pharmacies only if the fees couldn't reasonably be determined at the point of sale. This ruling has since led to increasingly variable DIR fees that may be based on pharmacies' clinical performance, operational performance, or participation in a preferred network in a "pay to play" environment.

While PBMs assert that DIR fees imposed on pharmacies help lower drug prices and keep pharmacies accountable, independent pharmacies find difficulty in understanding the fees, leading to unclear reimbursement and increased financial vulnerability.

Impact of DIR Fees on Pharmacies

DIR fees, which began as a good-faith attempt by CMS to improve clarity, have resulted in a confusing payment methodology that prevents pharmacies from accurately predicting their profits and losses because of the clawbacks imposed after the point of sale.

According to the Drug Channels Institute, in 2017 alone, the average independent pharmacy paid about $63,000 in DIR fees – roughly 8 percent of its total gross profit. These fees can cause revenue loss that may surpass the drug's acquisition cost, affecting the pharmacy's ability to care for patients, provide adequate staffing, stay competitive or even stay in business. In a survey conducted by NCPA, at least three-quarters of pharmacy owners report that DIR fees result in unpredictable cash flow, cause serious difficulties for anticipating operating revenue, and make it difficult to plan for the future of their business.

Compounding the issue is the significant rise in both frequency and total cost of DIR fees. Since 2010, the use of DIR fees has increased 45,000 percent. Additionally, over the past few years, many payers have moved from a flat-fee DIR to a percentage-based DIR. Under a percentage-based system, pharmacies experience much higher DIR fees when dispensing high-cost brand and specialty medications than they would with a DIR that is assessed as a flat fee.

The Rising Costs of DIR

DIR increases from 2013 to 2017, estimated from CMS's disclosure of the value of pharmacy price concessions in December 2018

What	2013	2017
Total DIR in Part D	$13.4 bilion	$35.1 billion
Manufacturers' rebate payments to Part D plans (largest component of DIR)	$12.2 billion	$29.5 billion
Net value of pharmacy price concessions	$229 million	$4 billion
Pharmacy DIR fees as a share of total DIR	1.7 percent	11.4 percent

-Drug Channels Institute

In addition, many pharmacies "pay to play" for preferred status on Medicare plans, with the expectation that preferred networks will drive more customers and other forms of revenue to their business. Preferred pharmacy networks usually have a lower reimbursement at the point of sale and may have higher DIR fees.

Because of this, pharmacies may opt for non-preferred contracts. But although a pharmacy may be receiving higher reimbursements and lower DIR fees on a non-preferred contract, patients may face a decision on whether to stay with that pharmacy and pay a higher copay, or switch to the savings of a preferred pharmacy.

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For 2019 Medicare plans, patients paid roughly $5 more on average for a preferred generic prescription at a non-preferred pharmacy. Ultimately, then, the decisions that pharmacies must make based on the amount of DIR fees could mean the difference in retaining or losing patients.

Impact of DIR Fees on Patients

In theory, the goal of DIR is to pass along savings from the PBM or Plan D sponsor to Medicare, ultimately lowering costs for patients. But because DIR fees are usually assessed weeks to months after a patient picks up a prescription, the use of DIR hyperinflates the cost at the point of sale. The issue has a direct impact on patients, as cost-sharing for Medicare beneficiaries occurs in real time.

The disconnect between patient payment and a DIR clawback results in patients reaching the Medicare Part D "donut hole" (coverage gap) more quickly than they should. Once patients reach the donut hole, they may be responsible for a much higher cost share than they experience in the initial coverage phase.

Many patients already struggle to pay for the prescriptions they need. Entering the donut hole early, because of the hyperinflated payment at the point of sale, further increases patients' financial burden and may lead to decreased drug adherence. Financial issues are a primary obstacle to drug adherence and can negatively affect patients' health outcomes.

Ultimately, the current system of assessing DIR fees increases the overall cost for patients' medications and may lead to higher health-related expenses due to medication nonadherence.

The Future for DIR Fees

After much discussion, CMS announced in May 2019 that it would not move forward with a proposal to account for DIR fees at the point of sale in 2020 Medicare Part D plans. Although the move would not have eliminated DIR fees, it would have ended the practice of retroactive clawbacks and improved transparency for pharmacies.

Much of the pharmacy industry, however, is still advocating for changes to the way DIR fees are determined and collected. Such changes are backed by a majority of the U.S. Senate Finance Committee, which sent a bipartisan request in September 2019 to CMS and the Department of Health and Human Services to consider DIR reforms. These include modifying the definition of "negotiated price" to include all pharmacy price concessions at the point of sale and eliminating retroactive DIR fees, to be finalized for the Medicare Part D plan in 2021.

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Several states have legislation in the pipeline that addresses DIR fees. Others, such as South Dakota, have been successful in passing DIR legislation. But despite state efforts, DIR fees remain the status quo on a federal level for the foreseeable future.

How a PSAO Can Help

Independent pharmacy owners are painfully aware of the financial stresses that unpredictable DIR fees can cause for their business and for their patients. As the rapid changes continue in the industry – and as the burden of DIR fees increases – pharmacies can benefit from enlisting the partnership of a PSAO to assist with DIR fee management and many related administrative challenges. Look for a PSAO partner that will support you in these ways:

- Provides contract terms for all plans with DIR fees, including point of sale reimbursement, range of DIR fee, and criteria determining overall DIR assessed
- Robust reporting and transparency that shows the exact amount of DIR that was accessed on a claim-by-claim basis
- Contract structure analytics for all pharmacies in the PSAO's network – identifying contractual provisions, tracking requirements, and identifying situations to intervene and assist
- Assistance with boosting performance on key indicators such as generic dispensing rates, drug adherence rates and medication therapy management, all of which can affect DIR fees
- Assistance in understanding mechanics of overall reimbursement – helps you understand the difference in operational vs. clinical performance measurements, how the measurements factor into the DIR calculation, and which has a greater significance for your pharmacy on a plan-by-plan basis
- Modeling contracts out, researching your claims data, and determining whether a given contract indicates a profit before you sign on the dotted line

As long as DIR fees are handled and collected as they are today, successfully managing these fees is vital for staying profitable and competitive. With the help of a PSAO that is dedicated to you and your pharmacy's unique issues, you can improve your understanding of DIR fees and prepare for them more thoroughly and proactively. The goal is a more positive experience and result for both you and your patients.

About the author

Todd Wormington, R.Ph, MBA is Vice President of Pharmacy Programs for Pharmacy First. He manages all operational and clinical support solutions delivered throughout a diverse network of over 2,300 retail pharmacies. Todd's 25 years of experience in the industry bridges the gap from early roles in a small independent retail pharmacy chain to building a class-leading, oncology-focused reimbursement hub service company. He has worked in a variety of business development roles with key technology providers in the retail pharmacy space, including pharmacy systems vendors and class leading robotics companies.

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