https://specialty.pharmacytimes.com/news/white-paper-dir-fees-simply-explained

White Paper: DIR Fees Simply Explained

Author: True North Political Solutions

Pharmacy benefit managers (PBMs) have been using direct and indirect remuneration fees (DIR) for many years. Recently, there has been a significant increase in the use of these fees, which affects both retail and specialty pharmacy. This white paper will explain what DIR is, how it is affecting pharmacy and its patients, and how policymakers are addressing the issue. Finally, we will discuss some suggestions from a strategic point of view on how to deal with these fees. This paper is designed to give the reader an overview of DIR fees in an easy to understand format.

What is DIR?

There are many ways in which DIR is defined. The Centers for Medicare and Medicaid Services (CMS) defines DIR as follows:

"Often, the Part D sponsor or its pharmacy benefits manager (PBM) receives additional compensation after the point-of-sale that serves to change the final cost of the drug for the payer, or the price paid to the pharmacy for the drug. Examples of such compensation include rebates provided by manufacturers and concessions paid by pharmacies. Under Medicare Part D, this post point-of-sale compensation is called Direct and Indirect Remuneration (DIR) and is factored into CMS' calculation of final Medicare payments to Part D plans."[1]

Where did DIR come from? These fees have been around since Part D was created and can be found in the federal rules (42 CFR 423.308). DIR fees were originally supposed to be a way to offer incentives instead of a way to "claw back" money from pharmacies.

The DIR rule includes the following: "discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, upfront payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits from manufacturers, pharmacies or similar entity."[2]

The rule basically states that any benefit that would bring the price down from the contracted price with Medicare needs to be reported. PBMs claim that most of the DIR funds that they receive are manufacturer rebates and they contend that pharmacy DIR fees are necessary to lower drug prices. This may be true in some aspects of DIR, although changes over the years regarding the implementation of DIR fees has created debate as to whether this is true.

What are DIR fees?

DIR are the fees that pharmacies may see PBMs charge outside of administration fees and are generally collected after the point of sale. We see them in many forms.

Originally, DIR fees were more commonly seen via a reconciliation between the claim and the negotiated price. Also, another common DIR fee that we see is when a pharmacy would pay the PBM in order to participate in a preferred network or "pay to play."

At times, the fee is based on the "performance" of the pharmacy. This means that the PBM can take money back from the pharmacy and create a situation where the pharmacy does not receive adequate reimbursement to cover its costs due to arbitrary "performance" standards that frequently serve as a moving goal post. Hence, DIR is now seen as a catch-all, since it has been expanded well beyond CMS' intended use of its definition.

Why is there so much debate around DIR fess in pharmacy?

Both retail and specialty pharmacies are affected by DIR fees. The fees create losses in revenue that, at times, may surpass the acquisition cost of the drug itself. Basically, DIR fees can create a situation in which pharmacies are losing money when they process a claim through Medicare Part D. PBMs argue that DIR fees lower drug costs and allow for savings. They even call DIR fees "pay for performance." This term is misleading, as many times the fee is applied no matter what happens. The fee is adjusted up or down according to performance of the pharmacy or the co-pay of the insured.

Flat fee versus percentage fee

Flat dollar DIR fees are more common in retail. These fees can be actually higher than the reimbursed rate from the PBM and result in a loss for the pharmacy. DIR fees are commonly seen with generic drugs. Many in the industry believe that the creation of maximum allowable cost (MAC) transparency laws on the state level may have increased the utilization of flat DIR fees.

DIR fees based on a percentage are more common in specialty pharmacy. The higher price of specialty drugs create a higher DIR fee under a percentage. PBMs can use this fee to charge thousands per claim instead of a smaller, flat fee.

Connection to star ratings

Many PBMs use the star ratings program as a basis for quality measures. The 5-star ratings program is actually a program for CMS to rate insurance plan sponsors and not pharmacies. Insurance companies who get a 5-star rating get extra incentive payments from CMS.

Ratings for plans covering health services fall into 5 categories: Staying healthy; screening tests and vaccines;

managing chronic long-term conditions; member experience with the health plan; member complaints and changes in the health plan's performance; and health plan customer service.

PBMs now use quality measures as a way to boost their own star ratings. The quality measures are based on retail medication therapy management (MTM) and chronic disease management. This includes patients with diabetes, patients with high blood pressure, and other chronic conditions. This will create lower scores for specialty pharmacies that do not fill for or manage those chronic diseases. Disease states such as cancer and HIV are not measured.

At some point, star rating measures got shifted from the plan to pharmacy providers to where the providers started to bear most of the risk. Additionally, what we have noticed as a side note is that there is no express mandate in CMS protocols requiring plans to share incentives with network providers.

Performance-based DIR fees are also weighted where PBMs compare the pharmacies regardless of whether they are retail or specialty on the same scale and then base the DIR fee on which percentile the pharmacy falls in. This is a major problem for specialty, as its ancillary services are vastly different from retail. Regardless of the differences between retail and specialty, both are impacted in regards to the star ratings program.

Clawbacks

One of the most debated parts of the issue with DIR fees are clawbacks. Clawbacks are when the PBM charges a DIR fee after the point of sale. These charges are most likely a percentage of the total cost of the prescription and many times create a negative reimbursement for the drug dispensed. DIR fees are hard to predict, as PBMs do not explain how they calculate performance-based DIR fees. Also, since the fees may come months after dispensing, it creates tax issues too.

Since the PBM takes back money from the claim well after the point of sale (sometimes weeks or months) it is called a "clawback." Both retail and specialty pharmacists focus on this part of DIR fees and will interchange the term "clawback" with DIR fees. This can be confusing when trying to push policy, as it focuses on the claim only and opens the door for the PBMs to confuse the issue to policymakers. That is why we explain them as a separate term.

What does this mean for patients?

Patients are likely to pay more out of pocket costs, as many PBMs will charge a co-pay that is higher than the drug's price without insurance. Later, they will "clawback" the difference from the pharmacy. There is no evidence that the clawback obtained from the pharmacy is ever credited back to the patient.

This happens more frequently with generics and it can vary by pharmacy. Also, this practice drives patients faster into the Medicare Part D doughnut hole. Once a patient reaches the doughnut hole, they may be

responsible for the full cost of the drugs until they reach a higher spending level. Many patients have extra insurance or help to cover the costs, though this results in higher premiums.

CMS Data

The CMS has released data recently in regards to DIR. It is important to remember that CMS sees DIR differently. It only sees what is reported via the insurer and manufacturers, and does not have data specifically from the pharmacy as to the clawbacks. This creates a disconnect between CMS and the pharmacies, as CMS is not required under law to get this specific data from the PBM.

They do not examine what the difference between the co-pay and the price without insurance would be. They have looked at how much DIR fees have risen and the effect on catastrophic costs. At the beginning of the year, CMS released data that showed these effects. DIR as a percentage of gross drug costs has risen steadily year over year, going from 11.3% in 2010 to 17.2% in 2015.

DIR per member per month in Medicare Part D has nearly doubled in that time. Also, CMS has recognized that DIR fees create more out of pocket spending, and that PBMs need more transparency as to the reporting of DIR.[3]

Federal Legislation

A federal solution has been proposed in Congress. The *Improving Transparency and Accuracy in Medicare Part D Spending Act* will prohibit Medicare Part D plan sponsors/PBMs from retroactively reducing payment on clean claims submitted by pharmacies under Medicare Part D, effectively eliminating the clawback for every Medicare Part D claim.[4] This would also help patients from falling into the doughnut hole and will save Medicare catastrophic costs. If this bill passes, it would solve this issue and create more transparency in regards to the DIR practices of PBMs.

Policy in the states

Several states have passed laws to help pharmacists and consumers deal with the negative effects of DIR fees. Georgia passed SB 103[5], which prohibits PBMs from using "gag clauses" in regards to information a pharmacist can share with the patient. Many insurers use these clauses to restrict pharmacists from disclosing how much a drug really costs or the amount of the patient's cost share compared with the cost of the drug without a co-pay.

Georgia also prohibits a fee to be charged in regards to the administration of the fee by the PBM and does not allow a patient's co-pay to exceed a certain level or allow for a clawback of the claim. The law also prohibits a PBM from retaliating against a pharmacy that acts under the law. This stops a PBM from dropping a pharmacy from its network as a result of any action under the law.

North Dakota[6] has eliminated the clawback, but they have gone a step further by regulating how a PBM may utilize pay for performance or quality measures of pharmacies. North Dakota requires that PBMs use an unbiased entity for the measurement of quality. This actually goes further than the Georgia law and regulates the use of performance-based DIR fees.

Texas and Maine eliminate the clawback in a more indirect fashion by focusing on the consumer side of the issue.[7] Both laws prohibit the PBM from charging a co-pay that is higher than the drug would be without insurance. This allows pharmacists to give patients the information about a drug's price. If the drug costs less than the co-pay, the pharmacist has the ability to charge the patient the lower price and avoid a clawback later regarding the co-pay.

North Carolina has limited what PBMs can charge via their own contracts. This gives pharmacists more transparency by requiring that the PBMs set the DIR fee via the contract or report the fee on remittance. This was done in order to eliminate the element of surprise that happens often with DIR fees.[8]

What you can do to deal with DIR

Dealing with DIR fees can be overwhelming and at times confusing. Here are some suggestions that you may want to add to your strategic planning.

First, you need to collect your claims data and find a way to analyze it in a way that can show how clawbacks affect your bottom line. Doing this will allow you to do two things.

1. See how DIR fees are exactly affecting you and which drugs may be targeted the most.
2. You will be able to have clear evidence of any negative effects.

Having this information will give you the ability to either use some of the state laws that we discussed earlier to your advantage if you are in one of those states or report your data to CMS. Another suggestion is to find an estimator of DIR fees. Many wholesalers have them and they could help in regards to preparing for these fees.

Also, it is a good idea to review any information that a PBM has released in regards to performance metrics. The best place to start this is medication therapy management practices.

Finally, we suggest that you start to have some type of interaction with local and state policymakers and educate them about the issue. Doing so may help in creating policy in your state if you do not have it already.

About True North Political Solutions

Here at True North we strive to make our clients smarter. Whether it be a regulation or legislation, we make sure our clients know what is ahead and how it will affect them specifically. Not only do we save our clients an

average of 1700 hours a year, we focus on our client's priorities and how policy can either help or hinder them.

We offer services that help in strategic planning, operations and lobbying. The Burn Factor is our signature service and provides you with up to date information on how your company's priorities are being impacted by market and government developments. Our proprietary system ranks each of your priority issues according to factors unique to you. Contact us to see how we can make your organization smarter.

---

[1] Centers for Medicare and Medicaid Services (CMS), 2017 Fact Sheet Items, Medicare Part D- Direct and Indirect Remuneration, January 19, 2017.

[2] Federal Code 42 CFR 423.308

[3] CMS January 19, 2017 DIR Fact Sheet.

[4] H.R.1038 - Improving Transparency and Accuracy in Medicare Part D Spending Act

[5] Georgia SB 103

[6] North Dakota SB 2258

[7] Texas SB 1076 and Maine LD 6.

[8] North Carolina HB 466