

Direct and Indirect Remuneration (DIR) Performance and the Impact on Pharmacies Serving Medicare Part D Beneficiaries

A WHITE PAPER BY INMAR INTELLIGENCE®

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A White Paper by Inmar Intelligence, commissioned by NACDS

Overview

Direct and Indirect Remuneration (DIR) is a component of Medicare Part D programs today. It is very complicated and has been implemented in a variety of different ways. The lack of clarity, fairness and transparency to all parties has created business challenges for pharmacies. NACDS is working on behalf of pharmacies to 1) eliminate post point-of-sale price concessions; 2) include quality-based incentives for pharmacies; and 3) require claim-level data be provided to pharmacies. This paper will provide data and insights into both DIR impact to date and the opportunities for improvement with these NACDS initiatives.

Inmar Intelligence processes more than one billion pharmacy claims annually on behalf of more than 20,000 pharmacies, serving more than 85 million patients. Inmar's pharmacy customers include national and regional chains, health system pharmacies, long-term care, specialty and independent retail pharmacies that, collectively, comprise approximately 25% of the entire pharmacy industry. This paper uses Inmar's large subset of industry data to illustrate and evaluate DIR trends and demonstrate how DIR is impacting the entire pharmacy market.

About NACDS

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate over 40,000 pharmacies, and NACDS' nearly 100 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 152,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 20 countries. Please visit nacds.org.

About Inmar Intelligence

We use technology, data science and analytics to improve outcomes for pharmacies, pharmaceutical manufacturers, hospitals, health systems, insurance organizations and the patients they serve. Our healthcare analytics, platforms and services create efficiencies to optimize results, strategic insights and to drive profitable growth.

Our solutions, such as prescriptive analytics, shopper and patient engagement, consumer activation technologies, and e-commerce platforms, are inspired by a new age of technology-savvy consumers with changing expectations and behaviors, illuminated through advanced analytics and behavioral economics. We help leading Fortune 500 companies and emerging brands grow while providing their consumers with tools to save money, improve health and safety, and more conveniently go about their lives.

Inmar has been a trusted healthcare intermediary for over 25 years. We manage billions of dollars of healthcare transactions, applying the highest standards for data and financial controls. For more information about Inmar, please visit us at inmar.com.

1. Situational Analysis

1.1 Pharmacy Business Environment

Community pharmacies have many more touchpoints with patients than insurance plans or other healthcare providers. Pharmacies are embedded in their communities and are increasingly important to the healthcare delivery system. Pharmacies need a stable business environment that enables them to maximize patient care without operating at a financial loss.

Prescriptions filled by patients who are paying in cash without any form of insurance account for 5-8% of the total volume of prescriptions. While 92-95% of the prescriptions filled have a payment component coming from Medicare Part D, Medicaid, or a commercial insurance plan, these plans are ordinarily administered by Pharmacy Benefit Managers (PBMs). The top three PBMs manage 70% of the volume. The top seven PBMs and plans manage 92% of the volume. This business environment makes it very difficult for pharmacies to negotiate equitable business practices and transparency, because the PBMs and plans have more commercial market power and leverage in the relationship due to their size and scale.

Current PBM and plan DIR approaches are complex, uneven and challenging. This results in substantial financial penalties being paid by pharmacies to plans and PBMs. This impact is compounded by the fact that pharmacy reimbursement rates have also declined since DIR was first implemented, and pharmacy DIR fees now total more than 6% of Medicare Part D pharmacy sales.

Additionally, significant variations in DIR approaches exist across plans and PBMs. Varying approaches often include incongruent and opaque DIR metrics, definitions, methodologies and processes by plans and PBMs, all of which needlessly penalize pharmacies. These variations and inconsistencies place an undue burden on pharmacies, requiring them to make a substantial investment in accounting and financial systems which add unnecessary costs to the healthcare system, and divert funds from further investment in pharmacy care. If CMS stopped DIR inconsistency and difficult-to-measure implementations by PBMs and plans by leveling the playing field and providing standard performance program criteria, pharmacies would have the opportunity to redirect resources to improve patient outcomes and reduce total cost of care. Accordingly, CMS should implement its proposals to:

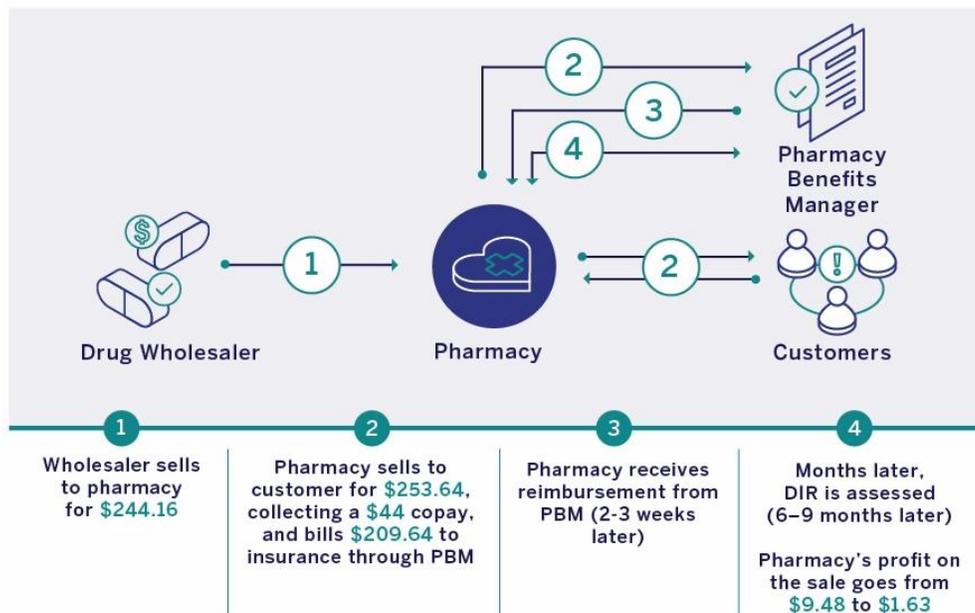
- Include all pharmacy price concessions in negotiated prices at the point of dispensing;
- Develop a standard set of pharmacy quality and cost measure in the Part D Program; and
- Align Medicare program incentives for improving pharmacy access and quality, and reducing costs

1.2 Definition of Direct and Indirect Remuneration

CMS created reporting requirements for DIR with the intention to: 1) provide visibility into the true cost of Medicare Part D medications; 2) ensure accurate Medicare payments to plan sponsors; and 3) reduce the financial burden on beneficiaries and CMS. DIR has, unfortunately, done the opposite on all three points. Additionally, the post-adjudication financial assessments imposed by PBMs have created a substantial and growing financial burden on pharmacies that is threatening their survival (Exhibit 1). Moreover, DIR processes vary substantially by sponsors. The status quo of DIR is inconsistent with the priorities of CMS, which seeks to minimize the burden on reporting entities and increase the focus on quality and health outcomes.

DIR was considered and implemented by Congress when the Part D program was created with the passage of the Medicare Modernization Act of 2003. Congress created the DIR concept to make sure that plans account for all costs and receipts in order to determine the net amount “actually paid.” This knowledge would help to ensure that neither CMS nor Medicare beneficiaries were paying more than intended by Congress.

Illustration of How DIR Fees Impact Pharmacies



Source: Inmar Intelligence

Exhibit 1: Example of a brand drug product

DIR comprises any and all rebates, subsidies, or other price concessions from any source (including manufacturers, pharmacies, enrollees, or any other person) that serve to decrease the costs incurred by the Part D Plan sponsor — whether directly or indirectly — for the Part D drug. DIR includes, “discounts, charge backs or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers from any source (including manufacturers, pharmacies, enrollees, or any other person) that would serve to decrease the costs incurred under the Part D plan.” (42 C.F.R § 423.308).

1.3 Current State Relative to Total Pharmacy Sales

Exhibit 2 illustrates total pharmacy sales for the last 15 quarters with an overlay of the percentage of those sales relative to DIR and other transaction service fees imposed by PBMs and plans. PBM service fees have been a part of the financial pharmacy business since online adjudication began. These are fees that PBMs and plans charge the pharmacies for a variety of purposes, such as the submission of claims and participation in pharmacy networks. While service fees have fluctuated through the years, they are a standard part of the contracts between pharmacies and PBMs and plans.

The other trend lines represent reimbursement rates as a percentage of Average Wholesale Prices (AWP) for both brands and generics. It is important to look at all of these pieces of data together. PBMs and plans claim that they have adjusted reimbursement rates to offset pharmacy DIR fees, but this data demonstrate that is not the case. In fact, reimbursement rates have declined since DIR was implemented, and DIR now amounts to more than 1% of total sales.

Combined DIR and Service Fees and Reclining Reimbursement Rates Create Overwhelming Financial Burden



Source: Inmar Intelligence

Exhibit 2

1.4 Current State Relative to Medicare Part D Overall

DIR originated in Medicare Part D Plans, and while a number of commercial plans have attempted to incorporate a DIR component, in the vast majority of cases DIR remains somewhat unique to the Medicare Part D program. Therefore, it's important to examine DIR fees relative to Medicare Part D sales exclusively.

Exhibit 3 shows Medicare Part D pharmacy sales for the last 15 quarters. The trend line overlay represents DIR fees as a percentage of Medicare Part D prescription sales. In Q3 2018, DIR fees exceeded 6% of Medicare Part D prescription sales.

DIR Fees Growing to Over 6% of Medicare Part D Sales



Source: Inmar Intelligence

Exhibit 3

1.5 Background on DIR

There are 11 categories of DIR enumerated by CMS, two of which directly impact pharmacy financials: Category 8 and Category 9. DIR Category 8 are amounts PBMs and plans receive from pharmacies which include the fixed amounts taken on each prescription during the adjudication process. DIR Category 9 are amounts PBMs and plans pay to pharmacies which include any dollars that top performing pharmacies may earn back following performance review periods.

In the pharmacy market, DIR is non-standard in construct, invoiced at various times throughout the year, and built around complex, ever-changing formulas. While DIR has always been a part of the Medicare Part D program landscape, it wasn't until recently that PBMs and plans leveraged pharmacy DIRs to their advantage and to the detriment of pharmacy.

As DIR proliferated in the pharmacy marketplace, it has caused CMS to take a look at the impact of DIR. In a January 2017 publication, CMS highlighted that the growth in DIR has led to several concerns, including higher point of sale prices and higher cost sharing obligations for patients when DIR is retroactively applied after the point of sale. The resulting movement of the patient through the coverage gap at a quicker pace leads to higher reinsurance costs to the government during the catastrophic phase. The changes in DIR in the pharmacy marketplace have increased the impact on the Part D program over the last few years.

Early DIR in the pharmacy marketplace had a fairly simple structure as a flat fee per prescription or based on percentage of ingredient cost (the amount the PBMs and plans will reimburse the pharmacy for the drug — excluding any dispensing fee, plus the copay paid by the patient). The regulation enabled plans to artificially inflate beneficiary cost sharing by excluding contingent pharmacy price concessions from negotiated prices. The assessments and calculus of DIR changed dramatically to include many more DIR fee criteria with the majority of DIR fees now occurring months after the initial transaction.

While the fundamental approach in place at the time, (a flat charge per prescription or a percentage of ingredient revenue or a percentage of AWP), didn't change, the criteria by which those calculations could be applied shifted. The change to a basis that is not determined when claims are adjudicated at the point of sale, but rather at some later date, effectively created a lack of transparency and an unpredictable liability on what pharmacies owed the plans down the road.

If DIR fees were calculated during the claim adjudication process at the point-of-sale, the pharmacy would know exactly what price they are selling the product for and how much it cost them. When DIR fees are applied after point-of-sale, pharmacies lose control over their own revenues and profitability, creating undue financial risk.

1.6 Inconsistent DIR: Types, Application, and Criteria— Varying Approaches of Plans and PBMs

The Part D program lacks a standard construct and standard measures for pharmacy DIR. Plans and PBMs have used various approaches as to how they implement DIR with pharmacies along with incongruent standards and definitions.

PBMs and health plans primarily take one of two approaches: 1) penalty scales whereby DIR is assessed by a takeback via a tiered performance scale; 2) pay-in-and-fined less whereby the PBMs and plans deduct a certain amount from each prescription (averages ranging from \$2-\$7/ traditional prescription based on (a) percentage of AWP; (b) percentage of the ingredient cost paid; or (c) a flat fee; and this amount can be more significant for specialty medications) with the possibility that pharmacies can mitigate the amount of the fine depending on their performance against contract criteria.

Despite what form the DIR takes, the result is mostly the same – loss of revenue by pharmacies. This occurs because in many cases, there are significant modifiers and additional vague criteria that influence DIR amounts that negatively impact pharmacies. These can include weighing pharmacy performance against an undefined network, peer group, or other benchmark, market share, weighting of certain categories like high risk medications, and completion of Medication Therapy Management (MTM) goals.

Additionally, the monies can be taken in a variety of ways, e.g., directly from the pharmacy reimbursement at the point of sale or withholdings against payments due in the 835-remittance advice or via invoice. Often, the clawing back of the DIR monies happens months after a prescription has been dispensed to the patient.

Final financial settlement for a particular plan year can take place as much as 18 months after a prescription was dispensed to a patient. Variations in assessment methodology and timing of assessments among PBMs and plans create significant business uncertainty and operational challenges for pharmacies.

1.7 Criteria Used for DIR Calculations

As the following chart illustrates, some plans and PBMs, capitalizing on the growing sentiment around driving providers to focus on improved patient outcomes, use clinical assessment data as the foundation for DIR calculation. This includes medication adherence metrics defined by Pharmacy Quality Alliance (PQA) for the CMS STAR Ratings program.

Additional clinical criteria affecting DIR may include identification of gaps in therapy, compliance with Plan formulary (the drugs covered by the plan), completion of Medication Therapy Management (MTM) goals and percentage of patients with High Risk Medications. The use of High-Risk Medications in the Elderly (HRM) measure is adapted from a Healthcare Effectiveness Data and Information Set (HEDIS®) measure, which assesses medication management in the elderly to prevent the risks associated with certain medications for this population.

At the same time, some PBMs and plans use cost containment metrics to determine the amount of DIR assessed to pharmacies. Increasingly, more and more DIR is being tied to 90-day prescriptions, Generic Dispense Rate (GDR) and Generic Effective Rate (GER), which are not determined at point of sale. At the end of the assessment period, PBMs and plans will compare actual generic payments made to the pharmacy — which are often based on Maximum Allowable Cost (MAC) to the calculated GER, the PBM will then adjust all payments to the GER amount. These adjustments are subsequently billed as DIR.

These criteria are used in both stand-alone assessments, where just a single criterion, such as GDR, will determine the DIR, or through the use of a complex matrices of criteria used to calculate a performance score that is then benchmarked against other participants and weighted to determine an amount (monetary fee or percentage) to be paid back.

Finally, some of the metrics employed are either out of the direct control of the pharmacy or are simply unattainable. For instance, some PBMs and plans use formulary compliance as a factor in determining the amount of DIR. Often the pharmacist is not alerted to the non-compliance, and while they have the ability to call a prescriber to make a recommendation to switch a prescription to the preferred formulary drug, they are ultimately subject to the prescriber-patient treatment decision. Both GDR and formulary compliance are enablers to the ambiguity in the system at the expense of the pharmacy and the patient.

Criteria Used for DIR Calculations by PBMs and Plans

	DIR Basis	DIR Mechanism	Medication Adherence	GDR	MTM	Other
PBM1	% of Ingredient Cost*	DIR Penalty Scale	Included 85% of Score	Not Included	Included	GER
PBM2	% of Ingredient Cost*	Pay In and Earn Back	Included	Included with Unachievable Targets	Not Included	
PBM3	% of Average Wholesale Price**	DIR Penalty Scale	Included 75% of Score	Not Included	Included	Formulary Compliance
PBM4	Sliding Scale per Rx	DIR Penalty Scale	Included as 20%	Included as 50%	Not Included	Formulary Compliance
PBM5	Flat Fee per Rx	Pay In and Earn Back	Not Included	Included	Not Included	
PBM6	% of Ingredient Cost	Pay In and Earn Back	Not Included			
PBM7	Sliding Scale per Rx	DIR Penalty Scale	Included	Included		

Source: Inmar Intelligence

Exhibit 4

*Ingredient cost is the submitted product component cost of the dispensed prescription

**Average Wholesale Price (AWP) is the generally accepted standard measure for calculating the cost of a particular medication.

***DIR Penalty Scale is the practice of pharmacies being measured against one another with a financial penalty charged to those that do not compare favorably.

****Pay In and Earn Back calls for pharmacies to pay a flat fee in but they may earn back based on performance. However, the net impact results in reduced revenue to the pharmacy. While it is possible for pharmacies to earn more revenue in certain cases, the net impact is negative to all pharmacies. Pay in and earn back today is not completed at Point-of-Sale. In most cases, the “pay in” happens in the payment cycle for the claim which is about 15-30 days later and payment is less than the real time adjudication amount because the “pay in” amount is subtracted at this point.

1.8 DIR Lack of Clarity, Consistency and Transparency Example: Generic Medications

While the DIR concept pushed by Plans and PBMs seems simple, i.e., “Do better and be charged less,” the reality is that the DIR negatively impacts pharmacies. Contract language for DIR, much like contract language for the overarching pharmacy-PBM/Plan contract, is of vital importance. Yet, pharmacies have little or no market power to amend these contracts. As such, pharmacies face a host of challenges which include performing against varying metrics and approaches, and forecasting, budgeting and reconciling DIR assessments to their best of their ability.

PBM and plan contracts that contain DIR provisions have been vague on many key contractual items that impact the final settlement of DIR. Clear and concise contract provisions and definitions are essential, yet terms like “brand drug” and “generic drug” are sometimes used vaguely, which negatively impact pharmacies. This is especially important when DIR is conditioned upon a “true-up” of GER. Ambiguity as to what counts as a generic drug can cause pharmacies to pay additional DIR fees while also creating mountainous reconciliation challenges when trying to determine if a true-up assessment is correct or not.

Additionally, the GER (sometimes referred to as Network Variable Rate) is a difficult metric to monitor as different PBMs and plans use varying brand/generic definitions and set different targets that pharmacies must reach. In some instances, some PBMs and plans have DIR that is specific to adherence to “specialty medications” but don’t provide pharmacies a list of those medications, and don’t provide a definition of what qualifies as a specialty medication on which the pharmacy will be measured. Without specific and standardized requirements, pharmacies are greatly limited in their ability to comply with DIR provisions.

As an example of a largely unattainable metric, to qualify for the lowest DIR fee with one PBM, a pharmacy must achieve a GDR of greater than 95%. Yet only 4% of pharmacies with a very unique business model dispensing a limited formulary that comprises almost entirely generic drugs achieved 95% or higher GDR. See Exhibit 5. Traditional community pharmacies do not generally come close to reaching the 95% threshold, making the upper metric threshold unachievable and unrealistic as demonstrated below.

Exhibits 5 and 6 show the disbursement of GDR performance during 2017. GDR is a DIR measure that is used by four of the seven PBMs and plans that assess DIR fees. GDR measurements vary by payer with tiers that range from 84% - 95%.

Average GDR Performance Falls at Low End of DIR Measurement Tiers

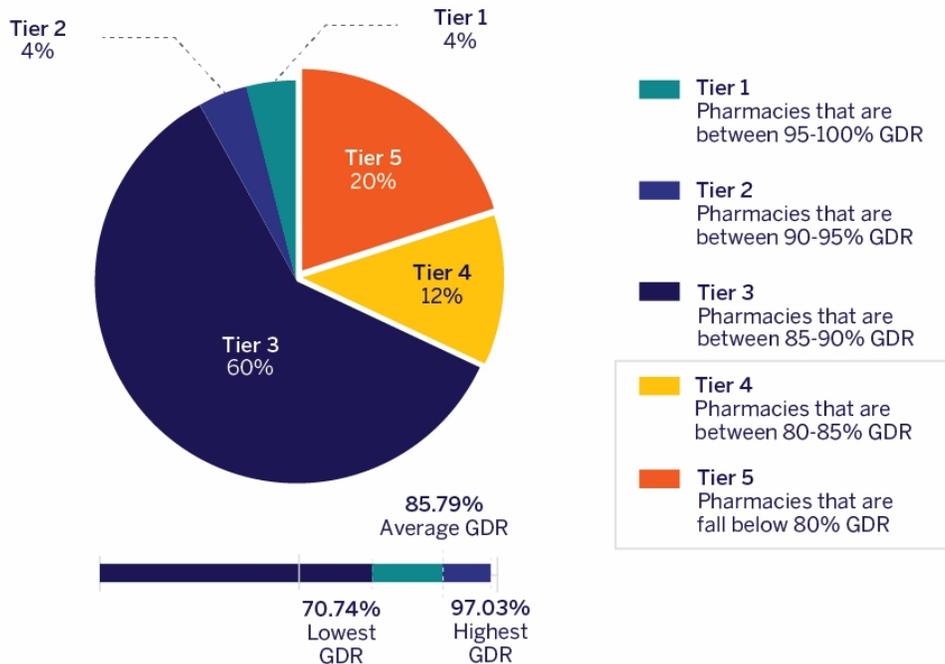


Source: Inmar Intelligence

Exhibit 5

Exhibit 6 illustrates that 32% of pharmacies fall below 85% DIR measurement tiers and pay higher DIR fees. Some of these are specialty pharmacies that prevent them from reaching the threshold. These services are an essential part of the healthcare delivery system and need to be encouraged, not penalized.

32% Are Below DIR Measurement Tiers and Pay Higher DIR Fees



Source: Inmar Intelligence
Exhibit 6

As previously indicated, the definitions for brand and generic are not consistent in the industry nor in application of DIR, making it difficult for pharmacies to forecast performance and financial impact.

1.9 Benchmarked Performance on Each DIR Measure

PERFORMANCE	MEDICATION ADHERENCE	GDR	MTM	GER	FORUMLARY COMPLIANCE
PBM and Plan DIR Expectations	Most plans do not publish target scores, with 80% PDC being a widely accepted target. Other plans benchmark pharmacies against each other and then identify tiers at a later date. Published targets range from 75% - 100%.	83% - 95%	When included, targets are not specific, but weighting is in 5-10% range of the total score	AWP minus 80% - 90%.	The expectation is not clearly stated.
Average performance Achieved	Averages fall below PBM and plan expectations	85.79%	Not measured in this study	AWP minus 82.6%.	Pharmacies are unable to measure today
Range of performance Achieved	47% - 97%	70% - 97%	Not measured in this study	AWP minus 78% -88%.	Pharmacies are unable to measure today

Source: Inmar

1.10 DIR Lack of Clarity, Consistency and Transparency: Pharmacy Performance Comparison Group

Another major challenge related to measurement is the use of comparison groups by PBMs and plans to rate pharmacy performance. Most notably, there is no transparency into which pharmacies are included in any given comparison group. The vague nature of many contracts often results in an individual pharmacy, or even a pharmacy chain, not knowing the makeup of the comparison pool they are measured against.

Some contracts are measured at the pharmacy level against all other pharmacies that participate in the network while other contracts compare at a chain level or a Pharmacy Service Administration Organization (PSAO) level against other chains or PSAOs. This can create a very tenuous position for a pharmacy contracting individually or a small chain that may only have six to 10 stores, as they have more risk exposure on the measured metrics.

Many of the assessments of DIR use the performance of a pharmacy, a pharmacy chain or those pharmacies served by a PSAO against other pharmacies placed in the comparison group by the PBM. These assessments are often factored as a percentile.

PSAOs contract with PBMs and plans on behalf of large numbers of individual pharmacies and smaller chain pharmacies to increase the size of the group operating under the same plan contract. Contracts and reporting of results are often vague as to which pharmacies are in the reference group used for comparison. There is no clear definition of peer groups or contract participants, so the pharmacies typically do not know who they are being compared against.

Some PBMs and plans will score selected pharmacies individually and some will score pharmacies at the chain level. For pharmacies that belong to a PSAO the calculations get murkier as some PBMs and plans score member pharmacies individually and some lump all pharmacies into the total performance of the PSAO. In this scenario, a pharmacy can find its financial performance tied to how another pharmacy or pharmacies perform against the designated metrics.

Hence, many times pharmacies are uncertain as to which entities they are being measured against and how that assessment is conducted. Improved transparency and understanding of specific metrics and comparisons would allow pharmacies to better perform and reduce unnecessary burdens.

1.11 DIR Lack of Clarity, Consistency and Transparency: Patient Groups and Patient Measures

Proportion of Days Covered (PDC) measures have been validated and tested at a health plan level for population health but have not been validated at the pharmacy level with much smaller patient counts. The PDC measures allow for the comparison of pharmacy results between and among stores and chains for Renin Angiotensin System Antagonists (RASA) medications for treating high blood pressure, medications for diabetes and cholesterol (“Statins”), and specialty medications. When this is a part of the DIR formula, it is usually documented in the contracts pharmacies sign with Plans and PBMs.

Further complicating the issue around PDC is patient attribution. That is, “who counts” for “which” pharmacy. Because patients can use multiple pharmacies, it becomes more complex to determine which pharmacy is responsible for a particular patient’s adherence to their medication regimen.

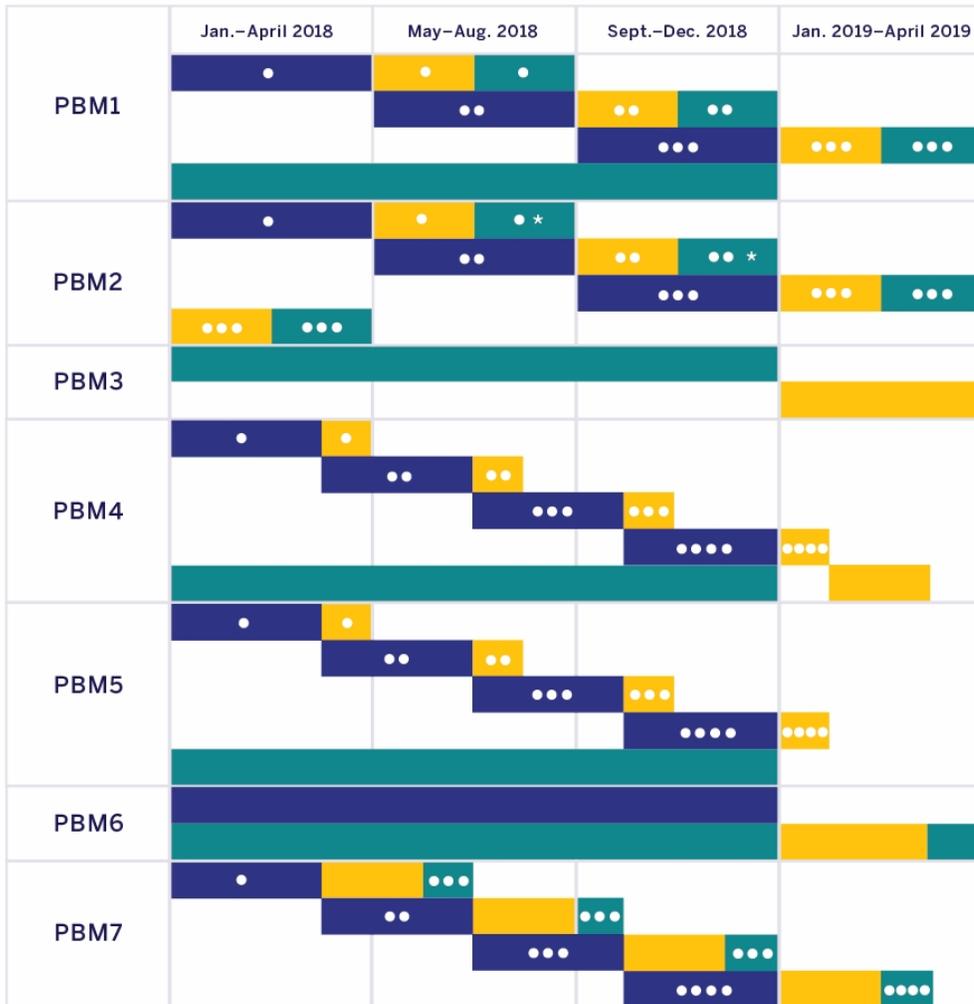
According to a study published in the Journal of The American Pharmacists Association by the University of Wisconsin, Multiple Pharmacy Use (MPU) is a growing trend and twice as high at 75% among patients using a mail service for some of their prescriptions. MPU further complicates the patient attribution issue.

For those plans and PBMs using the Pharmacy Quality Solution’s EQuIPP™ platform, attribution should be managed via their technology. EQuIPP™ is a performance information management platform used by both health plans and community pharmacy organizations, but the EQuIPP measurement platform does not identify patient level results to the pharmacy.

Exhibit 8 demonstrates that the complexity of managing DIR fees is compounded by the fact that pharmacies are expected to manage a different accrual calendar for seven different PBMs and plans. In the United States, there are 35 retail chains with more than 80 pharmacy locations each. These chains have to dedicate accounting resources and departments dedicated to managing DIR accruals.

There are, in addition, 35 retail chains which operate 20-80 pharmacy locations each, and 20 retail chains with 10-20 pharmacy locations. That leaves about 20,000 pharmacies that are small businesses with less than 10 pharmacy locations and that are operated and managed by the same owner. More than half of these own only one pharmacy. The complexity of the process required to manage DIR fee accruals is burdensome and negatively impacts a pharmacy's ability to provide care.

DIR Measurement and Assessment by PBMs and Plans



Claims	Calculation	Collection
Filled Performance Period	Filled for the Performance Period	Filled for the Performance Period
● Trimester 1	● Trimester/Q1	● Trimester/Q1
●● Trimester 2	●● Trimester/Q2	●● Trimester/Q2
●●● Trimester 3	●●● Trimester/Q3	●●● Trimester/Q3
●●●● Q4 2018	●●●● Q4 2018	●●●● Q4 2018

Source: Inmar Intelligence
Exhibit 8

It takes substantial time and resources to build the necessary infrastructure and capabilities to comply with each plan’s DIR process. The administrative burden associated with multiple plans’ DIR processes should be reduced by moving to annual agreements with standard measures. This would allow for more resources to be redeployed into a quality/outcome program, facilitating program efficiencies and greater opportunities to drive better beneficiary health.

1.13 Reconciliation Challenges: Lack of Claim Level Detail and Transparency for Pharmacies

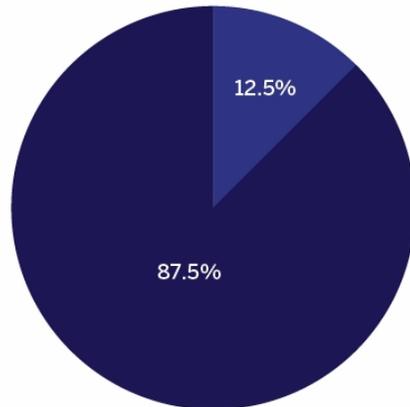
In most instances, pharmacies are powerless to perform standard business reconciliations – a reconciliation between DIR fees and prescription transactions — due to a lack of DIR transparency. Specifically, most pharmacies are unable to correlate DIR fees back to the original prescription claims to validate if incorrect amounts were taken back under their contracts. This business anomaly occurs in part because very few PBMs and plans provide claim-level reporting to pharmacies as to what amount of money is being withheld from each prescription.

Outside of a few situations from which DIR fees are being withheld at a claim level with remittance advice (electronic remittance files listing each claim and the amount paid both positive and negative) provided by the PBM or plan to support the claw back, most DIR is collected via a lump sum in the remittance advice. Lump sum fee assessment does not provide claim-level details — making it impossible for pharmacies to determine what money is being taken back for which claim and why. This uneven distribution of information about claim-level reporting and related fees further inhibits pharmacies from having control over their financial status and addressing any incorrect fees.

Some of the larger pharmacy chains can obtain supplemental claim-level detail to support their internal analysis and reconciliation, but this is a unique situation and not at all indicative of current data sharing practice within the industry. Even when supplemental data is provided, it is often in Excel or PDF formats, necessitating that manual procedures be employed by pharmacies. With more than one billion Medicare Part D claims made annually, this is a heavy administrative burden placed upon pharmacies – entities that are accustomed to a highly-automated and efficient industry, using standard claim and payment data transmission formats for decades.

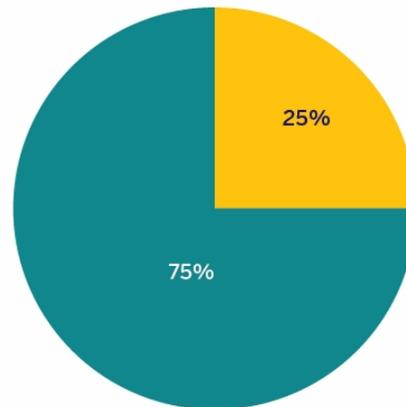
As portrayed in Exhibit 9, some PBMs and plans provide claim-level detail in electronic remittance detail, but only for a subset of claims. In other cases, the pharmacy will see only a lump sum DIR assessment. Exhibit 9 illustrates both the form of DIR and the Percentage of Plans that provide claim level detail as a routine business practice.

The Form of DIR Fees



- Execute DIR Fees via 835 file (both lump sum and claim level)
- Execute DIR Fees via invoice

The Ability to Receive Claim Level Detail



- Plans only provide claim level detail upon request
- Plans provide claim level detail in the 835 remittance file

Source: Inmar Intelligence
Exhibit 9

Standardization of the DIR process would reduce unnecessary administrative burdens, increase efficiencies, and improve the health of beneficiaries.

This will enable pharmacies to properly account for DIR, learn from their results and improve. Claim-level reimbursement data outside of DIR has been available to pharmacies for more than 20 years. DIR transactions should follow the same protocol so that pharmacies can better manage their businesses.

Today, there is limited ability for a pharmacy to determine if the retrospective take backs are aligned with what is allowed contractually to be taken post point-of-sale. All data relative to the initial transaction and any post-adjudication adjustments should be included in the EDI 835 files using standard protocols set by the industry groups that set all other pharmacy standards, allowing the pharmacy to tie out the initial claim to any amount taken back months down the road.

With the successful implementation of these three initiatives, pharmacies will be in a much better position to deliver access, quality and reduced costs to Medicare Part D beneficiaries.

1.14 Impact of DIR Fees on Pharmacies and the Industry Response

The impact of DIR has been felt far and wide by the pharmacy community. With DIR fees averaging greater than 1% of overall prescription drugs sales and more than 5% of gross profit, the topic of DIR has been the focus of many presentations, white papers and lobbying efforts. In fact, no fewer than three publicly traded retail pharmacy companies have brought up the DIR fee issue during quarterly conference calls with Wall Street; at least two in 2016 and one as recently as August of 2018. Additionally, two of the largest PBMs felt compelled to respond to the January 2017 CMS Fact Sheet on DIR via both press release and in analyst calls with Wall Street.

The impact on pharmacy entities has been substantial, with countless additional hours and resources devoted to pharmacy administrative and finance teams for DIR budgeting, forecasting and reconciliation. Because individual plans can have considerable changes in DIR from one plan year to the next, pharmacy performance expectations and participation also can change.

This leads to an evolving metric landscape as well as a lack of transparency in knowing who is in the pharmacy comparison group for purposes of measurement. The “goal posts” of DIR performance are therefore constantly moving, making business performance, projections and monitoring almost impossible.

Conclusion

Patients choose their doctors and their pharmacies / pharmacists. In many cases, patients do not choose their insurance plan, their PBM, or even the drugs they are taking. Pharmacists engage with patients many more times a year than doctors. With the goal to improve access to healthcare, while lowering healthcare costs, and, ultimately, improving patient outcomes, pharmacists are in the best position to work directly with patients to achieve this goal.

Pharmacies operate on very thin margins – the lowest of all entities in the healthcare system. There are over 60,000 pharmacies in the U.S. and approximately 21,000 owners of these pharmacies. The top three PBMs and plans manage 70% of the prescription volume; the top seven PBMs and plans manage 92% of the volume.

Regulations over business operating environments are designed to create guardrails for our free market economy. It is incumbent upon our leaders to ensure that pharmacists, who are in the best position to help reach our ultimate goals, are operating in a viable and sustainable business environment.

PBMs and plans are executing varying DIR fees practices that negatively impact pharmacies, patients and taxpayers. Pharmacies have the potential to deliver more care and improve patient outcomes and cost of care.

Inmar supports the CMS DIR pharmacy reform proposal and submits that CMS also should establish a standardized pharmacy quality program. Eliminating post point-of-sale price concessions will create a more reasonable operating environment for pharmacies.

Not only will pharmacies have greater insight into their total reimbursement when the product leaves the store, but they will also understand performance expectations under a set quality improvement program, which will eliminate unnecessary administrative burdens on pharmacies due to the inconsistent DIR processes, measures and methodologies.

Establishing such a program will also help create clarity around the program’s effectiveness and encourage robust engagement aimed at improving both pharmacy quality and health outcomes for beneficiaries. Pharmacy management teams will then be able to better understand the potential impact to their business, budget accordingly and deliver exceptional care to Medicare beneficiaries.

Finally, Medicare beneficiaries will benefit from lower out-of-pocket expenses, the transparency to the patient economics on the Medicare Part D Plan Finder tool will be greater, and entry to the coverage gap will be delayed for some patients.