

Pharmacy Direct and Indirect Remuneration (DIR) Fees

Recommendations for Reforms to Benefit Patients, Pharmacists, and Government

In recent years, pharmacy Direct and Indirect Remuneration (DIR) fees have created significant challenges for pharmacists, making it more difficult for them to provide care to their patients. Pharmacy DIR fees charged by pharmacy benefit managers (PBMs) and plan sponsors to pharmacy providers lack transparency, threaten the financial viability of pharmacies, increase costs to the Medicare program, and result in higher beneficiary out-of-pocket costs at the point of sale.

This white paper:

- Provides an overview of the history and emergence of DIR fees;
- Illustrates the challenges that DIR fees create for patients, pharmacists, and government; and
- Presents McKesson's policy recommendations to reduce the negative impact of DIR fees on pharmacists and government, and ensure that the benefit of DIR fees is shared with patients.

Background on Direct and Indirect Remuneration (DIR) Fees

Within the Medicare Part D program, the Centers for Medicare and Medicaid Services (CMS) reimburses Part D plan sponsors for prescription drug claims based on final costs to the plan. Often, Part D sponsors or PBMs receive rebates and other price concessions from manufacturers, pharmacies, or similar entities that are not knowable at the point-of-sale.² The concept of DIR was created to account for post point-of-sale transactions so that Part D plan sponsors could accurately report net costs of the plan to CMS.^{3,4} Part D plan sponsors estimate DIR as part of the Part D bid process and then CMS retrospectively reconciles any discrepancies by performing a true-up of actual versus estimated DIR.⁵

DIR is a longstanding part of the Part D program and can generally contribute to lower beneficiary premiums. However, Medicare patients do not benefit from lower cost sharing when Part D plan sponsors get substantial price concessions that are not reflected in the negotiated price – the price that beneficiary cost sharing is based upon.

In recent years, PBMs have increasingly levied retrospective fees, often referred to as DIR fees, on pharmacists. Pharmacy DIR fees are “[b]ackdoor’ fees, chargebacks or other recoupments imposed by PBMs on pharmacy providers after a drug claim is submitted, adjudicated, and even paid out to a pharmacy provider.”⁶ Pharmacy DIR fees include several types of fee arrangements such as network access fees, administrative fees, or “pay-to-play” fees between health plans or PBMs and pharmacies. Contract terms for DIR fees are proprietary; however, anecdotal evidence suggests that these fees can be substantial enough that pharmacists actually lose money dispensing a prescription.

Pharmacy DIR fees are increasing patient financial toxicity, and are making it increasingly difficult for pharmacists to care for patients in their communities.

Impact of Pharmacy DIR Fees on Patients, Pharmacists, and Government

Significant growth in pharmacy DIR fees in recent years has attracted scrutiny from a variety of stakeholders, including CMS and Congress. In 2014 alone, pharmacy DIR fees in Part D totaled approximately \$1 billion.⁷

An estimate showed that in 2016, pharmacists could have paid up to \$2.16 billion in DIR fees. Currently, there are no mechanisms in place to ensure that patients benefit from these fees. Additionally, the growth in pharmacy DIR fees has significant implications for government spending in Medicare Part D.

Pharmacy DIR fees do not reduce how much patients pay out-of-pocket for prescriptions. DIR generally does not reduce the cost of drugs for patients at the point-of-sale, where cost sharing is based on negotiated price. When Part D sponsors or PBMs collect pharmacy DIR in the form of rebates, price concessions or pharmacy fees, the amount a Medicare beneficiary pays for a prescription does not reflect the reduction in net cost to the Part D plan. For example, if a drug has a \$100 negotiated price and \$20 in DIR, the net cost to the PBM or Part D plan is \$80. However, when a Part D enrollee fills that prescription at the pharmacy, the cost sharing is based on the \$100 negotiated price rather than the \$80 net price. There needs to be a transparent mechanism to pass the cost reductions that PBMs and Part D plans collect as DIR, including DIR fees, through to patients, who are increasingly struggling to afford their medications. Since cost to the patient at

the pharmacy is the leading driver of non-adherence and drug abandonment, pharmacy DIR fees should actually help to reduce patient out-of-pocket costs at the pharmacy.

Pharmacists cannot accurately anticipate their reimbursement for dispensing a prescription.

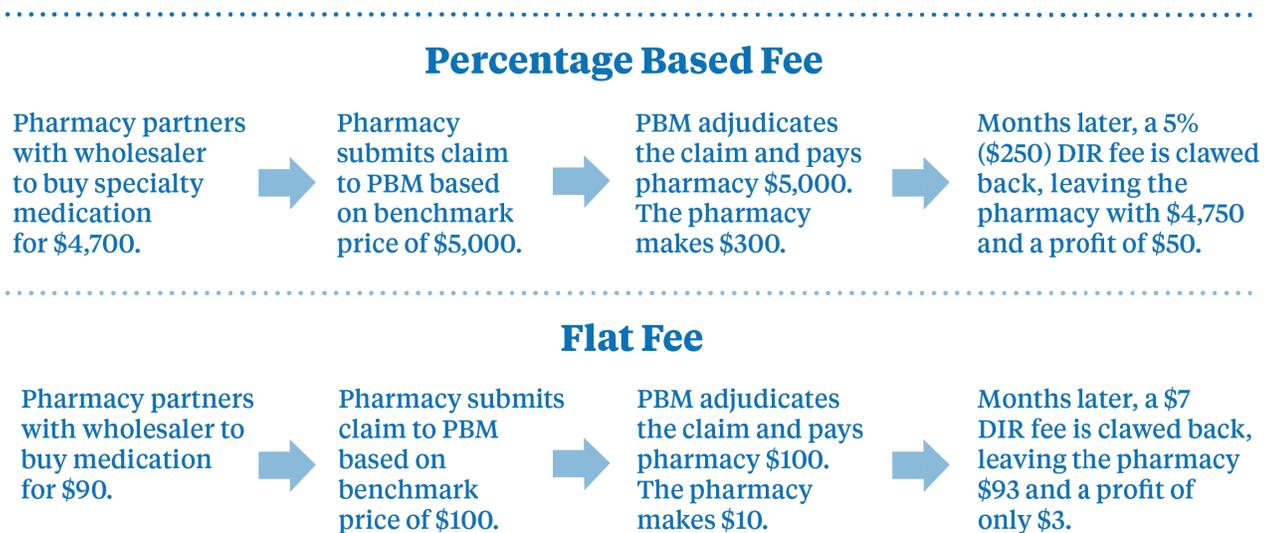
Pharmacy DIR fees are retrospective in nature, which means that the final price paid to the pharmacy for the drug can change at an unspecified time after a prescription is dispensed and a pharmacy has been reimbursed. As a result, pharmacists may wind up losing money for dispensing a prescription, as well as experience significant accounting and tax challenges, particularly when retroactive fees are assessed months after a prescription is dispensed. This leaves pharmacists at risk for revenue adjustments that would need to be reported and reconciled to determine tax burden. For example, retail pharmacies pay taxes on revenue that could end up being clawed back by the PBM after taxes were filed.

Pharmacists have little visibility into how PBMs and Part D plans calculate DIR fees. The method for calculating fees is not transparent, which leaves pharmacies unable to estimate for themselves what their DIR fees and resulting net payment will be. This can often lead to pharmacists losing money when dispensing a prescription. These “underwater claims” occur when the pharmacy’s cost to acquire and dispense the drug is higher than the amount that the pharmacy is reimbursed, net of DIR fees (see Figure 1).

Figure 1, Underwater Pharmacy Claim⁹



Figure 2, Pharmacy DIR fees can have material impact on pharmacy margins¹³



Pharmacy DIR fees can either be flat or percentage-based fees. One pharmacy owner reported an initial profit of \$9.49 on a \$145.53 eye drop prescription, but weeks later the owner received a \$8.09 flat fee that reduced his profit by 85% down to \$1.40.⁹ Percentage-based claw backs can also be extremely harmful, especially for specialty pharmacies dispensing high cost drugs. Percentage-based claw backs can result in thousands of dollars in DIR fees from a single claim (see Figure 2 above).

Pharmacy DIR fees are increasingly performance-based and can be dependent upon measures that pharmacies have no ability to influence. In many cases, pharmacy DIR fees are based on measures that pharmacies have little or no ability to influence. For example, Part D plans and PBMs can tie pharmacy DIR fees to Star Ratings for diabetes or other chronic conditions and apply these measures to a specialty pharmacy that is integrated into an oncology clinic and dispenses only oncology drugs.

Pharmacists have inadequate recourse to an appeals process for unjustly applied DIR fees. Maximum allowable cost (MAC) appeal laws can protect pharmacies by specifying reimbursement processes and timeframes for MAC appeals and payment adjustments, which generally includes “retroactive payments.”¹¹ While MAC appeal laws can clarify and set baseline protections for the appeals process between pharmacies and PBMs, they do not explicitly include DIR fees. Additionally, only 14 states require an appeals process for pharmacists to appeal MAC rates, according to PBM Watch.¹²

The growth in pharmacy DIR fees has significant implications for government spending in Medicare Part D. According to a January 2017 CMS memo on DIR in Medicare Part D, CMS reported its observation of “a growing disparity between gross Part D drug costs ... and net Part D drug costs, which account for all DIR.”¹³ Furthermore CMS stated, “as the growth of rebates and other price concessions places more of the burden on beneficiary cost-sharing, Medicare’s costs for these beneficiaries also grow. Higher beneficiary cost-sharing also results in the quicker progression of Part D enrollees through the Part D drug benefit phases and potentially leads to higher costs in the catastrophic phase, where Medicare liability is generally around 80 percent.”¹⁴

McKesson's Policy Recommendations

McKesson supports regulatory and legislative changes to public policy that would limit the practices that are adversely affecting patients, pharmacists, and the federal government. This includes changes that would increase transparency and predictability of how much a pharmacy can expect to get reimbursed, prohibit the ability of PBMs and Part D plans to retroactively penalize pharmacies financially, and ensure that any performance-based fees levied on pharmacies are based on measures that pharmacies are able to influence.

McKesson has advocated for regulatory reforms to pharmacy DIR fees since day one of the Trump Administration. In a January 2017 letter to the President's Domestic Policy Advisor, we named DIR reform as one of four health policy areas in need of immediate regulatory relief and reform.

We also made pharmacy DIR fees the sole focus of our response to CMS' April 2017 Request for Information (RFI) on ideas to improve Medicare Part D.

Regulatory Proposals

McKesson supports many of the proposals that were released in the November 16, 2017 Medicare Advantage and the Prescription Drug Benefit Program Proposed Rule and Request for Information (RFI).¹⁵ In the 2019 Medicare Part D final rule, CMS asserted its statutory authority to require that some portions of rebates and pharmacy DIR fees be applied at the point of sale. We encourage CMS to propose such changes through notice and comment rule-making as soon as possible and no later than in the next Part D proposed/final rule.*

In particular, McKesson recommends that CMS:

- **Adopt changes to ensure that patients and the government actually benefit from DIR fees assessed on pharmacies.** McKesson supports the intent of CMS' proposal in the RFI to pass all pharmacy price concessions through to consumers

at point of sale. In the RFI, CMS noted that they “do not believe that the existing requirement that pharmacy price concessions be included in the negotiated price can be implemented in a manner that prevents the shifting of costs onto beneficiaries and taxpayers.” **McKesson supports revising the definition of negotiated price to reflect the lowest possible pharmacy reimbursement, as put forth in the RFI. Since patient cost sharing is often based on negotiated price, CMS' proposal to reflect pharmacy price concessions in negotiated price would directly translate to lower patient out-of-pocket costs.** Government costs in Part D are also based on negotiated price, therefore pharmacy price concessions that reduce negotiated price would lower government spending.

- **Prohibit retroactive penalties based on performance.** As defined by CMS in sub-regulatory guidance, “DIR also includes price concessions from and additional contingent payments to network pharmacies that cannot reasonably be determined at the point-of-sale.” DIR fees have expanded beyond just contingent payments to network pharmacies and now include contingent payments from network pharmacies in the form of performance-based fees.¹⁶ This has become problematic, as CMS acknowledged in the proposed rule: “...pharmacies rarely receive an incentive payment above the original reimbursement rate for a covered claim. We gather that performance under most arrangements dictates only the magnitude of the amount by which the original reimbursement is reduced, and most pharmacies do not achieve performance scores high enough to qualify for a substantial, if any, reduction in penalties.”¹⁷

McKesson recommends that CMS eliminate the ability for plans, PBMs, and other entities to apply retroactive fees and penalties based on performance. This is consistent with what CMS seems to contemplate in the RFI through revising the definition of negotiated price to reflect the lowest possible pharmacy reimbursement. **McKesson supports the intent of CMS' proposal and believes this change would greatly reduce the incentive**

*The President's FY 2019 budget request includes ambiguous language that could undermine/counter the provisions outlined in the November 16, 2017 Medicare Advantage and the Prescription Drug Benefit Program Proposed Rule and Request for Information

for PBMs to apply retroactive penalties based on performance. However, McKesson also requests that CMS clarify that retroactive penalties based on performance are distinctly prohibited.

- **Preserve and enhance the extent to which plans employ performance-based programs that allow bonus payments to pharmacies for high performance on activities they are reasonably able to influence.** CMS could accomplish this goal by creating an incentive payment program that eliminates retroactive performance penalties and allows bonus payments for high performance based on factors that a pharmacy can reasonably influence. Tying performance to factors that a pharmacy can actually influence would eliminate situations such as the example of the pharmacy that exclusively dispenses oncology drugs being assessed pharmacy DIR fees based on Medicare Advantage Star Ratings measures focused on diabetes or hypertension.

Legislative Proposals

McKesson also calls on Congress to further examine the implications of pharmacy DIR fees on patients and pharmacies. In February 2017, lawmakers in the House and Senate introduced *The Improving Transparency and Accuracy in Medicare Part D Spending Act* (of H.R. 1038/S. 413), which would prohibit retroactive reductions in claim payments to pharmacies by Part D sponsors. The Wakely Consulting Group estimated that if enacted, the federal government could see \$3.4B in savings from 2018-2027 through the elimination of post point-of-sale pharmacy DIR fees.¹⁸ **McKesson strongly supports this legislation, and we will continue to work with National Community Pharmacists Association (NCPA) and others towards its passage in this session of Congress.**

Furthermore, we encourage Congress to enact policies that would accomplish the following:

- **Improve transparency and predictability so pharmacies can anticipate the net reimbursement for a given prescription.** Require clearer contracting terms and require PBMs to disclose how the fees are determined at contract initiation and at the time they are assessed. Limit the timeline for PBMs and plan sponsors to recoup DIR fees from a pharmacy to within 6 months after a prescription has been filled.
- **Expand avenues for pharmacies to appeal pharmacy DIR fees.** Clarify that PBM appeals processes include appeals of pharmacy DIR fees,

which would afford more protections to pharmacies. Another option is to mandate appeals laws at the federal level to ensure all pharmacies are given the opportunity to appeal payment adjustments.

- **Increase government oversight over how Part D plans are using DIR, including DIR fees.** This could include requiring Part D plan sponsors to report more detail on how DIR, including pharmacy DIR fees, are used by Part D plans.

In June 2017, McKesson hosted its first ever Advocacy Ambassadors Washington, DC Fly-In.

That week, 40+ employees engaged with 90+ Members of Congress/Staff to share stories about the impact of DIR fees on community pharmacists and to advocate for passage of federal legislation that would end retroactive pharmacy DIR fees.

Conclusion

As a company, McKesson is devoted to advancing impactful public policy solutions focused on better health for our customers and the patients they serve. We are committed to continuing our partnership with CMS, Congress, our customers, and all stakeholders to pursue the development of sensible DIR fee reforms that will reduce financial burdens for patients, enable pharmacists to continue to provide quality care for their patients, and protect government interests. For more information about the impact that DIR fees are having on patients and independent community pharmacies, or to partner with McKesson Public Affairs on these policy solutions, contact PublicAffairs@McKesson.com.

About McKesson and Health Mart

For over 180 years, McKesson has led the industry in the delivery of medicines and healthcare products. We deliver vital medicines, medical supplies, care management services and health information technology (IT) solutions that touch the lives of over 100 million patients in healthcare settings that include more than 25,000 retail pharmacies, 5,000 hospitals, 200,000 physician offices, nearly 12,000 long-term care facilities and 2,400 home care agencies.

Health Mart, America's fourth largest pharmacy chain, is the country's fastest-growing independent pharmacy franchise with more than 4,800 locally owned community pharmacies across all 50 states. Health Mart pharmacists provide personalized care and take the time to help patients understand their prescription-drug coverage, how to safely manage multiple medications, and how to take advantage of lower-cost medication options.

Our Efforts to Help Independent Pharmacies Manage DIR Fees

We have heard from countless pharmacy owners about the difficulty of staying in business due to unpredictable pharmacy DIR fees. As we have advocated for regulatory and legislative solutions, McKesson has led the way in helping its independent pharmacy customers estimate, manage, and lower DIR fees. McKesson developed the Health Mart Atlas DIR Estimator Tool and myHealthMart DIR Estimator Tool. Each tool allows a pharmacy to enter its own specific information and estimate accrual and incentive amounts, that may impact DIR payments, in order to plan accordingly. McKesson has always advised customers that DIR fees are here to stay until CMS changes its guidance. McKesson will continue to work with our customers to advocate for meaningful changes.

References

1. Community Oncology Alliance, PBM DIR Fees Costing Medicare and Beneficiaries: Investigative White Paper on Background, Cost Impact, and Legal Issues (Jan. 2017)
2. CMS. Medicare Part D Direct and Indirect Remuneration (DIR). Jan. 2017.
3. Ibid.
4. Under federal law, DIR includes “discounts, chargebacks or rebates...or other price concessions or similar benefits from manufacturers, pharmacies or similar entities...” 42 C.F.R. § 423.308 (2016).
5. Community Oncology Alliance, PBM DIR Fees Costing Medicare and Beneficiaries: Investigative White Paper on Background, Cost Impact, and Legal Issues (Jan. 2017)
6. Ibid.
7. March 2017 Report to the Congress: Medicare Payment Policy. MedPAC. March 15, 2017.
8. America’s Pharmacist. DIR fees are knocking down pharmacy profits (p. 17-23). November 2016.
9. Pharmacy Times. Pharmacies Face Financial Hardship with Rising DIR Fees. Nov. 2, 2015.
10. Star Ratings provide an overall rating of an MA-PD plan’s quality and performance for the types of services each plan offers
11. GW Law Faculty Publications & Other Works. Health Care Competition Law in the Shadow of State Action: Minimizing MACs. August 25, 2017.
12. PBM Watch. Current State Maximum Allowable Cost Legislation.
13. CMS. Medicare Part D Direct and Indirect Remuneration (DIR). Jan. 2017.
14. Ibid.
15. Centers for Medicare & Medicaid Services. CMS Proposes Policy Changes and Updates for Medicare Advantage and the Prescription Drug Benefit Program for Contract Year 2019 (CMS-4182-P)
16. CMS. Final Medicare Part D DIR Reporting Requirements for 2016. June 23, 2017.
17. Centers for Medicare & Medicaid Services. CMS Proposes Policy Changes and Updates for Medicare Advantage and the Prescription Drug Benefit Program for Contract Year 2019 (CMS-4182-P): <https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-25068.pdf>
18. Wakely Consulting Group, LLC. Impact of H.R. 1038/S. 413 on CMS Payments Under Part D. September 28, 2017.