

Medicare Part D DIR

Direct and indirect remuneration explained

Deana Bell, FSA, MAAA
Tracy Margiott, FSA, MAAA



The recently released 2019 Medicare proposed rule considers significant changes to the treatment of direct and indirect remuneration (DIR) in the Medicare Part D program.¹ As DIR continues to increase, it is important for Part D sponsors to consider the effect of potential regulatory changes on plans' bottom lines and operations.

Medicare Part D plan sponsors negotiate point-of-sale (POS) and post-POS price concessions paid by third parties that lower net claim costs to plans. Post-POS price concessions are reported to the Centers for Medicare and Medicaid Services (CMS) as DIR. The Code of Federal Regulations (CFR) defines DIR in the following way:

“Direct and indirect remuneration includes 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 entities...”²

Due to the revised definition of “negotiated prices” (see 42 CFR 423.100³), CMS has stated, “Any amount that could not be reasonably determined at the point-of-sale, and, thus, that was not included in the negotiated price, must be reported as DIR.”⁴ DIR plays an important role in the Medicare Part D program, and has garnered a great deal of attention from CMS, the pharmacy industry, and drug manufacturers, as “DIR reported by Part D sponsors has been growing significantly in recent years.”⁵ This increased focus has culminated in CMS requesting feedback on changes to the treatment of DIR as part of the 2019 Medicare proposed rule,⁶ which could have industry-wide implications.

Common types of DIR

CMS released final guidance for contract year (CY) 2016 Part D DIR reporting on June 23, 2017, the latest available.⁷ The guidance defines DIR and specifies the submission data reporting requirements for DIR submissions used in the final

Part D payment reconciliation with CMS. Plan sponsors submit two DIR reports: the summary-level report, which enumerates the DIR by plan—or plan benefit package (PBP) level—and the detailed level report, which reports drug manufacturer DIR by National Drug Code (NDC).

CMS included a summary table of what is considered DIR on page 11 of the guidance. At a high level, their examples follow the definition outlined in 42 CFR 423.308.⁸ Drug manufacturer rebates make up the majority of reported DIR. CMS reported that, in 2014, total DIR was \$17.4 billion,⁹ and \$16.3 billion¹⁰ (or 94%) of that was drug manufacturer rebates. Administrative fees and dispensing fees charged by pharmacy benefit managers and pharmacies are generally not considered DIR.

PHARMACEUTICAL MANUFACTURER REBATES

All drug rebates must be reported to CMS via the annual DIR report. Pharmaceutical manufacturers may pay rebates for their products to be included on formularies or placed on preferred formulary tiers.¹¹

¹ CMS (November 16, 2017). Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program, p. 306. Retrieved November 26, 2017, from: <https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-25068.pdf>.

² 42 CFR § 423.308. Retrieved November 26, 2017, from: <https://www.gpo.gov/fdsys/pkg/CFR-2011-title42-vol3/pdf/CFR-2011-title42-vol3-sec423-308.pdf>.

³ 42 CFR § 423.100. Retrieved November 26, 2017, from: <https://www.gpo.gov/fdsys/pkg/CFR-2011-title42-vol3/pdf/CFR-2011-title42-vol3-sec423-100.pdf>.

⁴ CMS (June 23, 2017). Final Medicare Part D DIR Reporting Requirements for 2016. Retrieved November 26, 2017, from: <https://www.healthlawpolicymatters.com/wp-content/uploads/sites/8/2017/06/Final-2016-DIR-Reporting-Req-Memo-06-23-2017.pdf>.

⁵ CMS (January 19, 2017). Medicare Part D – Direct and Indirect Remuneration (DIR). Retrieved November 26, 2017, from: <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-01-19-2.html>.

⁶ CMS, Contract Year 2019 Policy and Technical Changes, *ibid*.

⁷ CMS, Final Medicare Part D Reporting Requirements, *ibid*.

⁸ 42 CFR § 423.308, *ibid*.

⁹ CMS, Medicare Part D – Direct and Indirect Remuneration (DIR), *ibid*.

¹⁰ CMS 2014 Part D Rebate Summary for All Brand Name Drugs. Retrieved November 26, 2017, from: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/2014_PartD_Rebates.html#1-note.

¹¹ Other reasons pharmaceutical manufacturers pay rebates include competitive advantage and cost of doing business through contracting with the plan sponsor.

There is usually a lag from when a claim is incurred and when a drug rebate is paid to the plan sponsor. Because of this, CMS requires plan sponsors to report all drug rebates that are known at the time and the portion estimated to be paid to the plan later.

PBM REBATE GUARANTEES AND OTHER POST-POS CONTRACT PROVISIONS

Pharmacy benefit managers (PBMs) are third-party administrators of pharmacy benefits. Some plan sponsors negotiate drug rebates directly with pharmaceutical manufacturers, while others use PBMs to negotiate rebates on their behalf, which are then passed on (fully or in part) to the plan.

PBM and pharmaceutical manufacturer contracts with plan sponsors may have other provisions creating a post-POS price concession to the plan sponsor. Examples include minimum rebate guarantees, targets for market share, volume targets, value-based contracting, and inflation protection programs. Rebate guarantees are typically payments received from the PBM if minimum rebates, either per prescription or per member per month (PMPM), are not met after the annual reconciliation with the PBM is performed.

INCENTIVE PAYMENTS TO (OR RECEIVED FROM) PHARMACIES

There may be fees that are paid to pharmacies for achieving certain negotiated metrics such as generic dispensing rates, low adjudication errors, or other performance or quality measures.

The emergence of preferred pharmacy networks, where members pay lower cost sharing at certain pharmacies, have also created a post-POS price concession in the form of preferred pharmacy fees. Some preferred pharmacy contracts include pharmacy DIR, where the pharmacy pays the PBM to participate in the preferred network. Under this arrangement, members benefit from reduced cost sharing, the pharmacy benefits from increased foot traffic as more members choose to fill prescriptions at a preferred location, and plan sponsors benefit from the additional DIR revenue.

RISK-SHARING ARRANGEMENTS

Plan sponsors must report as DIR any amounts related to risk-sharing contracts and arrangements with providers or other parties. Only the risk-sharing arrangements that are related to Part D claims need to be reported. Examples include outcomes-based or risk sharing of savings and/or losses with accountable care organizations (ACOs), providers, hospital systems, or pharmacies.

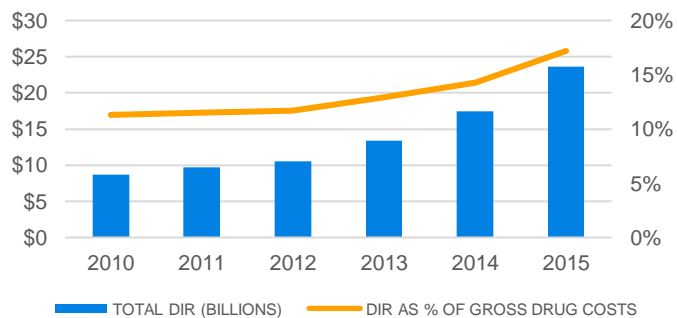
OTHER DIR

- Prompt pay discounts from pharmacies
- Pharmacy payment adjustments not part of the negotiated price at POS
- Judgment or settlement amounts from legal action
- Rebate administration fees charged to drug manufacturers that are greater than fair market value or do not qualify as bona fide service fees
- Rebates related to third-party payer claims or plan-to-plan claims
- Price concessions from manufacturers for administrative fees that result in costs lower than fair market value
- Grants from manufacturers for services or programs (e.g., utilization management, education, medical therapy management)
- PBM penalty payments not included in prescription drug event (PDE) records
- DIR not associated with a drug or a non-Part D covered drug
- Any other DIR not specified by CMS that can increase or decrease plan sponsors' Part D costs

Increasing DIR creates downward pressure on member premiums

CMS reported Part D DIR increased from less than \$9 billion in 2010 to over \$23 billion in 2015 (Figure 1).¹²

FIGURE 1: PART D DIR BY PAYMENT YEAR



¹² CMS, Medicare Part D – Direct and Indirect Remuneration (DIR), *ibid.*

While drug manufacturer rebates continue to make up the majority of DIR, pharmacy price concessions have increased at a faster rate than any other form of DIR in recent years.¹³ For 2018, all national individual prescription drug plans (PDPs) have a preferred network, which often includes pharmacy DIR arrangements.

Due to the competitive nature of the Part D program, plan sponsors have significant incentives to reduce premiums. Because the majority of DIR payments result in reductions to plan liability¹⁴ rather than reduced drug costs shared directly with the beneficiary at the pharmacy counter, DIR has become a popular mechanism with plan sponsors for reducing plan liability compared to focusing on improving contracted POS discounts with pharmacies. In the Part D market, expected reductions in plan liability are incorporated into pricing and are typically used to reduce member premiums or enhance other benefits as opposed to increase plan profits. Since the inception of the Part D program in 2006, average member premiums have increased by less than 1% annually, well below the annual trend in drug costs over the same time period.

Part D settlements with CMS

The Part D program structure includes payment mechanisms where CMS relies on reported prescription drug claims, or PDE data, and DIR to determine settlement amounts. There is a submission deadline for all records in a plan year to be included in the final reconciliation process in June of the year following the plan year. The DIR report is typically due around the same time.

After it receives all necessary PDE and DIR information, CMS calculates settlements to adjust for differences among prospective payments made by CMS for the low-income cost-sharing subsidy, the federal reinsurance subsidy, and the coverage gap discount program (CGDP) with manufacturers. There is also a settlement with CMS for the Part D risk-sharing arrangement with plan sponsors, known as risk corridors. The settlements are completed and received by plan sponsors in November of the following year. Of these four separate settlement amounts, two are dependent on DIR reported by plan sponsors:

FEDERAL REINSURANCE SUBSIDY

CMS pays 80% of the costs for beneficiaries above a specified out-of-pocket expense threshold. CMS makes prospective payments to plan sponsors for this coverage based on projected amounts filed in June prior to the plan year. The CMS settlement is the difference between the prospective reinsurance payment and the reinsurance based on actual claims.

¹³ CMS, Contract Year 2019 Police and Technical Changes, *ibid*.

¹⁴ A portion of Part D DIR is shared with the federal government.

The total DIR reported for a plan is used as part of the reinsurance subsidy reconciliation, where a portion of the DIR is shared with CMS to reduce its liability for the settlement. The shared DIR portion is calculated as gross drug costs above the specified out-of-pocket expense threshold divided by total gross drug costs. This portion, which we refer to as the “DIR ratio,” is dependent on the plan’s actual experience, and it typically ranges between 30% to 40%, depending on beneficiary morbidity, drug mix, low-income status, and other factors. DIR in excess of the projected amount filed with CMS further decreases the reinsurance settlement received from CMS (or increases the amount paid to CMS); the reduction (or increase) is adjusted for the DIR ratio and the 80% reinsurance level.

RISK CORRIDOR SETTLEMENT

CMS shares Part D plan differences from filed rates with plan sponsors above specified thresholds. The plan retains 100% of the first 5% of the defined standard cost margin (positive gains and negative losses), 50% from 5% to 10%, and 20% in excess of 10%. The plan margin is increased by the non-reinsurance portion of DIR $([1 - \text{DIR ratio} \times 80\%] \times \text{total DIR})$ adjusted by induced utilization. Depending on the starting margin level, the CMS risk-sharing settlement could be impacted significantly by DIR.

Recent CMS attention

Because DIR is currently reflected after the POS, it does not reduce the POS drug cost used to determine member cost sharing. CMS has recently requested feedback on proposed changes that would shift all or a portion of DIR to the POS.¹⁵ Unlike post-POS price concessions, POS price concessions are shared among all stakeholders that pay for POS drug costs. Depending on the final design of this proposed policy, this change may shift some of the DIR that is currently used to reduce member premiums and premium subsidies to reduce POS cost sharing for certain members, thereby increasing premiums. This may also reduce federal reinsurance and pharmaceutical manufacturer CGDP payments, as the POS drug cost would be lower, and may increase other federal government subsidies (e.g., direct subsidy). Given DIR’s integral role in the Part D program, any change to the treatment of DIR could result in other industry changes.

¹⁵ CMS, Contract Year 2019 Police and Technical Changes, *ibid*.

Conclusion

DIR has grown to be an important provision that Part D plan sponsors use to reduce their claim liabilities and thus member premiums. Through contract negotiations and special arrangements with drug manufacturers, pharmacies, and PBMs, post-POS reductions to plan costs structured as DIR have increased in magnitude and complexity. CMS and industry stakeholders have recently turned their focus to reviewing and proposing regulatory changes that would require plan sponsors to use a portion of DIR savings to reduce member cost sharing. Understanding the current role of DIR and the implications of potential changes is critical to the success of plan sponsors and other stakeholders in the Part D market.



Milliman is among the world's largest providers of actuarial and related products and services. The firm has consulting practices in life insurance and financial services, property & casualty insurance, healthcare, and employee benefits. Founded in 1947, Milliman is an independent firm with offices in major cities around the globe.

milliman.com

CONTACT

Deana Bell
deana.bell@milliman.com

Tracy Margiott
tracy.margiott@milliman.com

FOR MORE ON MILLIMAN'S PERSPECTIVE ON MEDICARE:

Visit milliman.com/medicare-insight

Visit our blog at healthcaretownhall.com

Follow us at twitter.com/millimanhealth