

MEDICARE PART D DIRECT AND INDIRECT REMUNERATION - WHERE IS IT HEADED?

By Lauren Haley and Jeff Low

There have been a number of changes to Medicare Part D since Part D Plan Sponsors (“Sponsors”) began offering prescription drug benefits on January 1, 2006. For example, the Centers for Medicare & Medicaid Services (“CMS”) has implemented enhanced clinical and quality efforts, such as Star Ratings. The Patient Protection and Affordable Care Act of 2010 phased in the reduction of costs to members in the coverage gap. Generally speaking, Medicare Part D has been considered a success, costing less than original Congressional Budget Office projections.¹

Something that has been less apparent to the general public is the growing complexity of direct and indirect remuneration (“DIR”) and its impact on Medicare Part D spending. CMS defines DIR within the definition of “actually paid.”² Simply, DIR is the total amount a Sponsor, or an entity acting on behalf of a Sponsor (e.g., a Pharmacy Benefits Manager), receives that ultimately reduces the actual drug costs incurred under the Part D plan. These amounts are received after a prescription is adjudicated at the point-of-sale and change the Sponsor’s final cost of a drug. Many think of DIR in terms of “rebates” from a pharmaceutical manufacturer. However, DIR is broader and includes any form of price concession “that serves to decrease the costs incurred under the Part D plan.”³ Since 2010 we have seen the amount of DIR collected by Sponsors increase and through new strategies. CMS has recognized this shift and discussed their observations in a Fact Sheet released on January 19, 2017 entitled, “Medicare Part D- Direct and Indirect Remuneration (DIR) (“Fact Sheet”).⁴ This article serves as a high-level summary of CMS’s findings as it relates to CMS, Sponsors, Pharmacies and PBMs.

DIR IN MEDICARE PART D

It’s important to think about DIR in the context of CMS’s payments to Sponsors. CMS makes payments to Sponsors based on the Sponsor’s annual bid. A Sponsor’s bid estimates what it will cost to provide Medicare Part D benefits to beneficiaries, such as drug costs, operational costs, formulary and plan design, and anticipated DIR amounts. CMS makes prospective payments to the Sponsor for each member based on its bid. There are several types of payments CMS will make to Sponsors for providing Part D benefits:

- *Direct subsidies* are the capitated payments CMS makes to Sponsors based on the Sponsor’s bid and calculated as a share of the adjusted national average of plan bids
- *Individual reinsurance* is the amount paid to Sponsors based on a percentage of drug spend above a member’s out-of-pocket threshold

1. See e.g., Congressional Budget Office, *Competition and the Cost of Medicare’s Prescription Drug Program*, <https://www.cbo.gov/sites/default/files/113th-congress-2013-2014/reports/45552-PartD.pdf>, July 30, 2014; L. Adler and A. Rosenberg, Health Affairs Blog, *The \$500 Billion Medicare Slowdown: A Story About Part D*, <http://healthaffairs.org/blog/2014/10/21/the-500-billion-medicare-slowdown-a-story-about-part-d/>, October 21, 2014.

2. 42 C.F.R. § 423.308.

3. CMS Memorandum, *Final Medicare Part D DIR Reporting Requirements for 2015*, pg. 10, May 31, 2016.

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



- *Low income premium subsidies* are the premium payments CMS makes to a Sponsor on behalf of eligible low income members
- *Low income cost-sharing subsidies* are the Part D cost-sharing payments CMS makes to a Sponsor on behalf of eligible low-income members

At the end of the plan year CMS reconciles the amount it paid with the costs actually incurred by the Sponsor. In calculating such costs, CMS considers any DIR the Sponsor received that reduced its actual cost of drugs. Sponsors must annually self-report DIR amounts as part of the reconciliation process.⁵

CMS provided a high-level analysis of DIR data submitted by Sponsors in the January 2017 Fact Sheet.⁶ Between 2010 and 2015, CMS's data shows: (1) total drug costs have increased about 12 percent per year; (2) DIR payments to Sponsors have increased about 22 percent per year; (3) CMS reinsurance payments to Sponsors has increased about 17 percent per year; (4) member premiums have remained essentially flat; and (5) plan liability per member declined nearly 5 percent.⁷ CMS uses these findings to illustrate that the increase of DIR leads to higher beneficiary costs and higher reinsurance responsibility in which Medicare has to pay.

KEY INDUSTRY PERSPECTIVE

CMS

CMS's data shows that the government has assumed greater responsibility for Medicare Part D costs between 2010 and 2015. While higher DIR has led to lower bids, putting downward pressure on beneficiary premiums, it has significantly increased the amount the government must pay in reinsurance.

Premium Subsidies. DIR amounts received after the point-of-sale are factored into a Sponsor's bid, which calculates beneficiary premiums and CMS's direct subsidy payments to Sponsors. Lower premiums decrease the national average bid amount as well as the Part D base beneficiary premium, which decreases the direct subsidy amounts paid to plans. Lower premiums also reduce government spending for low income premium subsidy payments made on behalf of eligible low income individuals.

Cost-Sharing. DIR dollars are accumulated after the point-of-sale, so members may not experience the actual lower cost of the drug reduced by DIR payments. Because DIR occurs through a separate transaction between the Sponsor and another entity, and after the drug has been dispensed, DIR does not directly impact the cost of the drug for the member. Thus, any cost-sharing amount tied to the drug cost would not account for the DIR payment, including in the coverage gap where a member is responsible for higher cost-sharing. This, in turn, will accelerate a member's progression through the Medicare benefit and move them into the catastrophic phase quicker. In the catastrophic phase of the Medicare Part D benefit, CMS covers 80 percent of drug costs through reinsurance. The Fact Sheet demonstrates that CMS's reinsurance costs have increased significantly, which CMS suggests is due in part to increased DIR payments paid to Sponsors.⁸

In addition, CMS pays a portion of cost-sharing on behalf of eligible low-income beneficiaries. Since DIR payments occur after the point-of-sale, CMS's cost-sharing payments made on behalf of low-income beneficiaries that are tied to the cost of the drug may not benefit from DIR payments.

Plan Sponsors

Sponsors rely upon DIR as part of calculating bids and when developing formularies. To remain competitive, Sponsors must offer the richest benefits at the lowest premiums (while remaining actuarially sound). Anticipated DIR payments reduce a Sponsor's bid, helping to reduce beneficiary premiums, as discussed above. The Fact Sheet suggests that increased DIR payments between 2010 and 2015 has helped to keep beneficiary premiums relatively unchanged, despite the fact that total gross drug costs grew about 12 percent per year in that span.⁹

Not only can lower premiums attract membership among beneficiaries who choose a plan, Sponsors whose bids are below the regional "benchmark" are able to receive auto-enrollment of low-income eligible members directly from CMS.

There are several reasons that might explain why DIR has increased during 2010 - 2015. During that time period, the Medicare Part D benefit matured and Sponsors, PBMs, manufacturers and pharmacies became more experienced in Part D utilization. As a result, the industry could make more informed decisions about utilization and develop more targeted DIR strategies. In addition, the marketplace lost a number of brand name drugs to patent expiration between 2010 - 2015.

5. CMS Memorandum, Final Medicare Part D DIR Reporting Requirements for 2015, May 31, 2016.

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

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

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

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

Once a patent expires the brand name drugs typically lose formulary status to the generic alternative. Pharmaceutical manufacturers tend to offer more generous rebates to keep brand name drugs on formulary, resulting in more DIR dollars for the Sponsor.

Pharmacies

Pharmacies are traditionally paid a negotiated rate between the PBM, on behalf of a Sponsor, and the pharmacy. When the pharmacy dispenses a prescription, it is paid according to the contracted rates for the drug based on real-time transactions at point-of-sale. It is a predictable business model; the pharmacy knows exactly what sales are made and the dollar amounts of those transactions.

These “straight forward” relationships are slowly changing with additional contract provisions involving DIR. Some pharmacy network agreements include DIR amounts that can either be paid to or by a pharmacy in addition to reimbursement for the cost of a drug, such as generic dispensing incentive payments, risk sharing arrangements, and pharmacy network rebates. These DIR arrangements are negotiated between the pharmacy and the Sponsor or PBM, and typically are paid after the point-of-sale transaction. DIR payments that do not occur at the point-of-sale do not directly benefit a member (or CMS, to the extent CMS makes cost-sharing payments on behalf of low income members) and adds another level of complexity to a pharmacy’s financials. Pharmacies and pharmacy advocate groups have argued that pharmacy network contracts are not forthcoming and often include sophisticated performance algorithms used to calculate the DIR amounts, making it difficult for pharmacies to forecast these expenditures.

LOOKING AHEAD

CMS released the draft Medicare Part D DIR Reporting Requirements for 2016¹⁰ (“2016 Draft Reporting Requirements”) on May 17, 2017. Interestingly, CMS proposes to refine how it collects data related to pharmacy DIR, which demonstrates that CMS appreciates the complexities of DIR payments to and from pharmacies as well as the government’s efforts to verify the accuracy of data that supports payments to Sponsors. However, despite the findings in the Fact Sheet, the 2016 Draft Reporting Requirements do not reflect a major shift in how CMS expects Sponsors to treat or report DIR.

Nevertheless, CMS will likely revisit its DIR policies and could require more specified DIR reporting in the future. Total drug costs continue to rise and DIR payments have increased. Although premiums have remained stable, many beneficiaries have higher out-of-pocket spending, pushing members into catastrophic coverage and increasing CMS reinsurance payments to Sponsors. *Yet plan liability has decreased.* By relying on DIR to keep premiums low, CMS seems to suggest that Sponsors are shifting costs to CMS via reinsurance, though admits “the net effects of these trends on costs for beneficiaries and the government are still unclear.”¹¹ Time will tell if the findings in the Fact Sheet will result in any significant changes to DIR policies or reporting in Medicare Part D.

BIO

Lauren Haley is a member of Strategic Health Law. She brings a wealth of knowledge and perspective to guiding healthcare organizations through complex legal and regulatory requirements, with a deep appreciation of the underlying business objectives. In the field of healthcare law, she has provided legal analysis and advice, compliance guidance, health policy strategy, and government relations support. Recognized as an authority on Medicare Advantage, Medicare Part D, and the Affordable Care Act, Lauren co-edited the Thomson Reuters treatise Regulation of Medicare Part D Plans.

Jeff Low is an Associate Director with Navigant. As a pharmacist he has practiced in direct patient care roles working with patients and providers in ambulatory and Long Term Care pharmacy settings, additionally in health plans, facilitating multidisciplinary efforts through nursing, mental health, physician, and network capacities. He also brings years of Pharmacy Benefit Management experience working in various clinical and operational roles focusing on Medicare Part D. These roles include developing clinical programs such as Medication Therapy Management and utilization management, delivery of Coverage Determinations and Appeals, formulary development / Pharmacy and Therapeutics Committee, and analytics.

10. CMS Memorandum, *Proposed Medicare Part D DIR Reporting Requirements for 2016*, May 17, 2017.

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

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