



National Community Pharmacists Association

The Impacts of Prescription Drug Direct and Indirect  
Remuneration under Medicare Part D

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## **EXECUTIVE SUMMARY**

### **Background**

This report has been developed by Wakely Consulting Group, LLC (Wakely) for the National Community Pharmacists Association (NCPA). This report presents an analysis of the impact of direct and indirect remuneration (DIR) for prescription drugs under the Medicare Part D program on numerous different parties. We focus primarily on the financial impact to these parties involved with Part D transactions, including Part D plan sponsors, Medicare beneficiaries, the Centers for Medicare and Medicaid Services (CMS), pharmacy benefit managers (PBMs), and pharmacies and to a limited degree, drug manufacturers.

This report is intended for NCPA and may be shared with CMS. Distribution of this report to other users is limited to NCPA members, CMS, and members of Congress and their staff. We do not intend this information to benefit any third party nor create reliance by any third party on Wakely. Distribution to such parties should be made in its entirety and should be evaluated only by qualified users. Distribution to other parties should only be made with Wakely's consent.

The authors of this report are financially independent and free from conflict concerning all matters related to performing the actuarial services underlying this analysis. In addition, Wakely is organizationally and financially independent to NCPA.

### **Summary of Results**

This report is divided into three key areas of analysis. First, we provide an in-depth description of how DIR is defined by CMS, how it fits in to the Part D program, why there are challenges related to transparency, and recent proposals and efforts to alter the treatment of DIR under Part D. Second, we provide numerical analysis of how DIR affects the multiple parties involved in all aspects of Part D transactions, and assess whether the trade-off between post-point-of-sale DIR and point-of-sale (POS) discounts is financially beneficial or harmful to each party. Third, we examine available data to assess recent trends in the amount and use of DIR in the Part D program.

Our main conclusions are summarized below.

### **The Amount of DIR Has Increased in Recent Years**

Both Wakely client data and national data reported by MedPAC and CMS show that the amount of DIR relative to allowed Part D costs has been increasing since 2012. In addition, the rate of increase has accelerated during years 2013 through 2015. It is unclear whether the increases are due to higher DIR dollar amounts or an increase in the classification of different forms of reimbursement as DIR. The downward trend in the national Part D bid averages every year during 2013 through 2017 also indirectly suggests increased DIR amounts.

### **As DIR Amounts Increase, Costs May Increase for Beneficiaries with Part D Claims**

When a plan favors post-point-of-sale (POS) price concessions using post-POS DIR over POS price concessions using discounts, our analysis shows that, for Beneficiaries with Part D claims, cost sharing will be higher in all benefit phases (i.e. initial coverage limit, gap, etc.) when the Part D sponsor negotiates equivalent amounts of DIR price concessions rather than point-of-sale discounts.

### **Increased Use of Post-POS DIR Increases Costs to CMS in Terms of Reinsurance and Low-Income Cost-Sharing Subsidies. CMS Will Pay out Less in Low-Income Premium Subsidies.**

Based on our modeling, we cannot say conclusively whether the net impact of increased post-POS DIR usage by plan sponsors has a positive or negative impact on CMS.

On one hand, we found that CMS always pays out the same or more for low-income cost-sharing (LICS) subsidies and will, on balance, pay out more for reinsurance. On the other hand, CMS will pay out less in low income premium subsidies (LIPS). The shift in price concessions from discounts to post-POS DIR can have a varying impact on federal reinsurance payouts, direct subsidies, and risk corridors. In addition, uncertainty and variation in DIR reporting (discussed further below) means that the ultimate Part D payments made by CMS may not be based on the actual paid cost as CMS intended.

### **Defining and Reporting DIR is Complicated, at Times Unclear, and Is Open to Interpretation**

While CMS provides documents that define DIR and describe the types of DIR and how they are to be reported, we believe these definitions are not always clear. In particular, risk sharing arrangements present a challenge to plans in terms of whether to report them as DIR. The presence of related party arrangements and risk sharing is a particularly complicated scenario where there is likely to be differing interpretations as to how to characterize expenses and risk sharing cash flows.

In its communications, CMS has acknowledged that it has concern over consistency in how price concessions are reported as DIR or as adjustments to costs in the PDE files.

### **There is a Disconnect between DIR in Part D Bids and the DIR Reports Submitted by Plan Sponsors**

As a practical matter, the DIR projected in bids is an estimate made in early June of the preceding year, and so is subject to errors in estimation. However, CMS does not have a formal process for checking on the reasonableness of DIR projected in the bids as compared with subsequent actual results. Given our other conclusion that most plans will view additional DIR as preferable to additional point-of-sale discounts, there is potential for plans to aggressively estimate DIR in bids in order to produce a lower bid and therefore more competitive product. If plans are aggressive with DIR estimates, there is a greater likelihood that a risk corridor payment will be triggered, and the benefits offered may have been richer (i.e. less cost sharing) than if a more realistic DIR amount had been projected.

### **There Is a Lack of Transparency in DIR reporting**

Although reporting of DIR from PBMs to plan sponsors and plan sponsors to CMS is subject to regulation and potential audit, no such authority exists between PBMs and pharmacies, PBMs and drug manufacturers, or PBM aggregators and drug manufacturers. Current industry practice varies, but PBMs have the most control over potential DIR, and to the extent this is not frequently and readily shared with pharmacies, DIR amounts can be difficult to project.

### **Plan Sponsors Have Incentives to Use DIR in Part D Bids and Are Generally in a More Favorable Financial Position with Increased DIR**

The calculations in the Part D bid tool produce a lower Part D bid if post-POS DIR amounts are favored over discount amounts (i.e. dollar for dollar). A lower Part D bid typically translates into increased plan sponsor profits, slightly decreased member premiums, or a combination of the two. While a lower bid does not come without risks to the plan sponsor, on balance our analysis shows that plan sponsors tend to generally be in a more favorable position financially if they favor post-POS DIR over point-of-sale discounts.

## 1) DEFINITION AND TYPES OF DIR

This section provides a definition of Direct and Indirect Remuneration (DIR) as used in the Part D program, a listing of the most common types of DIR used by plan sponsors and Pharmacy Benefit Managers (PBMs), how DIR is handled in Part D bids, and a brief discussion of current efforts by different interests to promote different treatment of DIR in Part D bids and reporting of DIR by plan sponsors.

### Basics of the Part D Program

The Medicare Part D benefit arose from the 2003 Medicare Prescription Drug Benefit, Improvement and Modernization Act (Medicare Modernization Act, or MMA). Benefits were first made available in 2006, and included prescription drug coverage for Medicare beneficiaries who enrolled in Prescription Drug Plans (PDPs) or Medicare Advantage plans offering a Part D benefit (MA-PD). Coverage for prescription drugs was not added to the “Original Medicare” benefit.

The MMA established a “defined standard” benefit that all PDP and MA-PD plans must offer at a minimum. The federal government, through the Centers for Medicare and Medicaid Services (CMS) would provide prospective funding for a portion of the defined standard benefit and also be responsible for 80% of all claim liabilities after a beneficiary reached a designated out-of-pocket threshold.

Appendix A provides a more detailed description of how prescription drug costs under the Part D program are shared between beneficiaries, PDP/MA-PD plans, and CMS; however, this paper will focus on:

- Covered drug prices set by contracts between PDP/MA-PD plans, pharmacy benefit managers and pharmacies, and
- The use of these covered drug prices by CMS in determining its payments to plans and liabilities to beneficiaries.

### DIR Definition and Its Role in the Part D Program

As noted above, CMS uses Part D sponsors’ allowable costs as the basis for determining its obligations. The final rule in 42 CFR 423.308, specifies that Part D costs incurred by plan sponsors must be net of all direct or indirect remuneration (DIR) from any source that would serve to decrease the costs.

Taken from a May 31, 2016 CMS Memo<sup>1</sup>, DIR is defined as follows:

*Per the regulations at 42 CFR 423.308, DIR is any form of price concession, received either by the Part D sponsor or by an intermediary contracting organization (a Pharmacy Benefits Manager, or PBM, for instance) with which the sponsor has contracted, from any source (including manufacturers, pharmacies, enrollees, or any other person or entity) that serves to decrease the costs incurred under the Part D plan by the Part D sponsor, either directly or indirectly.*

Although it is not entirely clear from this definition, we believe that CMS intends for DIR to represent all forms of price concessions **that cannot be determined at the point-of-sale**; therefore, throughout the remainder of this report, we will use the term DIR to mean all forms of price concessions that occur after the point-of-sale. The cost of the drug that is determined at the point-of-sale should be reported in the Prescription Drug Event (PDE) file submitted to CMS.

CMS has a vested interest in clearly defining “actual costs” of Part D sponsors (including identifying DIR), because it shares directly in Part D expenses through federal reinsurance and risk sharing (aka “risk corridors”). See Appendix A for an explanation of the Part D benefit and its associated components.

There are two main ways Part D sponsors must identify DIR. First, in the Part D bid filing, plans must submit a prospective estimate of costs to cover defined standard benefits, as well as a cost estimate to cover any benefits offered above and beyond defined standard. These costs must be net of all forms of DIR. Note that the reporting of DIR is actually labeled “Rebates” in the bid form. More detail on how DIR impacts the bid process is described in the “Impact of DIR by Party” section, below. Second, plan sponsors must submit a retrospective report of all DIR. This report must be filed by June 30 of the year following the reporting year (e.g. by June 30, 2016 for CY2015).

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<sup>1</sup> Cheri Rice, Medicare Plan Payment Group; “Final Medicare Part D Reporting Requirements for 2015”; May 31, 2016



## Types of DIR

There are many different types of DIR. In 42 CFR 423.308, the definition of “actually paid” costs notes that costs must be net of DIR, and that DIR includes the following:

- Discounts
- Charge backs
- Rebates
- Cash discounts
- Free goods contingent on a purchase agreement
- Up-front payments
- Coupons
- Goods in kind
- Free or reduced-price services
- Grants
- Other price concessions or similar benefits offered to some or all purchasers

Below we provide our interpretation of what some of these mean.

- **Discounts.** Within the context of DIR, we believe this refers to settlements related to guaranteed discounts. A settlement occurs if a PBM has guaranteed a discount off of AWP, but the actual claims are greater or less than the guarantee. For example, if a PBM guarantees that generic drugs will be 80% off AWP, but actual generic claims come in at 78% off AWP, then the additional 2% received through settlement would be classified as DIR. Note that it is possible for the DIR related to discount guarantees to be positive or negative.

Regardless whether a guaranteed discount is in effect, the discount off of AWP that is determined at the point-of-sale is not considered DIR.

- **Chargebacks.** Payments by a wholesaler reflecting the difference between the price agreed to with a drug manufacturer and the price agreed to with a Part D sponsor.
- **Rebates.** Amounts paid by drug manufacturers after the dispensing of a drug to a Part D sponsor or intermediary such as a PBM related to specific drugs, usually brand name drugs.
- **Up-front payments.** Situations where the beneficiary has paid the full cost for a prescription and later files a claim that requires reimbursement for the portion of the cost for which the beneficiary is not liable. This would be negative DIR.
- **Coupons.** Price reductions given to beneficiaries who use certain pharmacies or drugs.
- **Goods in kind.** Non-cash items provided to beneficiaries who use certain pharmacies or drugs.

## DIR Reporting, Transparency, and Consistency

When it comes to reporting and reconciling DIR, there are different interested parties, and different levels of detail that either must be reported (e.g. to CMS), or are reported as a practical matter, but are not governed by specific rules. Below, we describe how DIR is required to be reported to CMS and how DIR is reported between Part D sponsors, PBMs, and pharmacies. We provide our comments and observations regarding industry practices in reporting DIR and in submitting projections of DIR in Part D bids.

### Reporting to CMS

All Part D sponsors (MA-PD and PDP plans) are required to submit a detailed report on an annual basis to CMS that shows the amount of DIR received during the calendar year. As noted above, CMS has a vested interest in determining the final price of all drugs covered under the Part D program in order to accurately calculate risk corridors and reinsurance payments. We would note that CMS only requires plans to report DIR as it relates to the defined standard benefit. Any DIR associated with enhanced benefits accrues directly to the Part D sponsor.

On an annual basis, CMS publishes a guide for reporting DIR. Below we describe the key elements in the CMS document based on the May 31, 2016 guidance.

There are two main components to the CMS DIR report<sup>2</sup>:

1. **Summary DIR Report.** DIR amounts are reported for each Contract and Plan Benefit Package (i.e. PBP), and must further be separated into several categories. Below is a brief list of the sub-categories in which DIR must be reported (note that the descriptions are paraphrased and are not necessarily the exact language):
  - i. PBM-retained rebates. All manufacturer rebates that are retained by the PBM and not passed through to the Part D sponsor. These amounts are further separated into known amounts and estimated receivables.
  - ii. Rebates received by the Part D sponsor. Differences between any guaranteed rebate amounts and actual rebates would also be included. It is important to note that this category also includes any rebates estimated at the point-of-sale. Part D sponsors must also report these estimated point-of-sale rebates in the PDE files, so although they are

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<sup>2</sup> Cheri Rice, Medicare Plan Payment Group; “Final Medicare Part D Reporting Requirements for 2015”; May 31, 2016

submitted in the DIR report, it is necessary to remove any point-of-sale rebates reported in the PDE from the total DIR when calculating risk corridors and other reconciling items.

- iii. Rebate administration fees. Excess amounts above market value for fees related to administrative services charged to manufacturers by PBMs.
  - iv. Price concessions for administrative services. Amounts related to administrative services provided by the PBM or drug manufacturer where the charges are below market value.
  - v. Legal settlements. Amounts from lawsuits or other legal action which directly or indirectly impact drugs costs incurred by the Part D sponsor.
  - vi. All other price concessions. All price concessions not captured in i. through v.
  - vii. Generic dispensing incentive payments and adjustments. Amounts paid to or received from pharmacies related to the pharmacy's performance related to the dispensing of generic prescriptions.
  - viii. Other pharmacy incentive payments and adjustments. Amounts paid to or received from pharmacies related to the pharmacy's performance related to any measure other than the dispensing of generic prescriptions.
  - ix. Risk sharing arrangement payments and adjustments. Gains or losses attributable to drug costs where the Part D sponsor receives or pays amounts related to risk-sharing arrangements with entities other than CMS. Only the provider risk arrangement impact with respect to the defined standard benefit should be reported. It is unclear where the impact with respect to benefits above and beyond defined standard should be reported, or even if they should be reported.
2. **Detailed DIR Report.** This report requires the Part D sponsor to show DIR at the National Drug Code (NDC)<sup>3</sup> level of detail. Like the Summary DIR report, the amounts must be shown by PBP, but only two categories of DIR are required – Rebates and All Other. The total DIR in this report must match the total from the Summary DIR Report. It is worth noting that this reporting represents an average of DIR levels across the pharmacies within the Part D sponsor's network. Any variation in DIR between different pharmacies will not be apparent.

Although CMS provides numerous details regarding the reporting of DIR, we believe there is likely varying practice across Part D sponsors in terms of what amounts are reported as DIR. In a September 29, 2014 memo from CMS<sup>4</sup>, this inconsistency is acknowledged. Specifically, the memo states that CMS

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<sup>3</sup> From the FDA: "Drug products are identified and reported using a unique, three-segment number, called the National Drug Code (NDC), which serves as a universal product identifier for drugs"

<sup>4</sup> Cheri Rice, Medicare Plan Payment Group; "Direct and Indirect Remuneration (DIR) and Pharmacy Price Concessions", September 29, 2014

expressed “concerns regarding the differences with which Part D sponsors report costs and price concessions to CMS”.

In addition to inconsistency in reporting across different Part D sponsors, we also believe there is a high potential for inconsistency between how DIR is reported in the bids versus in the DIR reports. More specifically:

- The projected value in the bid is reported in late May or early June and is well before the actual DIR amounts become known. Although other aspects of the bid are subject to an “actual to expected” review by CMS, the DIR reporting is not one of them. Therefore, there is less compliance risk if a plan consistently reports a level of DIR in the bid that is different from that actually experienced. Despite our findings regarding the positive financial aspects of DIR for plan sponsors, there does not appear to be a strong CMS oversight or audit process to ensure that projected DIR amounts in the bid are consistent with the original filed amounts. Reporting risk sharing is challenging. If a capitation arrangement spans medical and pharmacy, plans have latitude in choosing how to allocate. Also, it is unclear whether the allocation method in the bid needs to match what is reported in the DIR report. Given the wide range of risk-sharing arrangements and related party rules in the bid instructions, it’s also unclear which types of risk sharing necessitate an allocation of DIR. We also have concern that there may be a disconnect between the allocation method used by actuaries and other staff submitting bids versus different staff that determines allocations for the DIR reports.
- We have observed that the projected values in the bid are not routinely compared with previous DIR reports and actuaries typically rely heavily on the projections provided by the Part D sponsor (which are likely through the Part D sponsor’s PBM).
- A June 2015 MedPac report<sup>5</sup> notes the following:
  - “The magnitude of DIR can be difficult for plan sponsors to predict. For example, one interviewee noted that his firm (a plan sponsor) had an especially contentious relationship with a major pharmaceutical manufacturer over rebates. At the time that bid submissions were due, the actuary believed there was only a fifty-fifty chance that the two sides could reach any agreement. In this situation, he used actuarial standards of practice—a conservative assumption about the magnitude of DIR in the sponsor’s bid”.
  - “...plan sponsors are required to apportion DIR evenly across spending, even if this allocation does not reflect how rebates are generated. This approach may contribute to

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<sup>5</sup> Medicare Payment Advisory Commission, Report to the Congress: Medicare and the Health Care Delivery System, June 2015. <http://www.medpac.gov/docs/default-source/reports/june-2015-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf?sfvrsn=0>

underestimates of spending above Part D’s catastrophic threshold.” More specifically, this refers to the issue that some brand drugs without therapeutic equivalents are far less likely to have rebates, yet plans must allocate DIR to these drugs.

These MedPac comments further reinforce our belief that projections of DIR in bids and allocations in DIR reporting have accuracy and consistency issues.

### **Reporting between the Part D Sponsor, PBMs, and Pharmacies**

Of all the parties involved in the dispensing of prescription drugs under Part D (plan sponsors, beneficiaries, CMS, PBMs, and pharmacies), PBMs almost certainly have the most information. The PBMs receive pricing information from the drug manufacturers, and then contract with pharmacies and Part D sponsors.

Part D sponsors negotiate with PBMs who offer discounts off of the Average Wholesale Price (AWP) of drugs as well as expected rebates and other DIR. Often the discounts are guaranteed minimums. Separately, PBMs agree to terms with pharmacies such that the PBMs will adjudicate claims submitted by pharmacies on a script-by-script basis, with settlements related to all forms of DIR occurring at different points in time, and typically in aggregate (rather than script-by-script basis).

The reporting of reconciliations related to different forms of DIR between PBMs and pharmacies can often lack transparency. The PBM is usually in full control of the flow of information regarding the expected amount of additional liabilities or receivables with pharmacies. For example:

- If a PBM has negotiated a guaranteed discount with the Part D sponsor, only the PBM will be aware of whether that guarantee has been met, especially if the measurement period is not complete. Until the period is complete the PBM would need to estimate the pattern of drug usage for the remainder of the period in order to calculate potential liabilities or receivables from pharmacies.
- Performance-based payments (from or to the pharmacy) often depend on the PBM tracking experience relative to all members associated with a given Part D sponsor. For example, an incentive payment based on the attainment of a minimum generic dispensing rate may depend on all scripts filled by a given population and again would require a forecast of future usage if the measurement period is not complete.
- If increased discounts are given based on volume-based measures, the PBM is again likely to have better control over the underlying data. If the PBM does not regularly share the status of the measures, the pharmacy may be in the dark as to a potential increase in discounts.

Poor transparency can impact Part D sponsors. When preparing the bid, an actuary must make assumptions with incomplete DIR information. For example, if the PBM offers a guaranteed discount, the actuary must judge whether the guarantee is likely to be exceeded. The actuary’s accuracy in this judgment will depend on how much information the PBM will disclose.

The lack of transparency on the part of PBMs in reporting to pharmacies can present significant challenges to pharmacies. It can be difficult to forecast financial results when there is uncertainty or a lack of reporting related to the various forms of DIR. Budgeting and contract negotiation also present challenges if DIR amounts are not well known when these activities take place. In addition, not having a full picture of final drug prices makes it more difficult to evaluate proposed contracts with PBMs and Part D sponsors, and makes it harder to assess if a given claim is consistent with the contractual terms.

## **Proposed Changes to the Treatment of DIR**

In general, the treatment of DIR in Medicare Part D bid submissions and year-end reporting has remained consistent since the inception of the Part D program in 2006. Below we summarize some past and current efforts to alter DIR treatment.

### **CMS Proposal to Revise the Definition of “Negotiated Prices”**

In a May 2014 proposed rule<sup>6</sup>, CMS proposed to revise the definition of “negotiated prices” to be “...inclusive of all price concessions from network pharmacies except those contingent price concessions that cannot reasonably be determined at the point-of-sale”. Thus, DIR arrangements such as performance-based payments or payment rates based on generic dispensing rates, market share, or other measures that could be estimated using recent experience should be applied at the point-of-sale and not be counted as DIR. The change was proposed to begin for CY2016.

Several reasons were given for this change, including:

- The original definition of DIR allowed plans to “elect which price concessions from pharmacies to report outside the PDE”, which “allows price concessions to be applied disproportionately to costs that plans are liable for, and thus may shift more low-income cost-sharing subsidy and reinsurance costs to the government, as well as to manufacturers”.
- Part D sponsors that shift price concessions in their favor could be at a competitive advantage versus those sponsors that do not in that a lower bid could be achieved.
- Drug prices used in the Medicare Drug Plan Finder are based on point-of-sale prices, so there is inconsistency in the pricing across plans if DIR is treated differently.

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<sup>6</sup> Federal Register / Vol. 79, No. 100 / Friday, May 23, 2014

Ultimately, this proposed rule change was not finalized. In a November 5, 2014 memo<sup>7</sup>, CMS indicated it reached its decision based on commenters' concerns that the revision would "effectively eliminate the regulatory exemption from negotiated price reporting for any price concessions" and on a desire to provide more time to assess Part D payment arrangements.

### **MedPAC Recommendations**

The Medicare Payment Advisory Commission (MedPAC) is an independent congressional agency that provides research and recommendations to the U.S. Congress regarding several aspects of the Medicare program, including Part D. Typically MedPAC produces a "Report to Congress" along with other topics of interest each year.

In recent reports, MedPAC has not offered any official recommendations related to the treatment of DIR specifically. In the June 2015 report<sup>8</sup>, MedPAC noted that "...it would be useful to understand more about the organizational level at which plan sponsors negotiate and allocate rebates—for example, whether by individual Part D plans, by contracts, or for a company's entire book of business. The ways in which plan sponsors allocate rebate dollars across lines of business may provide large plan sponsors with flexibility as they develop bids and determine actual plan costs".

However, at the March 5, 2015 meeting of MedPAC, staff presented on the topic of "Sharing risk in Medicare Part D" and noted that the disparities between bid amounts and actual costs has very real consequences for the federal government and the Medicare program in terms of risk corridors and financial responsibility or subsidy.<sup>9</sup> In addition, this same presentation noted that a potential mechanism to encourage the submission of more accurate bids would be to require more plan accountability for costs that exceed the catastrophic threshold.

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<sup>7</sup> Cheri Rice, Medicare Plan Payment Group; "Direct and Indirect Remuneration and Pharmacy Price Concessions"; November 5, 2014

<sup>8</sup> Medicare Payment Advisory Commission, Report to the Congress: Medicare and the Health Care Delivery System, June 2015; <http://www.medpac.gov/docs/default-source/reports/june-2015-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf?sfvrsn=0>

<sup>9</sup> Medicare Payment Advisory Commission, "Sharing risk in Medicare Part D," March 5, 2015; <http://www.medpac.gov/docs/default-source/meeting-materials/march-2015-meeting-presentation-sharing-risk-in-medicare-part-d-.pdf?sfvrsn=0>

## Current Proposals

In September 2016, a bill was introduced in the House, H.R. 5951, that would prohibit Part D sponsors or PBMs on behalf of Part D sponsors from retroactively reducing payments unless the claim is found to not be a “clean claim” (e.g. lack of sufficient documentation). The prohibition covers reductions only. Retroactive increases would still be allowed. This bill would certainly remove a significant portion of DIR; however, by not eliminating all forms, many of the negative aspects of DIR cited in the May 2014 CMS proposed rule<sup>10</sup> would still apply. However, this legislation would have a number of positive effects including ensuring that Part D beneficiaries have access to more accurate drug pricing information via Plan Finder (and can make more informed choices about their plan choice) and more clarity and accuracy for the pharmacist who will know exactly what his or her reimbursement will be at the point-of-sale.

There have also been efforts to give CMS the authority to negotiate drug prices under Part D. Currently, the “noninterference” section of the Social Security Act<sup>11</sup> prevents CMS from interfering with negotiations between drug manufacturers and pharmacies and Part D sponsors. For example, H.R. 3061, which was introduced July 2015, proposes to strike the non-interference section and replace it with language allowing the Secretary to negotiate prices, including discounts, rebates, and other concessions. The bill was referred to a subcommittee shortly after its introduction, with no further developments since.

There have also been efforts to give CMS authority to negotiate pricing for only certain categories of drugs such as high-cost drugs, biologics, and drugs that have no therapeutic alternative<sup>12</sup>.

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<sup>10</sup> Federal Register / Vol. 79, No. 100 / Friday, May 23, 2014

<sup>11</sup> 42 USC 1395w-111, section (i)

<sup>12</sup> Kaiser Family Foundation, “Searching for Savings in Medicare Drug Price Negotiations”, February 9, 2016; <http://kff.org/medicare/issue-brief/searching-for-savings-in-medicare-drug-price-negotiations/>



## 2) IMPACT OF DIR BY PARTY

### Introduction

In this section, we examine how different parties involved in the Part D program view DIR and are impacted by it. We consider the perspective of CMS, the beneficiary, pharmacies, PBMs, and Part D sponsors.

In addition to providing our observations on how these parties are affected, we also show how an equivalent point-of-sale discount and post-POS DIR amount impact Part D claims under different scenarios. To develop this estimated impact, we modeled how a claim would be adjudicated at different benefit phases and scenarios for an individual beneficiary. We then assessed whether the various parties to the transaction would be better or worse off with a fixed amount of discount versus the same amount of DIR. We also modeled how aggregate results trigger risk corridor payments or receivables under an assumption of the trade-off of a fixed amount of discount versus DIR.

In our analysis below we reference two scenarios according to the preference for point-of-sale discounts or post-POS DIR:

- Case 1: Point-of-sale discounts favored over DIR - in this case, the plan would receive slightly higher price concessions at point-of-sale and offsetting lower price concessions from DIR. In our modeling, we assume the plan negotiates a 20% AWP discount with a 5% rebate or DIR amount on a given drug.
- Case 2: DIR favored over point-of-sale discounts - in this case, the plan would receive slightly higher price concessions from DIR and offsetting lower price concessions at point-of-sale. Here, we assume a 15% AWP discount with a 10% rebate or DIR amount on that drug.

### Federal Government (CMS)

As mentioned in previous sections, CMS has a vested interest in determining the final cost of drugs after all price concessions whether point-of-sale or post-POS. This is because CMS shares the cost of the Part D drug benefit in several ways, through:

- Federal reinsurance for claimants with catastrophic drug costs
- Low-income cost-sharing subsidies, which pay the difference between the beneficiary cost-sharing defined by the plan's benefit and the amount that an LI beneficiary pays according to the LI benefit schedule for their income category
- The risk corridor, as discussed in the Appendix
- Low-income premium subsidies, which pay for a percentage of LI beneficiaries' premiums based on their income level
- The direct subsidy, which is the portion of the Part D bid revenue subsidized by CMS

We will examine the cost impact to CMS due to the timing of drug price concessions for each of these items separately. Briefly, our findings indicate that CMS will at least some of the time pay out more for direct subsidies, risk corridor payments, and federal reinsurance when plan sponsors favor DIR over discounts.

### **Federal Reinsurance**

Plans are required to share a portion of post-POS DIR with CMS for claims subject to federal reinsurance. In this way, federal reinsurance shares in both price concessions achieved at point-of-sale and those attained post-POS. The DIR attributable to federal reinsurance is calculated as 80% of the allowed drug costs incurred in the catastrophic phase as a percentage of total allowed costs, multiplied by the total DIR amount.

Looking at the claim adjudication examples in Exhibits A–D in the Appendix, we can draw the following conclusions:

- For claims that cross multiple benefit phases from first dollar for a defined standard or coinsurance-based benefit, federal reinsurance costs are lower under Case 1 (preferable discounts). This highlights the effect that lower price concessions at point-of-sale can have in that it can cause beneficiaries to advance through the benefit phases at a faster pace as a result of the higher drug costs incurred at point-of-sale. This may result in greater federal reinsurance costs due to beneficiaries reaching the catastrophic phase sooner and potentially incurring greater costs within the catastrophic phase once it has been reached.
- For claims incurred entirely in the catastrophic phase, federal reinsurance costs may be lower under Case 2 (DIR favored over point-of-sale discounts). However, our examples in Exhibits A–D assume a single claim, and allocate a proportionate share of DIR to reinsurance from that single claim. This differs from the reality of how DIR is allocated to reinsurance in that the reduction for DIR attributable to federal reinsurance is done in aggregate at the individual plan-level (i.e. Contract and PBP), rather than at the claim level. Therefore, it is possible that Case 2 may not produce lower costs depending on the amount of DIR actually allocated to federal reinsurance, which would be dependent on the individual plan's annual claim experience in aggregate.

### **Low-Income Cost-Sharing Subsidy (LICS)**

Within Part D, there are defined benefit schedules for LI beneficiaries which run parallel to the benefit plan that the beneficiary is enrolled in. There are four distinct LI benefit schedules, and the beneficiary's income level defines which schedule or category applies to the beneficiary. LICS is then calculated as the difference between the beneficiary's cost-sharing defined by the benefit plan that they enrolled in and the amount the beneficiary actually pays according to their particular LI benefit schedule. Therefore, the impact of the timing of drug price concessions on LICS is similar to the impact on beneficiaries' cost-sharing as discussed later in the report:

- LICS is equal or greater in all scenarios under Case 2 (preferable DIR) versus Case 1 (preferable discounts).

- LICs is lower under Case 1 in the following instances:
  - All phases of the defined standard benefit – therefore any benefit design using a deductible, a coinsurance-based benefit, and a defined standard catastrophic benefit
  - Claims in either the initial coverage phase or coverage gap when there is a co-pay benefit but the allowed cost falls below the co-pay
- When the allowed cost of a drug claim is higher than the copay amount, then LICs is unaffected by the type of price concession since the copayment is the same in either case.

We considered the most extreme case of LICs in our examples in Exhibits C–D in the Appendix: institutional LI beneficiaries. For this particular LI category, the beneficiary actually pays \$0 for all drugs in all benefit phases, resulting in the highest possible LICs amount equal to the beneficiary's cost-sharing responsibility as defined by the plan's benefits.

We draw the same conclusions from our examples as those we listed in the "Beneficiary" section later in the report. However, we still modeled this case separately since LI members have a defined standard gap benefit that differs from non-LI members. Therefore, dollar amounts in Exhibits C and D may differ slightly from those in A and B.

### **Risk Corridor**

In Exhibit F in the Appendix, we examine the impact on plan costs with respect to the risk corridor. Exhibit F-1 considers scenarios where actual costs fall within +/- 5% to 10% of expected costs, whereas Exhibit F-2 considers scenarios where actual costs fall within +/- 10% or more of expected costs. Within both exhibits, we look at a scenario with favorable experience where actual costs are lower than expected costs as well as a scenario with unfavorable experience where actual costs exceed expected costs.

When considering the impact on CMS's costs, we focus solely on the risk corridor transfer amounts. Exhibit F shows that in these examples, Case 1 produces a more favorable risk corridor transfer amount for CMS than Case 2 when the plan's actual experience is worse than expected, and vice versa. However, results may vary depending on the amount of price concessions being shifted from POS discounts to post-POS DIR, and resulting changes in the federal reinsurance and plan benefit ratios (i.e. paid-to-allowed ratios).

In recent years, CMS has collected more in risk corridor transfers than it has paid in aggregate for all MA-PD and PDP plans. Therefore, if this relationship holds, it would be in CMS's best interest, from a risk corridor perspective, if Part D plan sponsors shift price concessions away from POS discounts and into post-POS DIR.

### **Low-Income Premium Subsidy (LIPS)**

CMS subsidizes beneficiary premiums for LI individuals to varying degrees depending on the individual's income level. Therefore, any price concession arrangement that serves to reduce beneficiary premiums would also reduce CMS's costs for LIPS amounts. Greater reductions in plan costs due to DIR can result in lower beneficiary premiums, and as a result lower CMS payments for LIPS amounts.

### **Direct Subsidy**

CMS pays Part D plan sponsors a "direct subsidy" for each beneficiary, which is equal to the beneficiary's risk score multiplied by the plan's Part D bid amount, less the plan's basic premium amount. An illustration of the development of the direct subsidy is shown in Table 1 in the Appendix.

Exhibit G in the Appendix shows a pricing illustration under the same two price concession scenarios discussed in other sections above: Case 1 (preferable discounts) and Case 2 (preferable DIR). We then examine the impact on the CMS direct subsidy for different members based on the estimated Part D bid amount from each scenario. In our examples, Case 2 results in a lower Part D bid amount than Case 1 as shown in Table G-1 in the exhibit. In Table G-2 we see that the CMS direct subsidy is lower when the Part D bid is higher (as it is in Case 1) for risk scores less than 1.0. Conversely, the CMS direct subsidy is higher when the Part D bid is lower (as it is in Case 2) for risk scores greater than 1.0.

Therefore, the impact on CMS's costs associated with the direct subsidy due to the timing of price concessions (POS discounts vs. post-POS DIR) will vary based on members' risk scores. In theory, this should have a minimal impact on the overall direct subsidy amount for all Part D members given that risk scores are expected to average a 1.0 risk score. However, this effect could cause an overall increase or decrease in the direct subsidy depending on the distribution of risk scores for members within plans favoring POS discounts vs. post-POS DIR.

### **Beneficiaries**

From the beneficiary perspective, a plan that favors DIR over point-of-sale price concessions presents a trade-off between a slight reduction in premium versus the same or higher cost-sharing under most conditions for those who have Part D claims. Price concessions due to DIR may enable plans to pass that savings onto the members in the form of slightly lower premiums or richer enhanced benefits (medical or drug); however, beneficiaries with Part D claims may also find themselves paying more out-of-pocket because forgone discounts are no longer shared. This is discussed further in the "Part D Plan Sponsors" section below.

For example, consider if a plan had the option of receiving price concessions in the form of Case 1 (20% AWP discount and 5% rebate or DIR amount on a drug), or Case 2 (15% AWP discount with a 10% rebate or DIR amount on that drug). Both options would result in the same price concession; however, the first

option (Case 1) may share more of the savings with the claimant taking that drug, whereas the second option (Case 2) may share more of the savings with all members in the form of lower premiums.

In looking at the claim adjudication examples in Exhibits A and B in the Appendix, we can draw the following conclusions:

- Beneficiaries pay an equal or greater amount out-of-pocket under all scenarios under Case 2 (preferable DIR) versus Case 1 (preferable discounts), ignoring member premiums.
- Beneficiary out-of-pocket costs are lower under Case 1 in the following instances:
  - All phases of the defined standard benefit – therefore any benefit design using a deductible, a coinsurance-based benefit, and a defined standard catastrophic benefit
  - Claims in either the initial coverage phase or coverage gap when there is a co-pay benefit but the allowed cost falls below the co-pay
- When the allowed cost of a drug claim is higher than the copay amount, then beneficiary out-of-pocket costs are unaffected by the type of price concession since the copayment is the same in either case.

Higher negotiated costs at point-of-sale with greater price concessions post-POS (i.e. Case 2) may also result in claimants potentially not filling their prescription if the beneficiary's cost-sharing is too expensive for them to afford. If this were to happen, it could also have a negative effect on the plan sponsor in the form of lower drug adherence (a Medicare quality measure), or greater member attrition.

Some plans may even delay adding cheaper generic alternatives to some brand drugs to the formulary in some instances due to the high rebates they can receive from the drug manufacturer, despite that this can increase particular claimants' costs even if it does also serve to lower premiums slightly for all beneficiaries.

## Pharmacies

Pharmacies are at a distinct disadvantage when price concessions are taken or collected from pharmacies after the point-of-sale. The main reason for this is a distinct lack of transparency in the detail provided to pharmacies both at contract initiation and when calculations supporting DIR amounts are provided. Even though DIR fees are usually determined on a claim by claim basis, in practice they are assessed or charged to the pharmacy as a lump sum without claim-specific detail. In addition, DIR fees are assessed post-adjudication, or retroactively, which creates operational and cash flow challenges for the pharmacies.

This situation is further complicated by the fact that pharmacies are reimbursed for virtually all generic drugs (approximately 88% of all drugs dispensed) via “Maximum Allowable Cost” (MAC) lists—that are created, maintained and changed at the sole discretion of PBMs. The pharmacist does not “find out” what they will be reimbursed for any generic drug until such time as the claim is adjudicated or submitted to the PBM for payment just prior to that drug being dispensed to a patient. From a practical

standpoint, a pharmacy believes they are being reimbursed a certain amount based on the remittance they receive at the time the claim is adjudicated. However, once DIR fees are assessed months later, the ultimate reimbursement on that claim or any claim may be significantly lower. Typically, most PBMs do not provide any claim-level detail to pharmacies that would provide them with a clear picture as to how much money was extracted from each individual claim. In addition, without this level of detail, it is virtually impossible for the pharmacy to determine exactly what their reimbursement was for each claim or conversely how much money they lost. All of these factors make it extremely challenging for pharmacies both from a cash flow and business planning perspective.

It is also important to point out that pharmacies are also at a distinct disadvantage in terms of negotiating power with PBMs—particularly independent community pharmacies. The PBM marketplace is extremely concentrated and nearly three-quarters of all prescription claims were processed by just three companies<sup>13</sup>. Large pharmacy chains can certainly use their market power to attempt to push back on PBMs on pricing and payment practices; however, independent community pharmacies—even those who are represented by Pharmacy Services Administrative Organizations (PSAOs)—typically have very little negotiating power and often must agree to the offered terms or lose potential prescription business. Also, as detailed above, PBMs have virtually unilateral control over the pricing for 88% of all drugs dispensed and therefore have the ability to manipulate the interplay between the contractual pricing terms, the MAC list amounts and the DIR calculations affected by these prices.

## **Pharmacy Benefit Managers**

Based on our analysis of the impact of favoring DIR over point-of-sale discounts on other parties, it is apparent that pharmacy benefit managers (PBMs) will have several incentives to favor DIR.

First, it is common in the terms of PBM contracts with Part D plan sponsors for the PBM to retain a portion of rebates (a form of DIR) in lieu of higher PBM fees.

Second, as discussed below, plan sponsors have several reasons to favor DIR over point-of-sale discounts. The PBM will certainly seek to attract plan sponsor business partners, and has the data to effectively determine a DIR structure equivalent to a given point-of-sale discount.

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<sup>13</sup> <http://www.coapharmacy.com/hearing-the-state-of-competition-in-the-pharmacy-benefit-manager-and-pharmacy-marketplaces/>

Third, PBMs retain control over claim data and MAC pricing. To the extent that DIR arrangements are based on performance where MAC pricing is a factor, the PBM has the ability to continuously modify pricing to produce results that are financially favorable for the PBM.

An indirect consequence of increased DIR is that drug pricing is less transparent for both the Part D sponsor plans and pharmacies. This gives PBMs significant leverage in negotiations.

## **Part D Plan Sponsors**

Part D plan sponsors generally have an incentive to receive price concessions in the form of DIR rather than higher AWP discounts, all else being equal. This is due to the timing of when these price concessions are made or reflected in the costs, and which parties share in the costs at different stages. To illustrate this, we must consider how price concessions through discounts and DIR are treated from a claims perspective as well as in the CMS Part D Bid Pricing Tool (BPT).

As shown in Table 2.1 below, drug costs begin with a gross amount, typically the AWP, before any negotiated point-of-sale discounts. After applying reductions due to point-of-sale (POS) discounts, we arrive at the allowed amount. This allowed amount is used as the starting cost when the claim is adjudicated through the plan's benefit, and therefore it is used as the basis to calculate what other payers' (i.e. beneficiaries, CMS, and drug manufacturers where applicable) amounts will be at POS for the claim. Then, once post-POS DIR is available, plan costs and federal reinsurance are further reduced by a proportionate amount of any post-POS DIR. As a result, price concessions due to discounts, which are known at POS, are shared by the plan, beneficiary, drug manufacturers, and CMS; whereas, price concessions due to post-POS DIR are only shared by the plan and CMS, and can therefore be more beneficial to the plan in many scenarios, all else being equal. Note that the last row in Table 2.1 shows that drug costs net of discounts and DIR are equal in both cases. The difference in the final plan cost is attributable to the amount of price concessions available at POS vs. post-POS.

**Table 2.1 – Illustration of Payer's Costs at Point-of-Sale and After Post-POS DIR Adjustments**

		<b>Case 1: Preferable Discounts</b>	<b>Case 2: Preferable DIR</b>
A	Drug Cost Gross of Discounts	\$300	\$300
<b>Point-of-Sale</b>			
B	Allowed Cost (Net of Discounts)	\$240	\$255
C	Beneficiary Cost-Sharing	\$69	\$71
D	Manufacturer Gap Discount	\$61	\$63
E	Federal Reinsurance Gross of DIR	\$88	\$91
F = B – (C+D+E)	<b>Plan Cost Before Reductions Due to DIR</b>	<b>\$21</b>	<b>\$30</b>
<b>After Point-of-Sale</b>			
G	Total DIR	\$15	\$30
H = G * E / B	DIR Allocated to Federal Reinsurance	\$6	\$11
I = G – H	Plan-Retained DIR	\$9	\$19
J = E – H	Federal Reinsurance Net of DIR	\$83	\$80
K = F – I	<b>Plan Cost After Reductions Due to DIR</b>	<b>\$12</b>	<b>\$10</b>
L = B – G	Drug Costs Net of Discounts and DIR	\$225	\$225

In the Part D BPT, it is the plan cost after reductions due to DIR (i.e. item K from the above table) that would then be grossed up for non-benefit (administrative) expenses and profit margin to calculate the plan's Part D bid amount and beneficiary premiums. Therefore, greater reductions in plan costs due to DIR can result in lower Part D bid amounts and beneficiary premiums. This may give the plan a competitive advantage if they are able to offer beneficiaries either a comparable benefit plan at a lower premium, or alternatively a richer enhanced benefit at a premium that is comparable to their competitors.

Several other examples like those shown in Table 2.1 above are provided in Exhibits A – D in the Appendix. There, we examine the cost impact (after all price concessions) on each party or payer for a single claim under various scenarios: within each benefit phase, for a defined standard benefit with deductibles and coinsurance vs. an enhanced co-pay benefit structure, and separately for a non-low-income (NLI) individual vs. an institutional low-income (LI) individual. In each scenario, we conclude whether each party's costs would be lower under Case 1 (discounts favored) and Case 2 (DIR favored).

Our conclusions from the analyses and examples shown in Exhibits A through D are as follows:

- Part D plan sponsor costs are lower under Case 2 in the following instances:
  - Claims in the deductible phase
  - Claims in either the initial coverage phase or coverage gap when there is a coinsurance



benefit or if there is a co-pay benefit but the allowed cost falls below the co-pay

- Part D plan sponsor costs are lower under Case 1 in the following instances:
  - Claims in the catastrophic phase
  - Claims crossing multiple benefit phases, with a fair amount of costs falling in the catastrophic phase
- Part D plan sponsor costs are unaffected by the type of price concession for claims in the initial coverage phase or coverage gap if there is a co-pay benefit and the allowed cost exceeds the co-pay

We would expect the savings due to a preferable POS discount arrangement to generally be overshadowed by the savings generated by a preferable post-POS DIR arrangement for most plans, resulting in a preference on the Part D plans' part to seek out arrangements that shift price concessions from POS discounts to post-POS DIR.

In Exhibit F in the Appendix, we also examined the impact on plan costs with respect to the risk corridor. Exhibit F-1 considers scenarios where actual costs fall within +/- 5% to 10% of expected costs, whereas Exhibit F-2 considers scenarios where actual costs fall within +/- 10% or more of expected costs. Within both exhibits, we look at a scenario with favorable experience where actual costs are lower than expected costs as well as a scenario with unfavorable experience where actual costs exceed expected costs.

In each of the scenarios shown in Exhibit F, it is more favorable to the Part D Plan Sponsor to have a preferable DIR arrangement with slightly higher price concessions from DIR and offsetting lower price concessions from discounts when considering the plan's final costs after all price concessions and risk corridor. Despite that the plan's risk corridor payable is higher under Case 2 for scenarios where the plan has favorable experience, the plan's overall costs are still lower under Case 2 due to the added savings from DIR.

## **Drug Manufacturers**

Beginning in 2011, the Affordable Care Act required drug manufacturers to pay a "coverage gap discount" (CGDP) amount for brand drugs incurred by non-LI beneficiaries in the coverage gap in an effort to eventually eliminate the coverage gap by 2020 from a beneficiary cost-sharing perspective. The CGDP amount is based on the point-of-sale allowed cost of the drug under the defined standard gap benefit, and does not receive any proportionate share of post-POS price concessions from DIR. Under an enhanced gap benefit, the CGDP amount is calculated as a percentage of the beneficiary's cost-sharing rather than the allowed cost.

In looking at the claim adjudication examples in Exhibits A–B in the Appendix, we can draw the following conclusions:

- In all scenarios, manufacturers will pay an equal or greater amount of CGDP under Case 2 (DIR favored) versus Case 1 (point-of-sale discounts favored).
- CGDP costs are lower under Case 1 when:
  - A non-LI beneficiary in the coverage gap phase of a *defined standard* design has a brand drug claim.
  - A non-LI beneficiary in the coverage gap phase of an *enhanced gap benefit design using co-payments* has a brand claim where the allowed cost falls below the co-pay
- CGDP costs are unaffected by the type of price concession (Case 1 or Case 2) when:
  - A non-LI beneficiary in the coverage gap phase of an *enhanced gap benefit design using copayments* has a brand claim where the allowed cost exceeds the co-pay.
  - A claim is for a generic drug
  - The beneficiary has LI status

Another important consideration is that when point-of-sale drug costs are higher (Case 2: DIR favored), beneficiaries will reach the coverage gap faster (all other factors being equal). As more beneficiaries reach the coverage gap, more claims will be in the gap and CGDP costs will be higher.

### 3) TRENDS IN AMOUNT AND TYPES OF DIR

#### Background

In general, the usage of DIR under Part D by plan sponsors and PBMs has increased in terms of both dollar amounts and types of reimbursement classified as DIR over the last few years. We believe this is primarily due to the strong incentives created by the bid process for Part D sponsors and PBMs to use DIR.

#### Trends in DIR Reported in Part D bids

Both national data and Wakely client data show that there has been an increase in the per member per month (PMPM) amount of DIR reported in Part D bids over the last few years. A similar increase can also be seen when DIR is expressed as a percentage of total Part D prescription drug spend.

These conclusions are based on an analysis of Wakely clients who have filed Part D bids for contract years 2014 through 2017 and information provided in the March 2016 MedPAC report “Medicare Payment Policy: Report to Congress”.

#### Wakely Client Averages

The analysis of Wakely clients shows a steady increase in the actual (as opposed to projected) DIR PMPM and DIR as a percentage of allowed in 2012 through 2015. Table 3.1 shows our results. Please note that the term “Rebates” is used in the bid filings, but we use the term DIR below.

<b>Table 3.1</b> <b>DIR Reported in Medicare Part D Bids</b> <b>Wakely Client Average</b>					
<b>Experience Year</b>	<b>Bid Filing Year</b>	<b>DIR PMPM</b>	<b>Annual Trend</b>	<b>DIR as % of Allowed</b>	<b>Annual Trend</b>
2012	2014	\$6.48		4.5%	
2013	2015	\$7.20	11.1%	5.0%	11.2%
2014	2016	\$9.02	25.3%	5.4%	8.3%
2015	2017	\$16.09	78.3%	8.3%	54.0%

The average DIR PMPM in Table 3.1 is increasing each year, and increased very significantly in 2015, indicating that either amounts or types of DIR or both are being used by Part D sponsors and affiliated PBMs. The PMPM trend is also outpacing the trend in overall Part D drug spend, as can be seen by the increasing DIR as a percentage of allowed by year in Table 3.1.

In addition to these actual DIR amounts, the projected DIR in Part D bid filings has also been increasing. The projected DIR represents the Part D sponsor's estimate of all types of DIR it expects the PBM to collect (or pay) in the contract year. The average projected DIR for Wakely clients was consistently higher than the base period DIR, both as a PMPM and as a percentage of allowed costs. Table 3.2 shows the Wakely client averages for projected DIR by contract year.

<b>Table 3.2</b> <b>DIR Projected in Medicare Part D Bids</b> <b>Wakely Client Average</b>				
<b>Bid Filing Year</b>	<b>DIR PMPM</b>	<b>Annual Trend</b>	<b>DIR as % of Allowed</b>	<b>Annual Trend</b>
2014	\$9.42		6.5%	
2015	\$10.25	8.7%	5.7%	-13.0%
2016	\$11.54	12.7%	5.9%	4.2%
2017	\$22.11	91.5%	9.8%	64.7%

Table 3.2 shows that projected DIR is increasing by year, and that plans are projecting increases in DIR amounts from the base period to the contract period. For example, for CY2014 bid filings, the average base period DIR PMPM was \$6.48 (Table 3.1) for 2012, and the projected value for 2014 was \$9.41 (Table 3.2), or 45% higher.

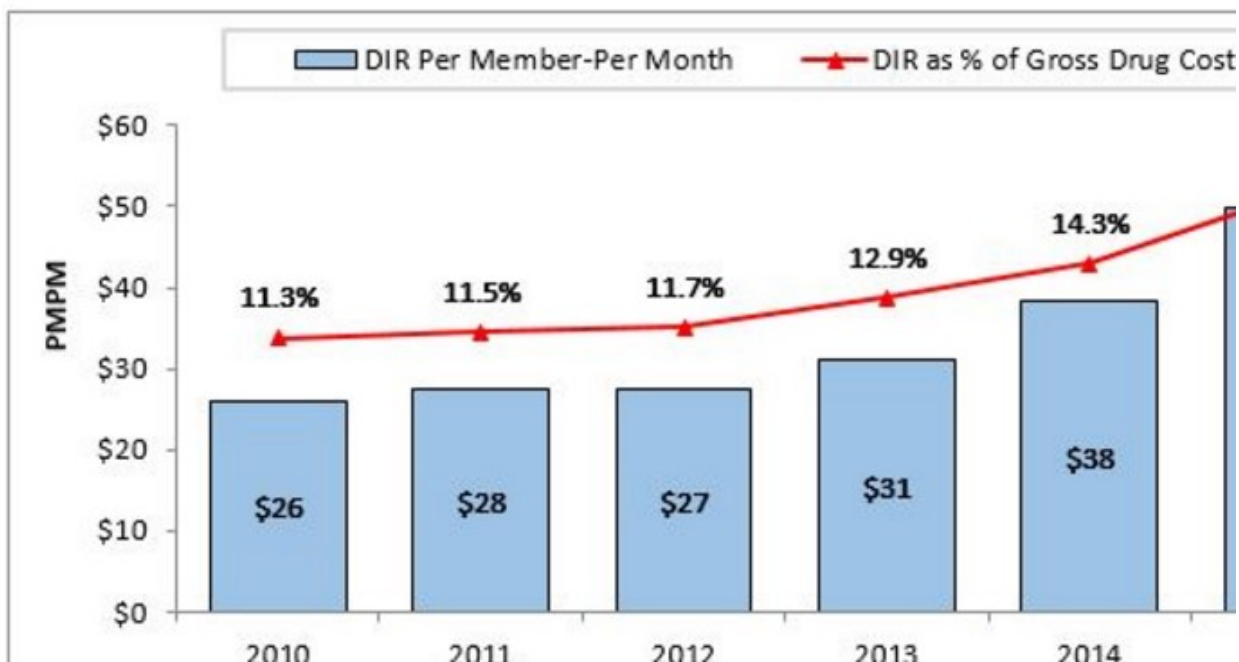
The Wakely client averages are based on all individual Part D bid filings for plans with experience that was at least 90% credible, based on the CMS formula (credibility % =  $\text{SQRT}(\text{member months} \div 18,000)$ ). We further limited the bids used by excluding all special needs plans (i.e. dual eligible SNPs and chronic condition SNPs).

### **National Averages**

#### *CMS Fact Sheet*

Recently, CMS released a Fact Sheet demonstrating significant growth in DIR in 2010 through 2015. Nationally, the average DIR PMPM and DIR as a percentage of gross drug costs has gone up since 2012, as shown in CMS's Figure 1:

Figure 1 – DIR by Payment Year



Source: <https://www.cms.gov/newsroom/mediareleasedatabase/fact-sheets/2017-fact-sheet-items/2017-01-19-2.html>

Not only have the costs been increasing, but the growth has been accelerating.

The impact of these increasing DIR amounts that CMS describes is similar to our analysis in the “Impact of DIR by Party” section earlier in this report. CMS notes that DIR does not reduce the cost of drugs at the point-of-sale; therefore potentially increasing beneficiary out-of-pocket costs. On the other hand, plan sponsors are seeing reduced plan liabilities as a result of increased DIR. In particular, high cost specialty drugs often coupled with high rebates have pushed more beneficiaries into the catastrophic phase of the Part D benefit, where plans are only responsible for approximately 15% of costs. The result is that the high-price, high-DIR trend disproportionately reduces plan liability.

Figure 3 from the CMS Fact Sheet shows a downward trend in plan liability as DIR has increased. It also shows that federal reinsurance spending has continued to increase even though DIR allocated to federal reinsurance has also increased.

Figure 3 – Final Annual Medicare Reinsurance and Plan Liability per Beneficiary<sup>[2]</sup>



Source: <https://www.cms.gov/newsroom/mediareleasedatabase/fact-sheets/2017-fact-sheet-items/2017-01-19-2.html>

Finally, the Fact Sheet also acknowledges that low-income cost-sharing payments are higher with the increased use of DIR since the benefits of reduced drug costs do not occur at the point-of-sale and thus are not shared with CMS in these instances.

#### *MedPac Reports and the National Average Part D Bid*

There are some other national measures that also point to increased amounts and usage of DIR in Part D.

First, the March 2016 MedPAC report<sup>14</sup> reported the DIR as a percentage of total allowed Part D costs have increased significantly from 2007 through 2015. Table 3.3 shows these statistics.

<sup>14</sup> Medicare Payment Advisory Commission, Report to the Congress: Medicare Payment Policy, March 2016; <http://www.medpac.gov/docs/default-source/reports/march-2016-report-to-the-congress-medicare-payment-policy.pdf?sfvrsn=0>

<b>Table 3.3</b> <b>DIR Projected in Medicare Part D Bids</b> <b>Nationwide Average</b>		
<b>Experience Year</b>	<b>DIR<sup>1</sup> as % of Allowed</b>	<b>Annualized Increase</b>
2007	9.6%	
2013	12.9%	5.0%
2014	14.4%	11.6%
2015	16.6%	15.3%
[1] Labeled "Rebates" in MedPAC report		

Similar to the CMS Fact Sheet and Wakely client averages, the MedPac reported data shows an acceleration in the amount of DIR used in the Part D program.

Second, though not explicit, increased DIR may be a cause of the counter-intuitive decreasing trend in the National Average Bid Amount (NABA) for Part D bid in recent years. The NABA represents a member-weighted average of all MA-PD and PDP plans' estimate to cover the defined standard benefit in a given year. Table 3.4 shows the NABA since 2011.

<b>Table 3.4</b> <b>History of National Average Bid Amount</b>		
<b>Year</b>	<b>NABA</b>	<b>Trend</b>
2011	\$84.50	
2012	\$87.05	3.0%
2013	\$79.64	-8.5%
2014	\$75.88	-4.7%
2015	\$70.18	-7.5%
2016	\$64.66	-7.9%
2017	\$61.08	-5.5%

Table 3.4 shows a clear pattern of the NABA decreasing each year since 2012. There are many factors that influence the NABA such as the parameters underlying the defined standard benefit, trends in drug prices, the mix of brand versus generic drug usage, contracts negotiated between carriers and PBMs, the changing membership by carrier which drives the weighted average, and other factors. Given all of these potential drivers, it is more difficult to confidently say that increased DIR is a cause; however, there are at least some reasons to think it is a reasonably possibility:

- The defined standard benefit parameters have generally kept pace with drug cost inflation, and in recent years have actually contributed to positive expected trend in the defined standard benefit due to the increased plan liability in the gap imposed by the Affordable Care Act.
- In every year since 2012, UnitedHealth Group, Inc., Humana Inc., and CVS Health Corporation have captured about 50% of the total Part D marketplace, so a significant portion of the NABA is driven by the same carriers each year. Given that it is unlikely these carriers are able to negotiate increasing discounts each year, it also seems very plausible that increased use of DIR is a major contributing factor – both in terms of the amount and in terms of additional forms or drug reimbursement being classified as DIR.
- Total drug cost trends have been non-negative over this time period. The annual Express Scripts Drug Trend Report showed flat or positive trend over 2013 through 2015. Table 3.5 shows these estimated trends.

Table 3.5			
Express Scripts Medicare Drug Trends <sup>15</sup>			
Year	Traditional	Specialty	Total
2015	4.80%	27.90%	10.90%
2014	6.40%	45.90%	13.80%
2013	0.00%	14.70%	2.60%

Although the very high specialty drug trends have a diluted impact on the defined standard benefit (i.e. because plan liability is very much reduced above the initial coverage limit and in the catastrophic benefit phase), even the traditional, non-specialty drug trends have been positive.

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<sup>15</sup> Express Scripts 2015 Drug Trend Report, March 2016; The 2014 Drug Trend Report, Express Scripts, March 2015; The 2013 Drug Trend Report, Express Scripts, April 2014



## 4) CONCLUSIONS

Trying to ascertain the impact of DIR on the Part D and its various invested parties is a broad and complicated task. This report has analyzed several aspects of this question, and we believe the following conclusions can be made.

- The amount of DIR reported in Medicare Part D bids has steadily increased since the inception of the Part D program. Based on Wakely client data, there appears to be an acceleration in the amount of DIR in 2015 and projected DIR in 2017 bids. Recent downward trends in the national average Part D bid also support the idea that DIR is increasing.
- The trade-off between equivalent amounts of DIR versus point-of-sale discounts is financially advantageous to Part D sponsors except in limited situations. The mechanics of the bid form produce a lower bid if DIR is favored over discounts, and Part D sponsors will most typically desire a lower bid in order to offer a more competitive product and gain market share. Favoring DIR over discounts also means that Part D sponsors will share price concessions only with CMS rather than CMS, drug manufacturers, and beneficiaries (claimants). Also, sponsors will fare better using DIR under all scenarios where a risk corridor payment is made, regardless whether the sponsor pays CMS or CMS pays the sponsor.
- From a cost-sharing perspective, beneficiaries are worse off if the Part D sponsor favors DIR over discounts. This is not the entire story; however, as use of DIR will ultimately result in lower premiums or enhanced benefits for beneficiaries. Given these opposite impacts, the net effect is essentially that use of DIR has some positive impact on all members of the plan while having a negative impact on individuals with Part D claims.
- CMS will pay out the same or more in low-income cost-sharing if sponsors favor DIR. On the other hand, CMS is likely better off on balance from a low-income premium subsidy and risk corridor perspective if plan sponsors favor DIR. CMS is not consistently better or worse off in terms of direct subsidy or federal reinsurance payments if Part D sponsors favor DIR.
- The primary difficulty for pharmacies is a lack of transparency in claims, which makes it difficult to estimate cash flows, budget for the future, and evaluate proposed contracts from PBMs. The increased use of DIR compounds these issues even further.
- There appears to be inconsistent practices of what reimbursement is reported as DIR versus inclusion in the PDE reports. The broad range of types of DIR, uncertainty in their definitions, and allocation decisions that have a wide range of interpretation are contributing factors to this inconsistency.
- We believe there is a disconnect between the projected DIR submitted in Part D bids and the DIR submitted to CMS in the Summary and Detailed DIR reports. Given plans' confusion as to what to report as DIR, and the lack of audit oversight by CMS, it is possible that the assumptions used in bids may not reconcile well with the values in the DIR reports. This disconnect presents a risk that Part D sponsors will be more or less aggressive in submitting bids as compared with actual DIR.

## **Appendix A**

### **Part D Defined Standard Benefit and Claim Obligations of CMS and Beneficiaries**

The Medicare Part D benefit arose from the 2003 Medicare Prescription Drug Benefit, Improvement and Modernization Act (Medicare Modernization Act, or MMA). Benefits were first made available in 2006, and included prescription drug coverage for Medicare beneficiaries who enrolled in Prescription Drug Plans (PDPs) or Medicare Advantage plans offering a Part D benefit (MA-PD). Coverage for prescription drugs was not added to the “Original Medicare” benefit.

### **Defined Standard Benefit**

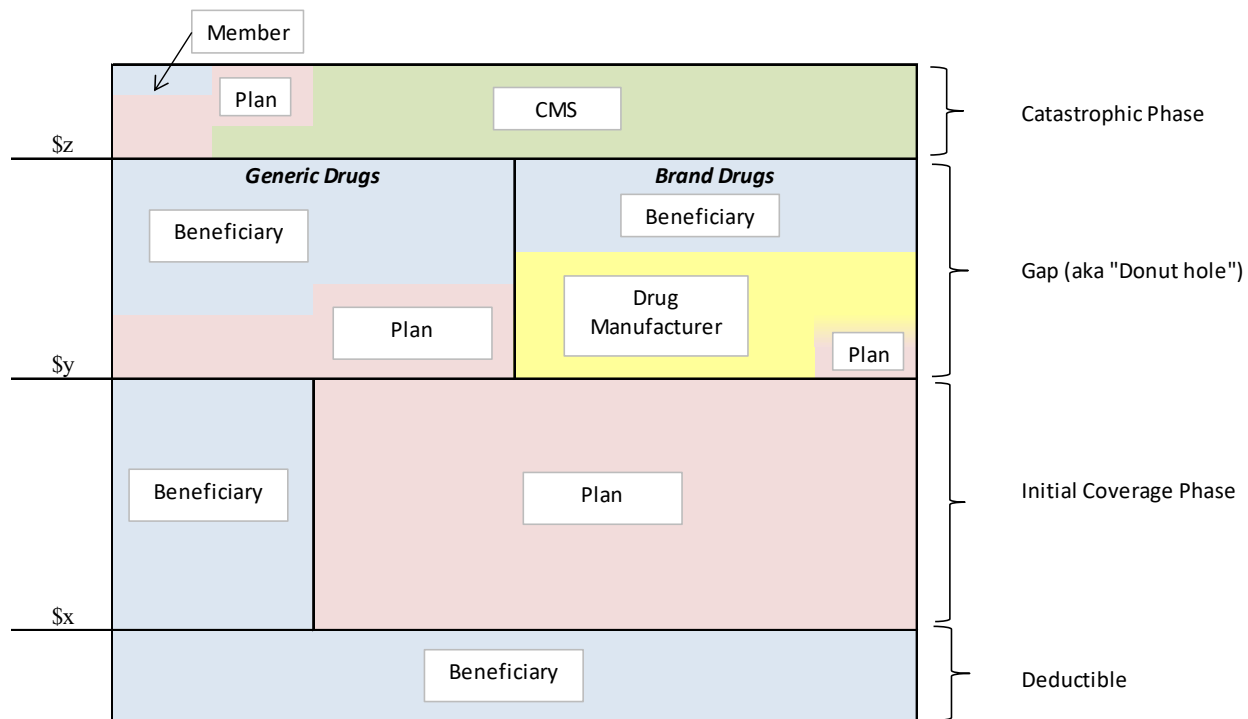
The MMA established a “defined standard” benefit that all PDP and MA-PD plans must offer at a minimum. The federal government, through the Centers for Medicare and Medicaid Services (CMS) would provide prospective funding for a portion of the defined standard benefit and also be responsible for 80% of all claim liabilities after a beneficiary reached a designated out-of-pocket maximum.

The defined standard benefit has followed the same basic structure since 2006, with some adjustments imposed by the Affordable Care Act, and is defined as follows:

- The beneficiary is responsible for all initial expenses up to a deductible (for 2017, it is \$400).
- The beneficiary and PDP/MA-PD plan share all expenses on a 25%/75% basis for all covered Part D drug expenses between the deductible and an initial coverage limit (“ICL”, which was \$3,700 for 2017).
- Expenses above the ICL are shared between the beneficiary, the PDP/MA-PD plan, and drug manufacturers until the beneficiary reaches a catastrophic True Out-of-Pocket (TrOOP) limit. The beneficiary’s cost-sharing depends on whether the drug is generic or brand and whether the beneficiary is low-income (LI) or non-LI. For generic drugs, a non-LI beneficiary is responsible for a portion of total expenses on a schedule that grades down to ultimately be 25% in 2020. For 2017, the percentage is 51%. For brand drugs incurred by a non-LI beneficiary, drug manufacturers must pay 50% of the negotiated drug cost, with the beneficiary and PDP/MA-PD plan splitting the remaining 50% on a schedule that again ultimately has the beneficiary paying 25% by 2020. For 2017, the brand drug coinsurance split between beneficiary and plan is 40% and 10%, respectively. For LI members, the member is responsible for 100% of the cost in the coverage gap, which is heavily subsidized by low-income cost-sharing subsidies.

Exhibit 1.1 below shows a graphic of which party is responsible at different levels of total Part D claim spend.

**Exhibit 1.1**  
**CMS Defined Standard Part D Drug Benefit**  
**Non Low-Income Member**



### Direct Subsidy

The prospective payment amount paid by CMS is called the “direct subsidy” and is determined as: Plan-specific 1.00 “Basic Bid” x Part D Risk Score – Basic Premium, where:

- The 1.00 Basic Bid is the PDP or MA-PD estimate of the expected claim expenses, administrative expenses, and profit to cover the plan liabilities of the defined standard benefit or a basic benefit that is actuarially equivalent to the defined standard benefit (i.e. the pink portions of Exhibit 1.1) for a member with a Part D risk score of 1.00.
- Basic Premium is the 1.00 Bid for the PDP or MA-PD less the national average bid plus the national base beneficiary premium, where:
- Base Beneficiary Premium is 25.5% of (National Average Bid + National Average Value of Federal Reinsurance).
- The Direct Subsidy is then equal to the 1.00 Bid multiplied by the risk score, less the Basic Premium.

Table 1 shows a hypothetical example for ABC MA-PD Plan:

<b>Table 1</b> <b>Plan ABC Part D Bid</b> <b>Calculation of Direct Subsidy</b>	
a. Expected Part D Risk Score for Covered Population	1.05
b. ABC Estimated Cost to Cover Defined Standard Benefit	\$57.00
c. ABC Non-Benefit expenses	\$14.00
d. ABC Target Profit (5.0%)	\$3.74
e. Basic Bid (b+c+d)	\$74.74
f. Basic Bid at 1.00 (e/a)	\$71.18
g. National Average Bid	\$61.08
h. National Base Beneficiary Premium	\$35.63
i. Basic Premium* (f-g+h)	\$45.73
j. Direct Subsidy (e-i)	\$29.01

\*Ignoring premium rounding

## Risk Corridor

Originally designed as a means to encourage Part D sponsors to participate in the program, CMS established a risk-sharing mechanism where plans that experienced actual claim costs that were significantly different from the expected values filed in Part D bids would share in gains or losses on a pro-rata basis with CMS. This was called the “risk corridor”, and has remained in place since 2006 (although the specific parameters changed once). The thresholds defining when risk sharing occurs increased in 2008 and have stayed the same ever since, even though CMS has had the authority to increase the threshold percentages further since 2012.

The graphic below shows the current risk corridor provisions, which have been in place since 2008.

