The AIDS Institute

Financial Incentives in Medicare Part D

Prepared by:
Milliman, Inc.

Adam J. Barnhart, FSA, MAAA
Consulting Actuary

Jason Gomberg, FSA, MAAA
Consulting Actuary

15800 Bluemound Road
Suite 100
Brookfield, WI 53005
USA
Tel +1 262 784 2250
Fax +1 262 923 3680

milliman.com

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I. EXECUTIVE SUMMARY

The unique nature of the Medicare Part D market and benefit design magnifies a plan's financial incentives to seek high rebates. As a result, many carriers seeking to target the lowest possible beneficiary premium have found that medications with higher point-of-sale (POS) prices and post POS rebates may actually be preferred financially relative to medications with lower POS prices. In this report, we look at three Part D market scenarios to illustrate the trade-off between POS price and rebates:

- The first scenario examines a beneficiary with $200 of total monthly generic medication spend. We compared the financial impacts to the Part D stakeholders if this beneficiary alternatively took $1,000 per month of brand medications with a total of $250 rebate post-POS. Under the defined standard Part D benefit, the brand medication would increase the beneficiary cost sharing while reducing the plan liability net of rebates.

- The second scenario examines a beneficiary taking a high-cost specialty medication ($50,000 per year). Similar to the first scenario, if the manufacturer offered a larger post POS rebate and a higher POS price, the plan liability net of rebates would decrease while the Medicare beneficiary cost-sharing would increase. Because of the Part D financial dynamics, the impact can be so significant that the plan sponsor could incrementally receive more money in rebates and federal reinsurance than it is responsible for (i.e., a negative net plan liability) when covering certain high cost drugs.

- The third scenario examines a beneficiary with the choice between a biosimilar medication and a similar branded specialty medication, priced at $4,000 per month. For Medicare, most newly available biosimilar medications are expected to be treated like a generic product for beneficiary cost-sharing purposes within the Medicare benefit and not participate in the coverage gap discount program (CGDP). Most expect the biosimilar to be priced 15% to 25% below the brand counterpart with potentially lower rebates. If the plan will get both lower rebates and there is no CGDP, the biosimilar will likely be at a disadvantage from both the beneficiary and plan sponsor perspective, despite being priced 15% less than the branded medication.

The above examples illustrate how the lowest POS medication is not necessarily the preferred financial choice for a plan sponsor focused on having the lowest premiums. The first two examples also illustrate that beneficiary cost sharing increases if the plan chooses the option with the lowest plan liability.

This report is focused on the point-of-sale beneficiary cost sharing for beneficiaries taking a particular medication and does not comment on the potentially offsetting impact to overall beneficiary premiums that are expected because of the change in plan liability and federal reinsurance.

There are strong incentives for many plans to provide benefits at the lowest premium, as this allows them to be competitive in the market and attract the most beneficiaries. Many plans' strategy includes qualifying for subsidized low income beneficiaries that are auto-assigned to plans whose premium falls below a low income premium benchmark in each Part D region. These incentives may drive plans to seek high rebates rather than seek the lowest POS price when selecting drug coverage.

While the trade-off between POS price and rebates can be simplified through examples, keep in mind that many of the contracts between the pharmaceutical manufacturers and health plans are complex, with many considerations involved in developing the contractual relationships. The examples selected were chosen to highlight extreme differences, but the issues will persist under a variety of situations.

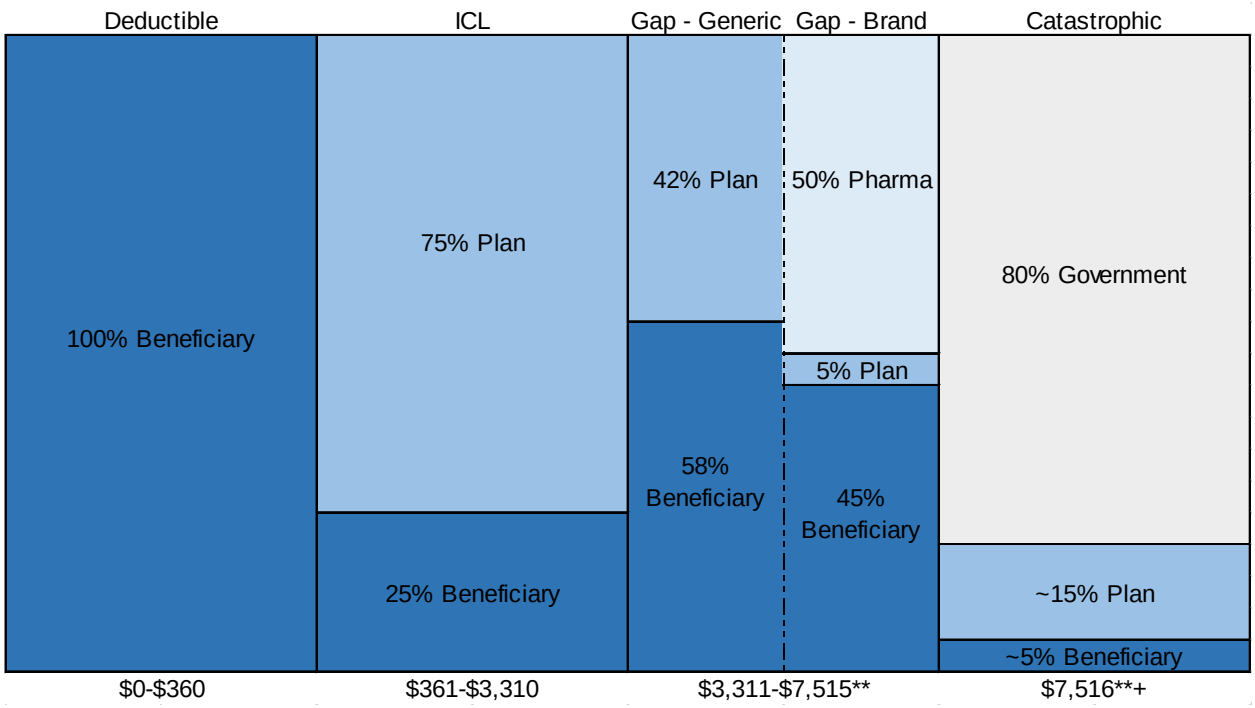
II. BACKGROUND ON MEDICARE PART D BENEFITS

Medicare Part D was introduced in 2006 as a program to fund the growing cost of pharmacy benefits, for which traditional fee-for-service Medicare did not provide coverage. Medicare Part D is managed by the Centers for Medicare and Medicaid Services (CMS) and is considered by many to have been a successful government program since its inception, with government costs emerging lower than originally projected.[1] The major financial stakeholders in the Medicare Part D market include the plan sponsor, beneficiaries, pharmaceutical companies (Pharma), and the federal government.

The defined standard benefit plan in Medicare Part D is unique and fairly complex, consisting of several benefit phases (i.e., the deductible, initial coverage limit [ICL], coverage gap, and catastrophic phases). The allowed medication cost is divided up amongst the various Part D payers at differing rates throughout the Part D benefit. Allowed medication cost is net of any contractual discounts, and will be referred to simply as medication cost or cost from here on.

The cost that each of the major stakeholders is responsible for in each benefit phase is shown in Table 1 for non-low income beneficiaries.

Table 1
Distribution of Spend in Part D Benefit Phases by Payer in 2016*



**Excludes rebates which are outside of phasing*
***Actual amount will vary based on beneficiary spend*

[1] Congress of the U.S. Congressional Budget Office (2014) *Competition and the Cost of Medicare's Prescription Drug Program*. Retrieved October 4, 2016, from https://www.cbo.gov/publication/45552.

In terms of stakeholders:

- The portion the beneficiary is responsible for is called beneficiary cost-sharing.
- The portion paid for by the government in the catastrophic phase is called the federal reinsurance subsidy.
- The portion Pharma is responsible for in the coverage gap is called the CGDP.

The Patient Protection and Affordable Care Act (ACA) introduced several provisions to help eliminate the Part D coverage gap and leave beneficiary cost-sharing at a similar level as the ICL (for Part D beneficiaries not otherwise receiving government cost-sharing subsidies). The CGDP started in 2011 under the ACA, where participating pharmaceutical manufacturers contribute 50% of the price of their products while non-low income beneficiaries are in the coverage gap (i.e., the donut hole). The beneficiary responsibility in the gap is decreasing annually, such that in 2020, the beneficiary will only be responsible for 25% of the medication cost in the gap (same as the ICL cost-sharing).

Part D classifies beneficiaries as either non-low income or low income (those below 150% of the federal poverty line). Low income beneficiaries have a majority of their cost-sharing and premium paid for by the federal government through the low income cost-sharing and low income premium subsidies. In this report, beneficiary cost sharing and beneficiary premium refer to cost sharing and premium from a non-low income beneficiary's perspective (i.e., inclusive of all low income subsidies).

Pharma also provides plan sponsors with rebates for some brand medications. These rebates reduce the plan sponsor and the federal reinsurance subsidy liability and help lead to lower premiums for all beneficiaries, but do not impact the cost-sharing for either the beneficiary taking the medication or the CGDP. Table 2 illustrates the cash flow from the starting cost for each of the stakeholders. The example uses a representative sample of 2016 medication costs and adjudicates the benefit based on the defined standard benefit phases above.

Table 2
Summary of Annual Cost Sharing by Payer for an Illustrative Beneficiary with Average Costs

Item	Cost Type	Formula	Annual Amount
A	Medication Cost	N/A	3,000
B	Beneficiary Cost-Sharing	N/A	675
C	CGDP	N/A	300
D	Reinsurance Before Rebates	N/A	960
E	Plan Liability Before Rebates	A – B – C – D	1,065
F	Total Rebates	N/A	450
G	Rebates for Federal Reinsurance	F * D / A	144
H	Rebates for Plan Sponsor	F – G	306
I	Net Plan Sponsor Liability	E – H	759
	Total Paid by Payer		
	Pharma	C + F – A	**-2,250**
	Beneficiary	B	**675**
	Federal Reinsurance	D - G	**816**
	Plan Sponsor	I	**759**

** Assumes non-low income beneficiary, with no plan administrative costs or profit.*
*** Pharma for this illustration assumes both manufacturers and distributors.*
****Total Paid by Payer represents revenue for Pharma, and costs for the other payers.*

The amount of rebates shared with the government is proportional to the amount of federal reinsurance paid by the government. The government retains rebates equal to the ratio of the total amount of reinsurance over the total medication cost, with the plan retaining the remainder. In the example summarized in Table 2, the government retains 32% ($960 / $3,000) of the rebates. The amount of rebates shared is the same for all of a plan's claims (i.e., the portion of rebates shared do not vary by medication based on the federal reinsurance and rebates associated with that particular medication).

The net plan liability in Table 2 (and in all examples in this report) is funded through beneficiary premium as well as a risk-adjusted direct subsidy from the federal government. As federal reinsurance and plan liability change, there are offsetting changes in beneficiary premium and direct subsidy. This report is focused on point-of-sale cost sharing net of rebates and does not comment on the offsetting impacts to beneficiary premium and direct subsidy payments.

III. ANALYSIS OF FINANCIAL INCENTIVES

CONTRACTING FOR HIGH COST BRAND MEDICATIONS

Inflation on the POS cost of brand medications has been more than 10% per year for the past several years according to the Express Scripts 2015 Drug Trend Report[2]. Given the increasing costs, plan sponsors or their pharmacy benefit managers try to negotiate substantial contractual discounts and rebates to reduce the plan sponsor liability. Pharmaceutical manufacturers are generally concerned with the net revenue collected and may be indifferent to whether price offsets come through a lower POS cost or higher rebates. However, due to the unique benefit design of Part D, the plan sponsor's liability can be greatly reduced by rebates paid post-POS. This is due to the POS price being shared with all of the Part D stakeholders, whereas rebates are shared only between the plan sponsor and the federal reinsurance subsidy, as illustrated in the examples below. Given this dynamic, rebates have a greater impact on reducing the plan sponsor liability and, therefore, premium, which impacts all beneficiaries, versus POS prices which impact the beneficiary cost-sharing.

Table 3 below illustrates the annual financial breakout for a beneficiary taking $200 per month of generic medications for treatment of a certain condition and a beneficiary taking $1,000 per month of brand medications with a $250 per month rebate for treatment of the same condition. Both scenarios assume the beneficiary is taking exclusively either the generic or the brand medication, and illustrate the difference in beneficiary cost.

Table 3
Summary of Annual Cost by Stakeholder for Illustrative Beneficiary Taking Either Generic or High Cost Brand Medications

Item	Cost Type	Formula	Generic Medications	Brand Medications	Difference
A	Medication Cost	N/A	2,400	12,000	9,600
B	Beneficiary Cost-Sharing	N/A	870	2,986	2,116
C	CGDP	N/A	0	1,817	1,817
D	Reinsurance Before Rebates	N/A	0	4,045	4,045
E	Net Plan Liability Before Rebates	A – B – C – D	1,530	3,153	1,622
F	Total Rebates	N/A	0	3,000	3,000
G	Rebates for Federal Reinsurance	F * (D / A)[1]	0	1,106	1,106
H	Rebates for Plan Sponsor	F – G	0	1,894	1,894
I	Net Plan Sponsor Liability	E – H	1,530	1,258	-272
	Total Paid by Payer[2]				
	Pharma	C + F – A	**-2,400**	**-7,189**	**-4,783**
	Beneficiary	B	**870**	**2,986**	**2,116**
	Federal Reinsurance	D - G	**0**	**2,939**	**2,939**
	Plan Sponsor	I	**1,530**	**1,258**	**-272**

[1] Uses the ratio of federal reinsurance to medication cost for the overall plan from Table 2 with an adjustment for the impact of the brand medication on the overall plan's ratio. This reflects the rebates for federal reinsurance for the brand medication net of the impact of the brand medication on retained rebates for all other drugs covered by the plan.
[2] Total Paid by Payer represents revenue for Pharma, and costs for the other payers.

In this example, the beneficiary pays approximately $2,000 more annually at the POS for the more expensive product, while the plan sponsor liability is slightly lower with the more expensive product.

[2] The Express Scripts Lab (2016). Express Scripts 2015 Drug Trend Report. Retrieved October 4, 2016, from https://lab.express-scripts.com/lab/~/media/e2c9d19240e94fcf893b706e13068750.ashx.

This scenario (as well as the two following) assumes that the change in rebates for the medications in the scenario does not impact the overall rebates received by the plan sponsor. In addition, the allocation of rebates between federal reinsurance and plan sponsor assumes this medication is used by less than 1 in every 100 beneficiaries, which is also true for all subsequent examples.

CONTRACTING FOR HIGH COST MEDICATIONS

Within the last few years, a number of high-cost medications have come on to the market. In Medicare Part D, plan sponsors have an incentive to prefer higher-priced medications that offer significant rebates over lower-priced medications with smaller rebates, all else being equal. If the rebate on a high-cost medication is sufficient, the plan sponsor's portion of the claim may actually be negative, meaning that the beneficiary cost-sharing, federal reinsurance, and CGDP pay for more than 100% of the net cost of the medication.

Table 4 illustrates a scenario where one person is taking a $50,000 medication without any rebates as part of treatment of a certain condition and the other person is taking a $100,000 per year medication with a $50,000 rebate for treatment of the same condition.

Table 4
Summary of Annual Cost by Stakeholder for Illustrative Beneficiary Taking High-cost Specialty Medications

Item	Cost Type	Formula	$50,000 No Rebate	$100,000 With Rebate	Difference
A	Medication Cost	N/A	50,000	100,000	50,000
B	Beneficiary Cost-Sharing	N/A	4,886	7,386	2,500
C	CGDP	N/A	1,817	1,817	0
D	Reinsurance Before Rebates	N/A	34,445	74,445	40,000
E	Net Plan Liability Before Rebates	A – B – C – D	8,852	16,352	7,500
F	Total Rebates	N/A	0	50,000	50,000
G	Rebates for Federal Reinsurance	F * (D / A)[1]	0	19,879	19,879
H	Rebates for Plan Sponsor	F – G	0	30,121	30,121
I	Net Plan Sponsor Liability	E – H	8,852	-13,769	-22,621
	Total Paid by Payer[2]				
	Pharma	C + F – A	**-48,183**	**-48,183**	**0**
	Beneficiary	B	**4,886**	**7,386**	**2,500**
	Federal Reinsurance	D – G	**34,445**	**54,566**	**20,393**
	Plan Sponsor	I	**8,852**	**-13,769**	**-22,621**

[1] Uses the ratio of federal reinsurance to medication cost for the overall plan from Table 2 with an adjustment for the impact of the brand medication on the overall plan's ratio. This reflects the rebates for federal reinsurance for the brand medication net of the impact of the brand medication on retained rebates for all other drugs covered by the plan.
[2] Total Paid by Payer represents revenue for Pharma, and costs for the other payers.

In the scenario with the $100,000 priced medication the beneficiary cost-sharing is $2,500 higher, the federal reinsurance is $20,000 higher, and the plan sponsor is paying about $23,000 less. In fact, the plan sponsor actually would receive more money in rebates than the plan sponsor covers in cost sharing.

CONTRACTING FOR BIOSIMILAR MEDICATIONS

Biologic specialty medications are starting to see competition in the market in the form of biosimilars. Biosimilars are similar to a generic medication in that they replicate an off-patent brand medication; however, the biosimilar does not have the exact same chemical make-up of the original brand medication because the biologic molecules can be more difficult to replicate exactly. Many stakeholders in the pharmaceutical industry believe biosimilar competition will help lead to significant savings.[3]

Within a year of introduction, many generic medications are typically discounted at 90% or more of the cost of the original brand medication. Since biosimilars are more difficult to both replicate and manufacture, the first biosimilars produced have been priced much closer to the price of the innovator brand product, around 15% less[4]. Many of the biosimilars being announced are in drug classes with high-cost medications and can be close to $4,000 per month.

Under current regulations, most new-to-market biosimilars are treated as generic medications for Medicare Part D in terms of beneficiary cost-sharing. This also means that pharmaceutical manufacturers do not have to pay the CGDP for them. Generic medications also typically do not use rebates, however, biosimilars are expected to provide rebates and behave more like a brand medication.

Table 5 illustrates the cost challenges a biosimilar faces in the Part D market. The first scenario shows how the current brand medication is financed if it has a $4,000 per month price with a 20% rebate, and how it will compare to a biosimilar priced at $3,400 per month with a 20% rebate.

Table 5
Summary of Annual Cost by Payer for Illustrative Beneficiary Taking Brand Versus Biosimilar Medications

Item	Cost Type	Formula	Brand	Biosimilar	Difference
A	Medication Cost	N/A	48,000	40,800	-7,200
B	Beneficiary Cost-Sharing	N/A	4,786	6,127	1,341
C	CGDP	N/A	1,817	0	-1,817
D	Reinsurance Before Rebates	N/A	32,845	25,230	-7,615
E	Net Plan Liability Before Rebates	A – B – C – D	8,552	9,443	891
F	Total Rebates	N/A	9,600	8,160	-1,440
G	Rebates for Federal Reinsurance	F * (D / A)[1]	3,072	1,815	-1,257
H	Rebates for Plan Sponsor	F – G	6,528	6,345	-183
I	Net Plan Sponsor Liability	E – H	2,024	3,098	1,074
	Total Paid by Payer[2]				
	Pharma	C + F – A	**-36,583**	**-32,640**	**3,943**
	Beneficiary	B	**4,786**	**6,127**	**1,341**
	Federal Reinsurance	D – G	**29,773**	**23,415**	**-6,358**
	Plan Sponsor	I	**2,024**	**3,098**	**1,074**

[1] Uses the ratio of federal reinsurance to medication cost for the overall plan from Table 2 with an adjustment for the impact of the brand medication on the overall plan's ratio. This reflects the rebates for federal reinsurance for the brand medication net of the impact of the brand medication on retained rebates for all other drugs covered by the plan.
[2] Total Paid by Payer represents revenue for Pharma, and costs for the other payers.

[3] Mulcahy, Andrew W.; Predmore, Zachary; and Mattke, Soeren (2014). *The Cost Savings Potential of Biosimilar Drugs in the United States.*
[4] Rockoff, Jonathan D. (2016). *Knockoffs of Biotech Drugs Bring Paltry Savings.* Retrieved October 4, 2016, from http://www.wsj.com/articles/knockoffs-of-biotech-drugs-bring-paltry-savings-1462458209.

The beneficiary and plan sponsor pay more for the biosimilar medication, despite the fact that the total net price of the medication is 15% below the innovator brand product. The beneficiary and plan sponsor pay less with the innovator brand medication, partially due to the CGDP paid by Pharma through the gap phase. The amount of cost passed to the government through federal reinsurance increases with the innovator brand medication due to the higher cost product being purchased and because CGDP counts as a beneficiary's contribution to the out-of-pocket maximum.

IV. CAVEATS, LIMITATIONS, AND QUALIFICATIONS

Adam J. Barnhart and Jason Gomberg are consulting actuaries with Milliman, Inc., members of the American Academy of Actuaries, and meet the Qualification Standards of the Academy to render the actuarial opinion contained herein. To the best of our knowledge and belief, this report is complete and accurate and has been prepared in accordance with generally recognized and accepted actuarial principles and practices.

The information in this report is intended for the use of The AIDS Institute to provide assessment better understanding of the financial incentives created by rebates and the benefit structure in Medicare Part D. It may not be appropriate and should not be used for other purposes.

This report may be distributed publicly at the discretion of The AIDS Institute. If shared externally, the report should be shared in its entirety unless otherwise approved by Milliman. We do not intend this information to benefit, or create a legal liability to, any third party, even if we permit the distribution of our work product to such third party.

Actual results may differ from those in this report due to several factors, including but not limited to different trends, changes in demographics, differences in benefit design, and changes to the Part D program. Results would be different using a different set of medications for each example, and will vary by year due to mandated changes to the standard Part D benefit design. The AIDS Institute may consider monitoring emerging results to better understand the cost difference between the intervention and control populations.

Our assessment is based on publicly available information from CMS. We accepted this information without audit, but reviewed the information for general reasonability and consistency. If the underlying data or information is inaccurate or incomplete, the contents of this report along with many of our conclusions, may likewise be inaccurate or incomplete.

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