Impact of offsetting midyear list price and rebate reductions in Medicare Part D

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Midyear drug price reductions, offset by reduced manufacturer rebates resulting in the same net price, would result in lower Part D patient out-of-pocket costs but could result in additional unintended financial consequences to other Part D stakeholders, including increased costs to the federal government.

Over the past several years, high drug prices in the United States have garnered increased attention from both the public and policy makers. Medicare Part D, in particular, has drawn attention due to its complex ecosystem and how rebates affect each of the stakeholders. The White House, both chambers of Congress, and many prominent researchers are exploring ways to manage increasing drug costs while also increasing price transparency for both patients and taxpayers within Part D. On February 6, 2019, the U.S. Department of Health and Human Services (HHS) issued a proposed rule that would eliminate the current safe harbor to the Anti-Kickback Statute, which allows manufacturers to provide rebates to plans and pharmacy benefit managers (PBMs), and creates a new safe harbor that would force the rebates to be passed through to the point of sale (POS).

In response to the many proposals, requests for information, and public pressure surrounding list prices and rebates, some manufacturers have preemptively decreased list prices on popular brand drugs. ^{2,3,4,5} List price reductions can be effectuated in several ways, including the launch of an authorized generic, the release of a new package for an existing identical product, or a complete reduction in list price on an existing product. In the case of the addition of new products, as in the authorized generic or new package scenarios, plan sponsors may choose which version of a given drug they cover, and may sometimes choose to retain coverage on the drug with the higher list price if rebates on that drug result in more favorable economics for the plan.

VOCABULARY QUIZ: LIST PRICE, NET PRICE, REBATES

We use the following terms frequently throughout this paper in reference to drug prices and payments made by drug manufacturers to health plans:

List price: Also known as *Wholesale Acquisition Cost* (*WAC*), the list price is a reference price for each drug set by the manufacturer. This price is often close to the cash price that would be paid by a patient at the pharmacy counter. Most rebates and discounts are set as a percentage of list price. Cost sharing paid by the beneficiary is generally based on this price.

Net price: This is the price ultimately paid by a Part D plan for a given drug, net of all rebates and other discounts. Usually, this price is lower than the list price of the drug. For brand drugs with rebates, net price is often substantially lower than the list price. Included in this cost is the amount paid by the patient in the form of cost sharing.

Rebate: Generally, a rebate is a payment made by the seller of a good or service to the buyer after the purchase has been made. In the case of prescription drugs (and in this paper), we are referring to payments made by pharmaceutical manufacturers and their pharmacy benefit managers (PBMs) in exchange for market share and/or favorable placement on a plan's formulary.

The structure of the Medicare Part D program produces interesting, and sometimes counterintuitive, financial outcomes when list prices are decreased and rebates are eliminated. In this paper, we analyze the impact of midyear drug list price reductions coupled with a reduction in rebates resulting in identical net price. These pricing actions could have more of a different impact on Part D plan sponsors and federal government expenditures than one might expect, particularly if these list price decreases were not anticipated at the time Part D plans set premiums in June of each year, for the following year. In particular, because beneficiary premiums and certain government subsidies are locked in for the year, stakeholders will experience a different impact of an unanticipated midyear price

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reduction than they would if the price reduction were announced prior to Part D plans setting premiums.

Impact of midyear list price reductions

While several existing reports outline impacts of requiring the sharing of rebates at the POS,^{7,8,9,10} we focus on the impact to stakeholders of a voluntary (and possibly unanticipated) midyear change in list price accompanied by an offsetting reduction in rebates. Because several manufacturers recently announced reductions in list price, likely in response to a combination of public pressure and the HHS Office of Inspector General (OIG) proposed rule, we believe this analysis to be especially timely.

In our analysis, we specifically estimate the potential financial impact in 2019 due to a reduction in list price offset by an identical reduction in rebates occurring at the midpoint of 2019 for two scenarios: an example therapeutic class with significant utilization and rebates equaling approximately half the list price, as well as the entire subset of brand drugs with manufacturer rebates. This differs from other POS rebate analyses because unanticipated midyear price reductions would likely not be accounted for in Part D bids, and may generate unexpected payments by the federal government.

Our analysis addresses the impact to Part D plans, Part D beneficiaries, the federal government, and pharmaceutical manufacturer payments to plans through rebates and the coverage gap discount program. The analysis does not address the impact to pharmacies, wholesalers, pharmacy benefit managers, or "supply-side" manufacturer impacts (i.e., the impact to fees and discount arrangements between manufacturers, wholesalers, and pharmacies).

Figure 1 outlines the potential one-year financial impact in 2019 of list price reductions occurring July 1, the midpoint of 2019, to beneficiaries, Part D plans, the federal government, and pharmaceutical manufacturers. This estimate assumes no other changes between the bid and actual results and is based on a mix of plan designs consistent with the actual national mix. Actual results will vary due to differences in rebate contracts between plans and other forces impacting each plan's claims relative to its individual Part D risk corridor target.

FIGURE 1: POTENTIAL 2019 ANNUAL COST IMPACT TO PART D STAKEHOLDERS OF LIST PRICE AND OFFSETTING REBATE REDUCTIONS OCCURRING JULY 1, 2019 (\$ IN BILLIONS)*

SCENARIO	PATIENT	GOV'T	MANUF	PLAN
LIST PRICE REDUCTION FOR DRUGS IN ILLUSTRATIVE CLASS ONLY	\$ (0.5)	\$ (0.3)	\$ (0.4)	\$ 1.2
LIST PRICE REDUCTION ON ALL BRAND DRUGS	\$ (0.5)	\$ 1.1	\$ (2.0)	\$ 1.3

^{*} Negative numbers indicate reduction in cost for stakeholder. Estimates assume no changes in stakeholder behavior and exclude impact for Employer Group Waiver Plans (EGWP) plans.

Patient cost includes member cost sharing. Government costs include reinsurance, risk corridor, and low-income cost-sharing subsidy payments. Manufacturer costs include coverage gap discount program payments. Plan costs include all other changes.

BENEFICIARIES

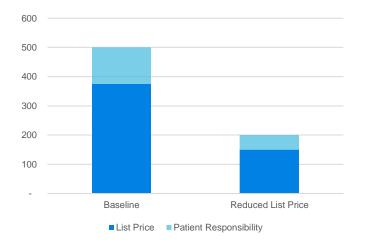
Non-low-income beneficiaries utilizing drugs with reduced list prices will see an immediate reduction in their cost sharing unless they are in the initial coverage period of their benefit and have a copay benefit for the utilized rebated drug.

Note that not all beneficiaries will be affected by list price reductions, because not all beneficiaries take brand drugs, and of those who take brand drugs, only those who take drugs that have list price reductions may be affected.

Low-income beneficiaries receive government subsidies to pay the majority of their cost sharing. These beneficiaries are unlikely to be directly impacted by list price changes.

Figure 2 contains an example of the potential impact to a non-low-income beneficiary taking a \$500 per month drug.

FIGURE 2: REDUCED LIST PRICE IN LIEU OF REBATES EXAMPLE



A patient with 25% coinsurance will pay \$125 on a \$500 brand drug as seen in the Baseline scenario above. If the list price is reduced by 60%, the new list price is \$200 and the new patient responsibility becomes \$50 as seen in the Reduced List Price scenario. However, members in plans with copays will see less savings as their copay amounts for each script are a flat fee and independent from the list price.

PART D PLANS

For 2019, Part D plans have already submitted their bids to CMS and cannot change their premiums to offset any unexpected change in plan liability, which could occur as a result of reduced list prices and/or reduced rebates. In the event a manufacturer or group of manufacturers drops the list price of their drugs while simultaneously reducing or eliminating rebates, plans could experience unexpected losses due to the loss in rebate revenue. List price changes could also affect plan cash flows and accruals, because certain revenue items are capitated by the federal government and settled in arrears. Reinsurance, low-income cost-sharing subsidy, risk corridor, and coverage gap discount program settlements could all be affected.

Risk protections in place in the Part D program may mitigate some of a plan's margin risk due to these changes, which would likely not be anticipated in their bid. Risk protection is provided to plans in the form of a government-funded risk corridor, which stipulates that plans and the federal government will share the risk (or benefit) of claims coming in higher (or lower) than indicated in their bids. This risk corridor only exists on the basic portion of the benefit, that is, the portion of plan costs that would have occurred if the plan had offered the defined standard benefit. In the event that claims deviate from target claims as calculated in the bid by more than 5%, the federal government will share in profits and losses with the plan. Note that basic claims will be more negatively impacted than supplemental claims because 100% of rebates are part of the basic benefit, while they would be split between basic and supplemental claims if rebates were instead moved to the list price.

Figure 3 illustrates the hypothetical per member per month (PMPM) impact to Part D plans for five illustrative plan designs of midyear price reductions and offsetting reduction in rebates for our illustrative therapeutic class. The illustrative examples below assume the national average mix of beneficiaries eligible for low-income (LI) subsidies and those who are not eligible within each plan design category. In each scenario, we estimate plans will see reduced retention (defined as revenue less claims expenses), which is offset by the risk corridor. As well, plans with higher LI enrollment have a larger impact due to LI members having more brand use and thus higher rebates on average.

FIGURE 3: ESTIMATED PMPM IMPACT TO PART D PLANS OF LIST PRICE AND OFFSETTING REBATE REDUCTIONS FOR AN ILLUSTRATIVE THERAPEUTIC CLASS OCCURRING JULY 1, 2019

PLAN TYPE	ALLOWED	RISK CORRIDOR	RETENTION + CORRIDOR	SETTLEMENT IMPACT
NON-SNP, BASIC ALTERNATIVE	-\$17.68	\$3.39	-\$4.10	-\$6.56
NON-SNP, ENHANCED (COINSURANCE)	-\$12.39	\$1.96	-\$3.18	-\$2.41
NON-SNP, ENHANCED (COPAYS)	-\$12.39	\$1.95	-\$1.65	-\$2.42
DUAL SNP, DEFINED STANDARD	-\$22.50	\$5.46	-\$5.04	-\$10.53
DEFINED STANDARD	-\$14.59	\$1.99	-\$3.34	-\$4.19

Figure 4 shows the results of a similar analysis; however, this analysis includes midyear list price reductions offset by a corresponding reduction in rebates for all brand drugs with rebates. Reducing list prices on all brand drugs with rebates has a similar net impact to plan retention as list price reductions to our illustrative therapeutic class; however, risk corridor amounts are significantly greater in this second scenario. In the case of the enhanced plan with copays, it is possible that plan retention is greater when all rebates move to the list price instead of only the illustrative class rebates because claims shifting in the benefit phases move costs from the supplemental benefit to the basic benefit, which is risk corridor-protected.

FIGURE 4: ESTIMATED PMPM IMPACT TO PART D PLANS OF LIST PRICE AND OFFSETTING REBATE REDUCTIONS FOR ALL REBATABLE BRAND DRUGS OCCURRING JULY 1, 2019

PLAN TYPE	ALLOWED	RISK CORRIDOR	RETENTION + CORRIDOR	SETTLEMENT IMPACT
NON-SNP, BASIC ALTERNATIVE	-\$54.57	\$13.76	-\$6.69	-\$19.48
NON-SNP, ENHANCED (COINSURANCE)	-\$38.25	\$11.16	-\$5.81	-\$11.43
NON-SNP, ENHANCED (COPAYS)	-\$38.25	\$11.15	-\$0.58	-\$10.67
DUAL SNP, DEFINED STANDARD	-\$69.43	\$21.54	-\$9.07	-\$30.81
DEFINED STANDARD	-\$45.02	\$11.16	-\$5.63	-\$13.07

In actuality, some plans will have better and some will have worse results based on other plan performance factors, including how their actual rebates compare to the change in list price.

PHARMACEUTICAL MANUFACTURERS

Reducing the list price of drugs will slow down the member progression through the coverage phases in Part D. This will reduce the number of beneficiaries who hit and/or exceed the initial coverage limit, as well as reduce the cost on each individual claim paid in the coverage gap on a rebated drug. This has the effect of reducing the amount of manufacturer responsibility for the Medicare Coverage Gap Discount Program (CGDP), because total program spending in the coverage gap would be reduced. As indicated in Figure 1, we estimate manufacturers could spend \$0.4 billion less on the CGDP under the first scenario (reduced prices on our illustrative class) and \$2.0 billion less under the second scenario (reduced prices on all brand drugs).

Decreasing the list price will have ripple effects in other markets for the manufacturer that the manufacturer will have to carefully consider, because a change in list price affects all sales as well as Medicaid best price, and not just Part D sales. As well, any list price change would have to affect all sales equally, whereas with rebates, some plans may have negotiated higher rebates than other plans.

FEDERAL GOVERNMENT

The federal government shares rebates with plans at a rate proportional to the government's reinsurance expenditure relative to a plan's total expenditure. In a scenario where manufacturers reduce list prices and substantially reduce or eliminate rebates, the government share of rebate revenue will also be reduced. Additionally, the federal government may experience an increase in risk-sharing expenses. Offsetting this loss in rebates and increase in risk-sharing expense, however, would be a reduction in government outlays for the federal reinsurance program as well as a reduction in low-income cost-sharing subsidies.

Figure 5 shows our estimates of the impact to federal expenditures under the two list price reduction scenarios.

FIGURE 5: ESTIMATED IMPACT OF LIST PRICE REDUCTIONS OCCURRING JULY 1, 2019 (\$ IN BILLIONS) TO FEDERAL GOVERNMENT PAYMENTS

	DIRECT			
	SUBSIDY &	LOW-INCOME	=	RISK
	LI PREM C	OST-SHARING	3	CORRIDOR
SCENARIO	SUBSIDIES	SUBSIDY	REINSURANCE	PAYMENTS
LIST PRICE REDUCTION ILLUSTRATIVE CLASS ONLY	-	(0.6)	(0.9)	1.2
LIST PRICE REDUCTION ON ALL BRAND DRUGS	-	(2.1)	(2.5)	5.7

OTHER CONSIDERATIONS

A market-wide set of actions taken by drug manufacturers to reduce list prices would be unprecedented in this industry of consistently increasing prices and actual changes may only occur with subsets of drugs. List price reductions could upend other portions of the pharmacy supply chain, including the wholesale industry, which captures fees based on a percentage of list price. Retail pharmacies and hospitals may also be impacted, as their drug purchasing is generally based on list prices.

Methodology and assumptions

We estimated the impact of reducing list prices and removing a corresponding amount of rebates for two scenarios. In one scenario, we removed estimated rebates and reduced list prices by a corresponding amount only for an illustrative class. In the other scenario, we eliminated rebates and reduced list prices by the estimated rebate amount for all brand drugs in all therapeutic classes. We assume list price reductions occur on July 1, 2019. We summarize the change in key values due to the reduced list prices and rebates. All estimates assume a formulary representative of a national carrier in 2019. Discounts and dispensing fees are set equal to the 50th percentile among Part D plans in 2019 based on internal Milliman surveys. The composite starting rebate is set equal to the 80th percentile among Part D carriers in 2019 from internal Milliman surveys. We estimate individual brand drug rebates using a combination of publicly available information and industry knowledge. Note that manufacturers could change list prices and still allow rebates to some plans. This scenario was not contemplated in our analysis. As well, the rebates and list price changes on this work are considered high-level estimates of the authors, as actual rebates are highly confidential and vary plan to plan.

The "Illustrative Class Rebates Removed" scenario reduces rebates in our illustrative class to zero while maintaining all other rebates. The illustrative therapeutic class includes brand drugs with list prices of approximately \$500 per monthly script, total costs averaging approximately \$20 per member per month, and rebates equal to about half of the list price. In addition to reducing rebates, we assumed the list price for each brand drug will be reduced by the amount of the lost rebate. Therefore, we discounted drugs in the illustrative class by the amount of the lost rebate such that the net price is the same in each scenario. We adjusted cost sharing accordingly, based on Part D payment mechanics.

The "All Rebates Removed" scenario methodology is the same as the "Illustrative Class Rebates Removed" with the exception that cost sharing and list prices reflect the reduction of all brand rebates to zero. Figure 6 depicts benefits used for each of the five example plan types.

FIGURE 6: ASSUMED BENEFIT DESIGNS AND LOW-INCOME PERCENTAGE

PLAN TYPE	LI %	DEDUCTIBLE	BENEFIT DESIGN
NON-SNP, BASIC ALTERNATIVE	59%	\$350, Tiers 3-5	\$2/\$10/\$40/45%/25%
NON-SNP, ENHANCED (COINSURANCE)	16%	\$150, Tiers 3-5	\$2/\$7/35%/45%/25%
NON-SNP, ENHANCED (COPAYS)	16%	\$0	\$0/\$10/\$47/\$100/33%
DUAL SNP, DEFINED STANDARD	98%	\$415, All Tiers	25%, All Tiers
DEFINED STANDARD	34%	\$415, All Tiers	\$25%, All Tiers

Limitations

This report was developed to help readers better understand the impact of potential midyear changes to rebates in the Medicare Part D program. This information may not be appropriate, and should not be used, for other purposes.

Milliman does not endorse any specific policy or regulatory action on matters discussed in this report.

In preparing our estimates, we relied on a Milliman database of Part D claims data as well as other internal and publicly available data sources. Actual results will certainly vary for specific health plans due to differences in demographics, trends, discount arrangements, formulary, utilization patterns, and rebate arrangements, among other factors.

The authors are actuaries for Milliman, 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 information is complete and accurate and has been prepared in accordance with generally recognized and accepted actuarial principles and practices.

This report outlines the review and opinions of the authors and not necessarily that of Milliman.



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Endnotes

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