MILLIMAN REPORT

Impact of Medicare Part D Drug Manufacturer Rebates at the Point of Sale

How Point-of-Sale Manufacturer Rebates Could Affect Stakeholder Costs

Commissioned by the Pharmaceutical Care Management Association (PCMA)

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Executive Summary

In May 2018, the Trump Administration released the American Patients First Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, which includes potential changes to the United States healthcare system aimed at "bringing down the high price of drugs and reducing out-of-pocket costs for the American consumer."[1] One potential change identified in the Blueprint is "requiring Medicare Part D plans to apply a substantial portion of rebates at the point of sale." Since then, the Trump Administration, the Centers for Medicare & Medicaid Services (CMS), and the Department of Health and Human Services (HHS) proposed changes to federal government programs, including Medicare Part D, aimed at addressing the stated goals in the President's Blueprint. In July of 2020, the Trump Administration issued an executive order on Lowering Prices for Patients by Eliminating Kickbacks to Middlemen, which indicates that HHS shall complete the process to "exclude […] retrospective reductions in price that are not applied at the point-of-sale" in Medicare Part D.[2] Prior to implementation, the executive order requires HHS to confirm the order is not projected to increase federal spending, beneficiary premiums, or patients' total out-of-pocket costs.[3]

KEY FINDINGS

The Pharmaceutical Care Management Association (PCMA) requested we estimate the ten-year (2022 to 2031) financial impact to key stakeholders of potentially reflecting drug manufacturer rebates at the point of sale (POS) in the Medicare Part D market. This is an update to a previously published report estimating the impact of proposed Medicare Part D program changes.[4] Most drug manufacturer rebates are currently applied as post-POS price concessions, meaning the rebate amounts are paid after drugs have been dispensed.[5] Under the proposed scenario, drug manufacturer rebates are instead used to reduce drug costs at the POS.

- This change would reduce cost sharing for certain beneficiaries and increase premiums and premium subsidies on average for most beneficiaries. In aggregate, we estimate the cost sharing savings would outweigh the beneficiary premium increase.
- This change could increase overall federal government costs by approximately 5% over ten years, primarily due to an increased risk-adjusted direct subsidy.
- This change could reduce drug manufacturer coverage gap discount program (CGDP) payments by approximately 35% over ten years, because fewer beneficiaries would reach the coverage gap phase due to lower POS costs and assuming the CGDP would be based on a lower POS cost.

It is unclear what terminology would be used to refer to these equivalent POS price concessions. In this report we use "drug manufacturer rebates at POS" to refer to reflecting current post-POS rebates at the POS. We assumed no behavioral changes among any stakeholders, though we expect stakeholders may change behaviors in some way.

ESTIMATED FINANCIAL IMPACT

Figure 1 illustrates the estimated cost (savings) from 2022 through 2031 of reflecting manufacturer rebates at the POS.

FIGURE 1: ESTIMATED TEN-YEAR (2022-2031) COST (SAVINGS) OF REFLECTING MANUFACTURER REBATES AT POS FOR THE INDIVIDUAL PART D MARKET[1, 2]

	BENEFICIARY PREMIUM	BENEFICIARY COST SHARING	FEDERAL GOVERNMENT	DRUG MANUFACTURER CGDP
Dollar Change (Billions)	$28.7	($43.0)	$59.5	($45.1)
Percent Change	16%	(12%)	5%	(35%)

[1] Impacts are relative to a baseline scenario in which drug manufacturer rebates are applied after the POS. Appendix I includes baseline values.

[2] The individual Medicare Part D market includes standalone prescription drug plans (PDPs) and Medicare Advantage plans providing drug coverage (MA-PDs), and excludes Employer Group Waiver Plans (EGWPs).

[1] The U.S. Department of Health and Human Services (May 2018). American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. Retrieved October 2, 2020, from: https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf

[2] The White House (July 24, 2020). Executive Order on Lowering Prices for Patients by Eliminating Kickbacks to Middlemen. Retrieved September 23, 2020, from: https://www.whitehouse.gov/presidential-actions/executive-order-lowering-prices-patients-eliminating-kickbacks-middlemen

[3] The White House (July 24, 2020). Executive Order on Lowering Prices for Patients by Eliminating Kickbacks to Middlemen, ibid.

[4] D'Anna, Samantha and Margiott, Tracy (April 5, 2019). Impact of Potential Medicare Part D Program Changes. Milliman report commissioned by the Pharmaceutical Care Management Association (PCMA). Retrieved October 2, 2020, from: https://www.pcmanet.org/wp-content/uploads/2019/04/Part-D-Program-Changes_FINAL.pdf

[5] In Medicare, drug manufacturer rebates and other price concessions applied after the POS are often referred to as direct and indirect remuneration (DIR).

The Figure 1 stakeholder cost estimates reflect the following:

- **Beneficiary.** The overall beneficiary impact is the sum of the beneficiary premium and cost sharing components. Beneficiary premium excludes the low income premium subsidy (LIPS), and beneficiary cost sharing excludes the low income cost sharing subsidy (LICS). These are subsidies paid by the federal government for low income (LI) beneficiaries and are included as federal government costs.
- **Federal government.** Includes the risk-adjusted direct subsidy, federal reinsurance, LIPS, and LICS. The direct subsidy is a risk-adjusted payment from CMS to plan sponsors to cover the portion of a plan sponsor's costs related to the defined standard benefit. The federal government covers 80% of beneficiaries' allowed costs in the catastrophic phase of the Part D benefit through federal reinsurance, reduced for a portion of post- POS price concessions that the plan sponsor collects on all drugs.
- **Drug manufacturer CGDP.** The drug manufacturer CGDP covers 70% of the cost of brand and biosimilar drugs in the coverage gap phase of the Part D benefit for non-low income (NLI) beneficiaries.

Beneficiaries, the federal government, and drug manufacturers through the CGDP are included in Figure 1 because these stakeholders fund the Medicare Part D program. There are other stakeholders that do not directly fund the program that may be affected by potential program changes, including plan sponsors, pharmacy benefit managers (PBMs), wholesalers, pharmacies, and drug manufacturers through items other than the CGDP.

We estimate cost sharing may decrease for a subset of beneficiaries, while beneficiary premium and premium subsidies may increase for most beneficiaries (premium could increase for some beneficiaries and decrease for others). The estimates in Figure 1 reflect the overall estimated cost or savings for the entire individual Part D market. The financial impact for a particular beneficiary may differ from the overall impact shown above. For example, we estimate that reflecting drug manufacturer rebates at the POS would increase beneficiary premiums and premium subsidies on average. However, this change would decrease cost sharing for certain beneficiaries taking brand drugs subject to rebates. Market wide costs or savings do not imply a majority of beneficiaries would realize that impact. The effects on beneficiaries with different characteristics are described in the next section of this report.

The estimates in Figure 1 assume no changes in stakeholder behavior as a result of these potential changes, though we expect stakeholders could change behaviors in some way. For example, plan sponsors may adjust contracting strategies and formularies to improve competitive positioning, and beneficiaries may switch to a different plan based on premium changes, cost sharing changes, or other factors. The results of this analysis may change if stakeholders or other entities change their behavior in response to potential Part D program changes. While our estimates do not reflect behavioral changes, we comment on potential behavioral changes in the next section of this report. We cannot opine on the likelihood of any particular change or behavioral response occurring in the future.

Our estimates assume changes are implemented for plan year 2022, and that plan sponsors reflect the expected impact of these changes in their June 2021 bid submissions to CMS. Estimates would differ if changes are implemented later than 2022, or if plan sponsors do not reflect these changes in their bid submissions.

Appendix I provides additional detail on the estimated impact for each cost component for Part D stakeholders.

Stakeholder Impact and Considerations

Most drug manufacturer rebates are currently applied as post-POS price concessions, meaning the rebate amounts are paid after drugs have been dispensed. With this change, drug manufacturer rebates are instead used to reduce drug costs at the POS. HHS cites the possible reduction of beneficiary out-of-pocket costs and potential improved formulary coverage of lower list price drugs as support for potentially requiring drug manufacturer rebates to be reflected at the POS.[6]

To estimate the impact of reflecting drug manufacturer rebates at the POS, we modeled replacing drug manufacturer rebates with equivalent POS price concessions on brand drugs. We assumed drug manufacturer rebates apply primarily to brand (applicable)[7] drugs including specialty brands, and did not adjust the cost per script for generics. We assumed no change to the total dollar amount of rebates.

STAKEHOLDER IMPACT

In Medicare Part D, rebates paid after the POS are typically used by plan sponsors to reduce beneficiary premiums and government subsidies (including federal reinsurance, LIPS, and the direct subsidy) as a result of reduced plan liability. While these post-POS rebates are sometimes also used by plan sponsors to enhance benefits, they do not typically directly reduce a beneficiary's drug cost at the POS.

Unlike post-POS rebates, rebates reflected at the POS would be shared among all stakeholders paying a portion of POS drug costs. This includes beneficiaries through cost sharing, the federal government through federal reinsurance and the LICS, and drug manufacturers through the CGDP. Any remaining drug costs (plus any non-benefit expenses and profit margin) are reflected in the plan sponsor's claim liability and are ultimately funded through the direct subsidy, LIPS, and beneficiary premium.

- **Beneficiaries**. We estimate this change would increase premiums and premium subsidies on average for most beneficiaries. It would, however, decrease cost sharing for certain high-cost beneficiaries, and in aggregate, those cost sharing savings would outweigh the average beneficiary premium increase. The potential cost or savings for each beneficiary will vary based on an individual's income, health status, plan choice, pharmacy choice, drug use, and benefit design. For example:
  - Certain NLI beneficiaries would be impacted by this change, while full subsidy-eligible LI beneficiaries would see a smaller or no effect because the majority of premium and cost sharing for LI beneficiaries is already subsidized through LIPS and LICS. We project approximately 65% of 2022 individual Part D beneficiaries will be NLI.

FIGURE 2: PROJECTED 2022 INDIVIDUAL PART D MARKET BENEFICIARY ENROLLMENT BY END-OF-YEAR PART D CLAIM PHASE AND INCOME STATUS (AS A % OF TOTAL ENROLLMENT)

	NLI	LI	TOTAL
$0 Claimants	5%	5%	10%
Deductible	25%	9%	34%
Initial Coverage Limit (ICL)	25%	11%	36%
Coverage Gap	7%	5%	12%
Catastrophic	3%	5%	8%
Total	**65%**	**35%**	**100%**

  - A beneficiary taking no drugs may see an increase in premium without benefitting from lower out-of-pocket cost sharing. We estimate that approximately 10% of beneficiaries will have no claims in 2022 (see Figure 2).

[6] HHS (February 6, 2019). Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees, ibid.

[7] Brand drugs are defined as those applicable to the CGDP.

- We estimate that the beneficiaries most likely to realize reduced overall costs with this change could be the 10% (=7%+3%) of beneficiaries we estimate are both NLI and end the year in the coverage gap or catastrophic (post-ICL) phases (see Figure 2). This is a result of the following combined effects:
    - *Beneficiaries taking drugs subject to coinsurance (as opposed to fixed dollar copays) could realize savings with this change*, because their cost sharing could be based on a lower POS cost. In Part D, drugs in the deductible phase are subject to 100% coinsurance, and drugs in the catastrophic phase are typically subject to 5% coinsurance. Drugs in the ICL could be subject to either copays or coinsurance, depending on the drug formulary tier and benefit design. In the coverage gap, benefit designs may also vary, but most individual Part D plans have 25% coinsurance on brand drugs.
    - *Higher-cost brand and specialty drugs are typically subject to coinsurance.* Based on CMS data, many plans offer coinsurance on high cost brand and specialty drug tiers in the ICL phase, while lower-cost generics are typically subject to fixed copays.[8] Nearly all brand and specialty tiers are subject to coinsurance in the coverage gap. Beneficiaries taking these higher-cost brand or specialty drugs are more likely to end the year in the coverage gap or catastrophic phases of the Part D benefit, where their reduction in out-of-pocket costs is more likely to outweigh the increased premium.

  We estimate that NLI beneficiaries that end the year in the pre-ICL phases would typically have higher overall costs (premium plus cost sharing) if drug manufacturer rebates were reflected at the POS. However, some of the pre-ICL NLI beneficiaries, as well as partial subsidy LI beneficiaries, may also realize reduced overall costs.

  Beneficiaries taking drugs subject to fixed copays would typically not see a reduction in out-of-pocket costs with this change. However, it is possible that their cost sharing decreases if the reduced POS cost is less than the copay. This is because, in Part D, beneficiaries pay the lesser of the POS drug cost and the fixed copay amount. This situation would only potentially occur if a drug for which rebates applied were subject to a copay; CMS data shows that many brand drugs are subject to coinsurance.
- Beneficiaries enrolled in plans with higher aggregate drug manufacturer rebate levels will be more impacted than those in plans with lower rebate levels. Typically, nationwide plan sponsors (e.g., large PDPs) can negotiate higher rebate levels than smaller regional plan sponsors. Therefore, NLI beneficiaries enrolled in plans offered by large nationwide plan sponsors may realize greater out-of-pocket cost reductions with this change, but may also see higher premium increases. As a result, some NLI beneficiaries may migrate to lower-cost plans or MA-PDs if they are sensitive to premium changes.

- **Federal government.** We estimate this change could increase overall federal government costs, driven by an increase in the risk-adjusted direct subsidy, as well as increase in LIPS to a lesser extent. The direct subsidy increases as plan sponsors cover a greater proportion of claim costs. The higher direct subsidy is partially offset by a decrease in federal reinsurance as fewer beneficiaries reach the catastrophic phase due to reduced cost sharing and because reinsurance is based on lower POS costs. It is also offset to a lesser extent by a decrease in LICS.
- **Drug manufacturer CGDP.** This change could reduce drug manufacturer CGDP payments, because the CGDP could be based on lower POS drug costs and it may take beneficiaries longer to reach the coverage gap phase of the Part D benefit due to lower POS costs in other benefit phases.

KEY CONSIDERATIONS

- **Senior Savings Model.** On March 11, 2020, CMS announced the Part D Senior Savings Model (SSM) to offer lower out-of-pocket costs for insulin. The SSM is a voluntary model that will go into effect in 2021. The SSM restructures how plan sponsors offer supplemental benefits in the coverage gap, by applying the 70% CGDP payment to the full negotiated drug price instead of the value of the supplemental benefit. This limits the plan

[8] CMS. Medicare Advantage/Part D Contract and Enrollment Data. Benefits Data. Retrieved September 24, 2020, from: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Benefits-Data

sponsor's liability in the coverage gap. To participate in the SSM, plans must offer a maximum $35 copay per 30-day supply for a select set of insulins in the deductible, ICL, and coverage gap phases.[9]

It is unclear how POS rebates might affect beneficiaries enrolled in plans participating in the SSM compared to those that do not participate. Plans that participate in the SSM may expect to enroll a greater share of insulin-taking beneficiaries compared to non-participating plans. Insulins typically are associated with relatively high drug manufacturer rebates which help plan sponsors manage the higher costs of these beneficiaries. Typically, beneficiaries enrolled in plans with higher aggregate drug manufacturer rebate levels could see greater premium increases with POS rebates compared to those in plans with lower rebate levels. However, the potential premium increase for these plans may be mitigated because plan sponsors retain a greater portion of POS cost reductions when beneficiaries pay fixed copays as opposed to coinsurance.

- **Operational complexity.** This change could pose operational challenges for plan sponsors, PBMs, and other parties, which could increase administrative costs. However, it also could potentially reduce plan sponsor administrative costs for rebate data collection and reporting activities.
- **Rebate transparency.** Rebate contracting terms between drug manufacturers and plan sponsors or PBMs are confidential. This change could make drug manufacturer rebate terms transparent, which could reduce drug manufacturers' incentive to negotiate the same level of rebates with plan sponsors as they do today. This may result in increased costs if transparency undermines plan sponsors' ability to control formulary placement of specific drugs. It is unclear how rebate transparency will affect leverage in negotiations between drug manufacturers and plan sponsors or PBMs. As a result, we did not model any behavioral change scenarios related to differing leverage.
- **Drug adherence.** This change reduces POS costs, which may reduce cost sharing for certain beneficiaries. With lower cost sharing, beneficiaries may increase drug utilization and adherence. Increased drug adherence may result in improved clinical outcomes and reduced medical costs. It could also lead to increased government outlays in Medicare Advantage if the adherence increases drive star rating improvements and higher bonus payments. Our analysis does not reflect the impact of increased adherence or other potential beneficiary behavioral changes.
- **Benefit design.** Some plan sponsors will need to adjust benefit designs to maintain actuarial equivalence with the defined standard benefit, which could reduce copays and coinsurance for all beneficiaries in impacted plans. This could reduce cost sharing at both preferred and non-preferred pharmacies.
- **Benefit parameters.** CMS may need to reevaluate the Part D benefit parameters, which could result in a reduction to the defined standard deductible, ICL, and true out-of-pocket (TrOOP) threshold for catastrophic coverage following the implementation of this change. Our analysis does not reflect the impact of potential changes to the Part D benefit parameters due to reflecting rebates at the POS.
- **Risk adjustment.** Any program change that affects market wide plan liability will require a corresponding change to the risk adjustment mechanism to align federal reimbursement with the level of risk retained by plan sponsors. Part D risk scores are developed using plan liability prior to rebates.[10] If POS drug costs are reduced because rebates are reflected at the POS, this could cause meaningful changes to the risk adjustment mechanism, impacting beneficiary risk scores. CMS would need to recalibrate the risk adjustment model to reflect the change in expected plan liability. We have not modeled any changes to the risk adjustment model given the uncertainty of impacts.
- **Beneficiary disruption.** Part D beneficiaries have the option to choose a new plan each year. For many beneficiaries, premium is a key consideration when selecting a Part D plan. If the current drug manufacturer rebate structure changes, some plan sponsors may experience higher than average enrollment changes to the extent their plan premium changes relative to other plans in the market. This may lead to greater disruption in the PDP space, as these types of plans typically compete based on premiums and tend to have higher rebates than MA-PD plans. In addition, some LI beneficiaries are automatically enrolled in Part D plans based on premium levels, so greater than average premium changes could result in more LI beneficiaries changing plans than typical.

[9] CMS (April 24, 2020). Part D Senior Savings Model. Retrieved September 24, 2020, from: https://innovation.cms.gov/innovation-models/part-d-savings-model

[10] CMS (February 1, 2018). Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 draft Call Letter, p. 45. Retrieved September 24, 2020, from: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2019Part2.pdf

Switching plans can be disruptive to beneficiaries, as they may need to navigate new drug formularies, pharmacies, and cost-sharing structures, for example.

- **Pharmacy cash flow.** With this change, pharmacies may receive lower upfront POS reimbursement for drugs, and may not be reimbursed for the full negotiated drug cost until later. Lower upfront reimbursement under this potential "chargeback" approach may pose capital challenges for pharmacies.
- **Plan sponsor reaction**. While plan sponsors are primarily financial intermediaries in the Part D program, they have an interest in maintaining a competitive bid position to retain and attract beneficiaries. While the potential change to reflect drug manufacturer rebates at the POS would reduce POS costs, it could also place upward pressure on Part D bids, which could result in the following plan sponsor responses, among others.
  - **Formulary management.** Plan sponsors' focus may shift to incentivizing products with lower POS costs. In the current post-POS rebate environment, higher cost drugs subject to rebates sometimes result in lower net plan liability, and thus a more competitive premium, compared to lower cost drugs not subject to rebates. If rebates were reflected at the POS, a lower cost drug may be more likely to result in lower net plan liability. Plan sponsors may therefore implement generic-focused contracting strategies or target the lowest net cost brands. For example, they may decide to include a generic drug on the formulary instead of a brand drug subject to rebates, or they may include a low cost brand drug with low rebates instead of a high cost, high rebate alternative. Plan sponsors might also implement more utilization management programs for high-cost drugs.
  - **Cost mitigation.** Due to the competitive nature of the Part D program, plan sponsors may look for new ways to mitigate the potential upward pressure on bids. This could include attempting to negotiate deeper discounts or rebates with pharmacies, attempting to negotiate increased rebates with drug manufacturers, or looking for ways to improve administrative efficiencies, among other strategies. Any attempt to negotiate deeper contracting terms would depend on the drug manufacturers' and pharmacies' willingness to negotiate. For MA-PD plan sponsors, there may be more emphasis on Part D quality metric reporting and adherence, as it impacts a MA-PD sponsors' star rating and revenue.
  - **Contracting innovation.** Contracts with plan sponsors and drug manufacturers may no longer be allowed to include contingencies based on post-POS metrics and results. This may simplify drug manufacturer rebate contracting in the near term, but new contracting strategies may emerge. For example, some plan sponsors have implemented value-based or outcomes-based contracting with drug manufacturers. It is unclear whether these would be allowed, though the 2019 proposed rule stated HHS did not intend to impact value-based arrangements.

Methodology

Modeling detail: Our analysis begins with a cost model calibrated to the 2021 market-wide national average bid results under a defined standard benefit design. The 2021 national average bid amount, national average member premium, and federal reinsurance are $43.07, $33.06, and $86.58, respectively. Milliman's manual Part D data is used as the pricing basis. The manual rates, adjustment factors, assumed demographics, and risk scores in the model are based on recent Part D claims experience from over 80 million member months across 34 U.S. regions and Puerto Rico. Our approach relies on separate LI and NLI claim probability distributions (CPDs) that provide allowed spend levels based on the average price by formulary tier (preferred generic, non-preferred generic, preferred brand, non-preferred brand, and specialty) and distribution method (retail and mail order). We did not account for any potential risk adjustment model changes resulting from these proposed changes. 2021 reflects the expected effect of the COVID-19 pandemic to the extent plan sponsors reflected this in their 2021 bids.

2022 to 2031 projection: We based our impact analysis on the estimated nationwide average individual Medicare Part D market for a ten-year projection period (2022 to 2031). To develop our 2022 to 2031 baseline projections, we trended the 2021 results using enrollment and trend projections developed from the 2020 Medicare Trustees Report and Milliman Part D cost and utilization trends. The 2022 to 2031 baseline projections assume no additional adjustment for potential impacts of the COVID-19 pandemic. Ten-year estimates are on an undiscounted basis and do not reflect any time-value-of-money adjustments.

Enrollment: Our enrollment estimates reflect the individual Medicare Part D market, including standalone PDPs and MA-PDs, and excluding EGWPs. We used the 2020 Medicare Trustees Report to estimate nationwide individual Medicare Part D average enrollment by income status.

Trend: The pricing projections for years 2022 to 2031 reflect allowed cost trends based on the Part D per capita cost trend from page 142 of the 2020 Medicare Trustees Report. Trends for 2030 and 2031 were assumed to equal those for 2029. The projections are based on separate generic, brand, and specialty trends. We calibrated to the Trustees Report trends by scaling generic, brand, and specialty unit cost and utilization using Milliman's standard Part D 2021 trend assumptions. We assumed brand cost, specialty cost, and specialty utilization would be the primary drivers of changes in future trends.

Contracting terms and non-benefit expenses: Discounts off average wholesale price (AWP), dispensing fees, margin, and administrative fees were based on an annual survey of Part D sponsors conducted by Milliman and are representative of a typical individual Part D plan.

Benefit parameters: 2021 benefit parameters reflect those in CMS' CY2021 Medicare Advantage and Part D Advance Notice. Benefit parameters for years 2022 to 2031 are based on the projections on page 192 of the 2020 Medicare Trustees Report. In line with the 2020 CMS Medicare Part D Rate Announcement, 2030 and 2031 benefit parameters were projected using the same trends in Part D expenditures used for allowed costs or the consumer pricing index (CPI). We assume the LIPS program subsidizes 95% of the average premium for LI beneficiaries.

Rebates: We model changes in the treatment of drug manufacturer rebates, so the estimates in this analysis are sensitive to the assumed level of total rebates. Different rebate assumptions could lead to different results. We modeled drug manufacturer rebates as a percent of brand allowed cost, before adjusting for federal reinsurance. We assumed 2021 manufacturer rebates to be approximately 24% of allowed cost based on Milliman's annual survey of Part D sponsors. We estimated total 2021 rebates (including manufacturer rebates and pharmacy rebates) based on Milliman's annual survey of Part D sponsors and assumed that pharmacy rebates would continue to be reflected after the POS. For 2022 to 2031, we assumed the same drug manufacturer rebate as a percent of brand allowed cost as estimated for 2021. This results in projected drug manufacturer rebates equal to approximately 25% of allowed cost by 2031. Future rebates could vary depending on behavior changes resulting from proposed program changes.

Appendix I: Scenario Detail

Figure 3 provides the estimated financial impact from 2022 through 2031 by stakeholder component. Federal government cost components include the risk-adjusted direct subsidy, federal reinsurance, LIPS, and LICS. The beneficiary impact is the sum of the beneficiary premium and cost sharing components, excluding LIPS and LICS. Drug manufacturers fund the CGDP.

FIGURE 3: ESTIMATED TEN-YEAR (2022-20231) COST (SAVINGS) OF DRUG MANUFACTURER REBATES AT POS FOR THE INDIVIDUAL PART D MARKET[1]

STAKEHOLDER COMPONENT	BASELINE (BILLIONS)	DOLLAR CHANGE FROM BASELINE (BILLIONS)	PERCENT CHANGE FROM BASELINE
Federal Government	**$1,285.8**	**$59.5**	**5%**
Risk-Adjusted Direct Subsidy	$49.3	$227.1	460%
Federal Reinsurance	$737.6	($102.9)	(14%)
LIPS	$78.6	$12.4	16%
LICS	$420.2	($77.1)	(18%)
Beneficiaries	**$531.3**	**($14.3)**	**(3%)**
Premium	$181.9	$28.7	16%
Cost Sharing	$349.5	($43.0)	(12%)
Drug Manufacturer CGDP	**$127.6**	**($45.1)**	**(35%)**

[1] Totals may not tie exactly with the sum of components due to rounding.

Appendix II: POS Rebate Background

Reflecting drug manufacturer rebates at the POS was most recently included in the July 2020 executive order on Lowering Prices for Patients by Eliminating Kickbacks to Middlemen.[11] Prior to that, a similar proposal was included in the February 6, 2019 "Removal of Safe Harbor Protection for Rebates" HHS Office of Inspector General (OIG) proposed rule, which refers to safe harbors under the Anti-Kickback Statute (AKS).[12] The AKS prohibits payments in exchange for federal healthcare program services. Currently, drug manufacturer rebates are exempt from the AKS (and thus allowed) through safe harbor regulations. The HHS proposed rule outlined the removal of safe harbor protections for drug manufacturer rebates and the creation of a new safe harbor protection for certain POS price concessions. With the current program structure, drug manufacturer rebates are typically reflected after the POS. This change would mean that drug manufacturer rebate contracts would need to be modified from the current structure. The Congressional Budget Office (CBO) explains, "Manufacturers could offer discounts to beneficiaries either by reducing their list price or by making a payment to the pharmacy of the full amount of the negotiated discount […]".[13] This proposal was withdrawn in July of 2019.[14]

HHS stated that with this change, "there may be an improved alignment of incentives among [drug manufacturers and plan sponsors] that may curb list price increases, reduce financial burdens on beneficiaries, lower or increase Federal expenditures, improve transparency, and reduce the likelihood that rebates would serve to inappropriately induce business payable by Medicare Part D and Medicaid MCOs."[15] CMS, the Trump Administration, and HHS have considered similar changes to the drug manufacturer rebate structure since November 2017.[16]

On July 24, 2020, the Trump administration issued an executive order directing HHS to "complete the rulemaking"[17] for this process and exclude safe harbor protections for drug manufacturer rebates not applied at POS for Medicare Part D. This executive order brings attention back to the HHS proposal that was previously withdrawn.

The executive order requires that HHS confirm that this "is not projected to increase Federal spending, Medicare beneficiary premiums, or patients' total out-of-pocket costs."[18]

CMS, the Congressional Budget Office (CBO), the Office of Management and Budget (OMB), the Office of the Actuary (OACT), and the Assistant Secretary for Planning and Evaluation (ASPE) have previously evaluated the impact of manufacturer rebates at the POS. Figure 4 summarizes estimates of reflecting drug manufacturer rebates at the POS from published reports. For ease of comparison, this table shows estimates that exclude the impact of potential behavioral changes resulting from reflecting rebates at the POS, if available. This table is not a comprehensive list of published estimates.

[11] The White House (July 24, 2020). Executive Order on Lowering Prices for Patients by Eliminating Kickbacks to Middlemen, ibid.

[12] HHS (February 6, 2019). Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees. Retrieved October 2, 2020, from: https://www.govinfo.gov/content/pkg/FR-2019-02-06/pdf/2019-01026.pdf

[13] Congressional Budget Office (CBO) (May 2019). Incorporating the Effects of the Proposed Rule on Safe Harbors for Pharmaceutical Rebates in CBO's Budget Projections—Supplemental Material for Updated Budget Projections: 2019 to 2029, p. 2, 3. Retrieved October 15, 2020, from: https://www.cbo.gov/system/files/2019-05/55151-SupplementalMaterial.pdf

[14] OIRA (July 10, 2019). OIRA Conclusion of EO 12866 Regulatory Review. September 24, 2020, from: https://www.reginfo.gov/public/do/eoDetails?rrid=129208

[15] HHS (February 6, 2019). Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees, ibid, p. 2343-2344.

[16] Alston, Maggie, et al. (February 8, 2019). Changing the Rebate game: A primer on the HHS Proposed Rule to Shift Drug Rebates to POS, Figure 2: Sequence of Federal Government Activities on Price Concessions. Retrieved October 2, 2020, from: http://us.milliman.com/insight/2019/Changing-the-rebate-game-A-primer-on-the-HHS-proposed-rule-to-shift-drug-rebates-to-POS/

[17] The White House (July 24, 2020). Executive Order on Lowering Prices for Patients by Eliminating Kickbacks to Middlemen, ibid.

[17] The White House (July 24, 2020). Executive Order on Lowering Prices for Patients by Eliminating Kickbacks to Middlemen, ibid.

[18] The White House (July 24, 2020). Executive Order on Lowering Prices for Patients by Eliminating Kickbacks to Middlemen, ibid.

FIGURE 4: ESTIMATED TEN-YEAR IMPACT OF REFLECTING DRUG MANUFACTURER REBATES AT THE POS, PUBLISHED REPORTS (BILLIONS)

SOURCE	FEDERAL GOVERNMENT (BILLIONS)	BENEFICIARY PREMIUM (BILLIONS)	PERCENT OF REBATES SHIFTED TO POS	PROJECTION YEARS	BEHAVIOR CHANGES MODELED
Milliman for PCMA, October 2020	$59.5	$28.7	100%	2022-2031	None
Milliman for PCMA, April 2019[19]	$48.1	$25.5	100%	2020-2029	None
CMS[20]	$82.1	$28.3	100%	2019-2028	None
Milliman for ASPE[21, 22]	$34.8	$26.4	100%	2020-2029	None
CBO[23]	$43.4	n/a	33% (assumed)[24]	2019-2028	Unknown
OMB[25]	$42.2	n/a	33% (assumed)[22]	2019-2028	Unknown
CBO[26]	$170.0	n/a	Total rebates reduced by 15%, remaining rebates shifted to POS.	2020-2029	Assumed manufacturers retain 15% of rebates
OACT[27]	$196.1	$58.0	Total rebates reduced by 15%. Of remaining 85%, 75% shifted to POS and 25% used to reduce list prices.	2020-2029	Assumed manufacturers retain 15% of rebates

[19] D'Anna, Samantha and Margiott, Tracy (April 5, 2019). Impact of Potential Medicare Part D Program Changes. Milliman report commissioned by the Pharmaceutical Care Management Association (PCMA), p. 4. Retrieved October 2, 2020, from: https://www.pcmanet.org/wp-content/uploads/2019/04/Part-D-Program-Changes_FINAL.pdf

[20] Department of HHS, CMS (November 2017). Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program, p. 328, 338. Retrieved October 6, 2020 from: https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-25068.pdf

[21] Klaisner, Jake, et al. (January 31, 2019). "Impact of Potential Changes to the Treatment of Manufacturer Rebates". Milliman report commissioned by Assistant Secretary for Planning and Evaluation (ASPE), p.1. Retrieved October 6, 2020, from: https://aspe.hhs.gov/system/files/pdf/260591/MillimanReportImpactPartDRebateReform.pdf

[22] This report also modeled several scenarios with behavioral changes for various levels of formulary controls, price concessions, and trends. These scenarios result in a range of impacts to the federal government and beneficiary premiums.

[23] Congressional Budget Office (CBO) (February 2018). Proposals Affecting Medicare—CBO's Estimate of the President's Fiscal Year 2019 Budget, p. 1. Retrieved October 6, 2020, from: https://www.cbo.gov/system/files?file=115th-congress-2017-2018/dataandtechnicalinformation/53906-medicare.pdf

[24] Executive Office of the President of the United States (February 2018). 2019 Budget Fact Sheet. Lower the Price of Drugs by Reforming Payments, p. 2. Retrieved October 7, 2020, from: https://www.whitehouse.gov/wp-content/uploads/2018/02/FY19-Budget-Fact-Sheet_Reforming-Drug-Pricing-Payment.pdf

[25] Office of Management and Budget (OMB) (February 2018). An American Budget, Fiscal Year 2019, p. 127. Retrieved October 6, 2020, from: https://www.whitehouse.gov/wp-content/uploads/2018/02/budget-fy2019.pdf

[26] Congressional Budget Office (CBO) (May 2019). Incorporating the Effects of the Proposed Rule on Safe Harbors for Pharmaceutical Rebates in CBO's Budget Projections—Supplemental Material for Updated Budget Projections: 2019 to 2029, p. 1, ibid.

[27] Office of the Actuary (OACT), CMS (August 30, 2018). Proposed Safe Harbor Regulation, p. 5. Retrieved October 6, 2020 from: https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/ProposedSafeHarborRegulationImpact.pdf

Appendix III: Medicare Part D Background

Medicare Part D was enacted as part of the Medicare Modernization Act of 2003 and took effect on January 1, 2006. The voluntary prescription drug benefits are offered through private plan sponsors who contract with CMS to administer the benefit. Costs are partially subsidized for Medicare beneficiaries, who may choose between enrolling in an MA-PD or PDP. More than 45 million people are enrolled in a Part D plan,[28] and a majority (54%) are in a MA-PD.

Medicare Part D bids are highly regulated and are subject to a bidding process. The program is funded through government subsidies, beneficiary premiums, and drug manufacturers. Plan sponsors are risk-bearing intermediaries that sell and administer subsidized plans to beneficiaries; they are not a primary source of funding for the program. Potential gains and losses for plan sponsors are limited due to risk-sharing arrangements with CMS.

THE DEFINED STANDARD DRUG BENEFIT

The Part D benefit is divided into four distinct cost sharing phases: the deductible phase, initial coverage phase, coverage gap phase, and catastrophic phase. Beneficiaries accelerate through the phases based on distinct spending amounts. Each stakeholder's liability changes throughout the benefit year as the beneficiary moves through the four phases.

There have been several recent proposals to alter the structure of the standard benefit in future years. We assumed no change to the current benefit phase structure, given no proposals have been finalized at this time.

Part D plan sponsors may offer a defined standard Part D benefit, actuarially equivalent benefit, or an enhanced benefit plan. CMS updates the defined standard benefit parameters each year. The defined standard benefit is outlined with the latest 2021 parameters:

Deductible phase: In the deductible phase, the beneficiary is responsible for 100% of drug costs up to the deductible ($445). Drug cost is defined as negotiated drug price after POS discounts and prior to application of post-POS rebates.

Initial coverage phase: After the deductible is met, the beneficiary pays 25% of drug costs until $4,130 in total drug costs, the 2021 initial coverage limit (ICL), is reached. The plan sponsor pays the remaining 75% of drug costs in this phase.

Coverage gap phase: Claim liability in the coverage gap phase is shared between the beneficiary, plan sponsor, and drug manufacturers, and varies for brand and generic drugs. Beneficiary liability in the coverage gap was closed under the Affordable Care Act (ACA). In 2021, beneficiaries pay 25% of drug costs for both generic and brand drugs. For generic drugs, plan sponsors pay the remaining 75%. For brand drugs, plan sponsors pay 5%, and drug manufacturers pay the remaining 70%, referred to as the CGDP payment. LI beneficiaries eligible for cost sharing subsidies do not receive the CGDP payments because the federal government pays subsidies through all phases of the benefit.

Catastrophic phase: Beneficiaries reach the catastrophic phase when their annual out-of-pocket expenditures reach $6,550, the 2021 TrOOP. CGDP payments also contribute toward the TrOOP. In the catastrophic phase, the beneficiary pays approximately 5% of drug costs, the federal government subsidizes 80% of drug costs, and the plan sponsor pays the remaining cost (approximately 15%).

MEDICARE SUBSIDIES

The federal government subsidizes Part D program costs through the direct subsidy, federal reinsurance, LIPS, and LICS.

Direct subsidy: The direct subsidy is a risk-adjusted capitated payment meant to cover the plan sponsor's costs related to the defined standard benefit. The remaining portion of a plan sponsor's costs is covered through beneficiary premium.

Federal reinsurance: The 80% of drug cost covered by the government in the catastrophic phase is referred to as the federal reinsurance subsidy. The federal reinsurance subsidy is net of the full calendar year rebates (i.e., that is collected for all claims during the four coverage phases for a beneficiary). The amount of rebates attributed to federal reinsurance is proportional to federal reinsurance as a share of annual drug costs.

LI subsidies: CMS subsidizes costs for LI beneficiaries through LIPS and LICS payments. LI beneficiaries pay no (or a reduced) premium or deductible and have minimal copays. Nearly 123 million people receive these subsidies.[29]

[28] Henry J Kaiser Family Foundation (June 4, 2019). 10 Things to Know About Medicare Part D Coverage and Costs in 2019. Retrieved September 24, 2020, from: https://www.kff.org/medicare/issue-brief/10-things-to-know-about-medicare-part-d-coverage-and-costs-in-2019/

[29] Henry J Kaiser Family Foundation (June 4, 2019). 10 Things to Know About Medicare Part D Coverage and Costs in 2019, ibid.

RISK SHARING PROGRAMS WITH PLAN SPONSORS

In addition to federal reinsurance payments, the Medicare Part D program provides the following ways to mitigate financial risk for Part D plan sponsors:

Risk corridor payments: Risk corridors limit the gains and losses of Part D plan sponsors when actual claims differ from expected claims filed in Part D bids. Based on specific thresholds, a plan sponsor pays CMS if plan performance is better than expected and CMS subsidizes the plan sponsor if performance is worse than expected. No payments are made if actual experience is within 5% of the target amount. The payments cover 50% of claims in the 5% to 10% corridor and 80% of claims in excess of the 10% threshold. Administrative costs and projected gain/loss margin are excluded from the risk corridor calculations.

CMS-RxHCC risk adjustment: The direct subsidy payments are risk-adjusted to reflect the health status of the enrolled beneficiaries using CMS' Hierarchical Condition Category (HCC) risk adjustment model. Less healthy individuals are designated by higher risk scores. By design, the risk adjustment mechanism pays plan sponsors more for less healthy beneficiaries. One important element of the risk adjustment process in Part D is that the risk score coefficients are developed using plan liability prior to rebates. If POS drug prices are adjusted to reflect rebates, CMS will need to adjust the RxHCC model to re-align risk-adjusted direct subsidy payments.

Disclosures

Tracy A. Margiott is a principal and consulting actuary for Milliman. I am a member of the American Academy of Actuaries and meet the Qualification Standards of the American Academy of Actuaries to render this opinion. To the best of my 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 Milliman report has been prepared for the specific purpose of estimating the effect of potential Medicare Part D program changes on stakeholder costs. This information may not be appropriate, and should not be used, for any other purpose. Milliman does not endorse any public policy or advocacy position on matters discussed in this report.

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The results presented herein are estimates based on carefully constructed actuarial models. Differences between our estimates and actual amounts depend on the extent to which future experience conforms to the assumptions made for this analysis. It is certain that actual experience will not conform exactly to the assumptions used in this analysis. Actual amounts will differ from projected amounts to the extent that actual experience deviates from expected experience.

Actual results will vary for specific Medicare organizations and other stakeholders due to differences in demographics, trends, discount arrangements, formulary, utilization patterns, and rebate arrangements, among other factors. Our analysis does not reflect possible changes in stakeholder behavior that could result from these potential program changes. Results will vary based on how beneficiaries and other stakeholders react to the changes, if implemented.

In performing this analysis, we relied on data and other information from the Centers for Medicare and Medicaid Services (CMS). We have not audited or verified this data and other information but reviewed it for general reasonableness. If the underlying data or information is inaccurate or incomplete, the results of our analysis may likewise be inaccurate or incomplete.

This report outlines the review and opinions of the authors and not necessarily that of Milliman. Milliman does not provide legal advice, and recommends that Pharmaceutical Care Management Association consult with its legal advisors regarding legal matters. The terms of Milliman's Consulting Services Agreement with Pharmaceutical Care Management Association dated August 2, 2013 and the Indemnification agreement in the engagement letter dated September 11, 2020 apply to this report and its use.

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