MILLIMAN REPORT

Impact of Point of Sale Manufacturer Rebates in Medicare Part D

How Point of Sale Manufacturer Rebates Could Affect Stakeholder Costs

Commissioned by the Pharmaceutical Care Management Association (PCMA)
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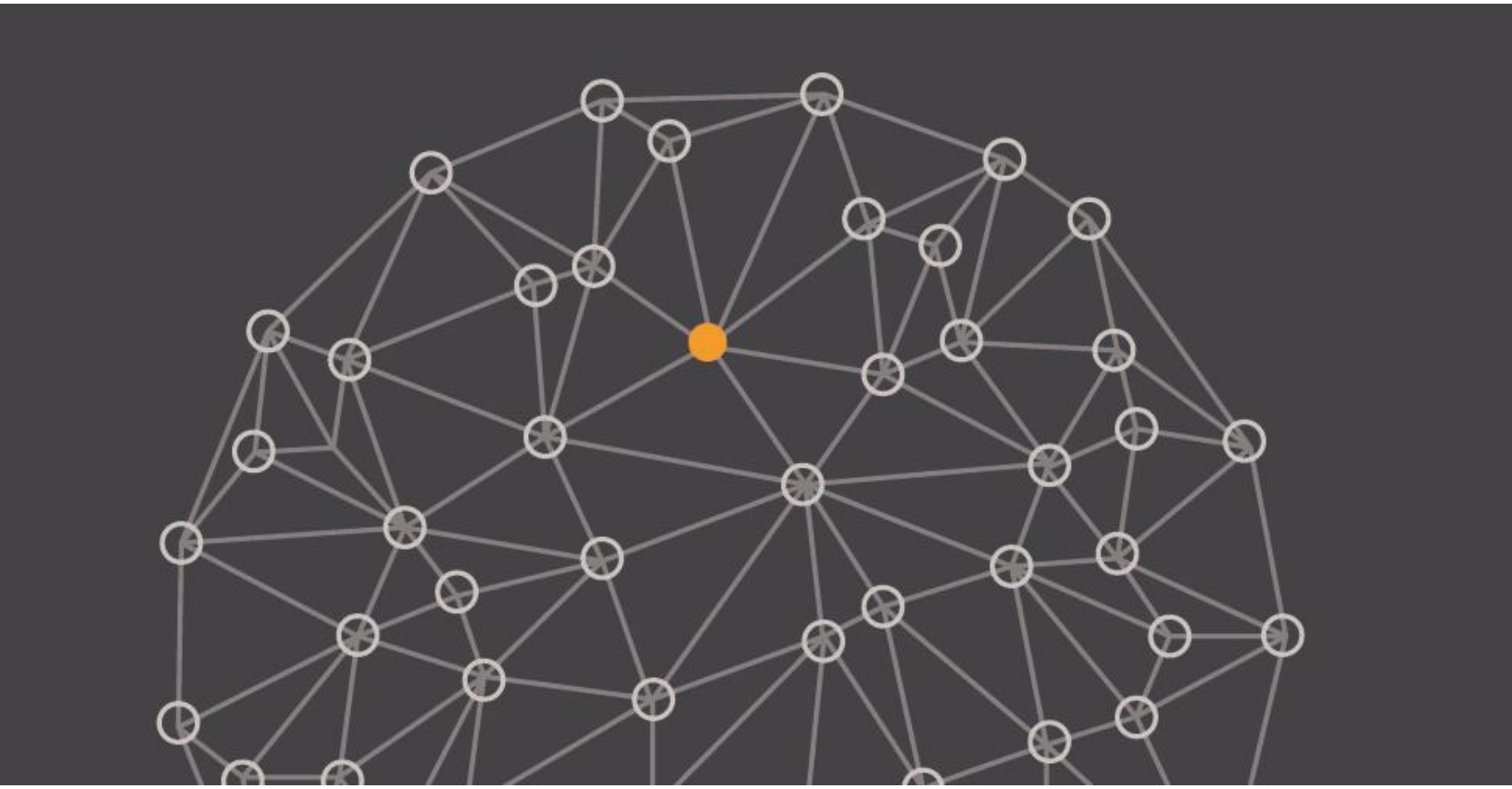

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Table of Contents

Executive Summary

In February 2019, the Department of Health and Human Services (HHS) issued a proposed rule to modify the Anti-Kickback Statute (AKS) safe harbors and require drug manufacturer rebates currently paid after the point of sale (POS) to be reflected in the POS drug price.[1] Subsequently, in April 2019, HHS released additional guidance on a proposed risk corridor demonstration program intended to help mitigate Part D plan sponsors' risk from the uncertainty around the proposed rule.

KEY FINDINGS

The Pharmaceutical Care Management Association (PCMA) requested we estimate the ten-year (2020 to 2029) financial impact of the proposed POS drug manufacturer rebate change on key stakeholders. Most drug manufacturer rebates are currently applied as post-POS price concessions, meaning the rebate amounts are paid after drugs have been dispensed.[2] 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.
- This change could increase overall federal government costs by approximately 4% over ten years, primarily due to an increased risk-adjusted direct subsidy.
- This change would reduce drug manufacturer coverage gap discount program (CGDP) payments, 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.

BACKGROUND

Reflecting drug manufacturer rebates at the POS was most recently 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 AKS.[1] 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 would remove this safe harbor protection for drug manufacturer rebates and create 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 any drug manufacturer rebates would instead need to be used to reduce the POS drug cost.

HHS believes 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."[3] The Centers for Medicare and Medicaid Services (CMS), the Trump Administration, and HHS have considered similar changes to the drug manufacturer rebate structure since November 2017.[4]

The ten-year financial impact estimates in this report assume all drug manufacturer rebates are reflected at the POS

[1] 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 February 28, 2019, from: https://www.govinfo.gov/content/pkg/FR-2019-02-06/pdf/2019-01026.pdf

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

[3] 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.

[4] 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 February 28, 2019, from: http://us.milliman.com/insight/2019/Changing-the-rebate-game-A-primer-on-the-HHS-proposed-rule-to-shift-drug-rebates-to-POS

for all ten years, including for plan year 2020. Our estimates do not reflect the recent CMS guidance and demonstration program announced on April 5, 2019. CMS advised plan sponsors to submit bids consistent with the laws and regulations in effect at the time of the bid submission deadline, including those pertaining to the treatment of manufacturer rebates.[5] Therefore, the ten-year financial impact estimates are illustrative and do not necessarily represent what we expect to occur for plan year 2020. This timeframe is consistent with timeframe in the HHS AKS safe harbor proposed rule. Similar to the estimates in this report, the estimates included in the HHS AKS safe harbor proposed rule also do not include the impact of the April 5, 2019 CMS guidance or the risk corridor demonstration program.

[5] CMS (April 5, 2019). Guidance Regarding Part D Bids. Retrieved May 13, 2019, from: https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/Downloads/HPMS-Memos/Weekly/SysHPMS-Memo-2019-Apr-5th.pdf

Estimated Financial Impact

Figure 1 illustrates the estimated cost (savings) from 2020 through 2029 by stakeholder of reflecting manufacturer rebates at the POS.

FIGURE 1: ESTIMATED TEN-YEAR (2020-2029) COST (SAVINGS) OF REFLECTING DRUG MANUFACTURER REBATES AT POS FOR THE INDIVIDUAL PART D MARKET BY STAKEHOLDER[1,2,3]

	BENEFICIARY PREMIUM	BENEFICIARY COST SHARING	FEDERAL GOVERNMENT	DRUG MANUFACTURER CGDP
Dollar Change (Billions)	$25.5	($42.1)	$48.1	($31.5)
Percent Change	15%	(13%)	4%	(32%)

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

[2] Ten-year values assume plan sponsors reflect drug manufacturer rebates at POS in bid submissions for all ten years, including for plan year 2020. This differs from CMS's plan year 2020 guidance that plan sponsors should bid as if POS drug manufacturer rebates are not required, regardless of whether or not POS rebates will be required for 2020.

[3] 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).

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 NLI 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 this potential change, though we expect stakeholders would 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 resulting in premium changes, cost sharing changes, or other factors. The results of this analysis may change if stakeholders or other entities change their behavior. 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.

On April 5, 2019, CMS released guidance to Part D plan sponsors related to the proposed rule for the 2020 plan year: "plan sponsors will submit bids for CY2020 in a form and manner that is consistent with the Anti-Kickback Statute law and regulations in effect as of the [June 3, 2019] bid submission deadline."[6] CMS clarified on an April 8, 2019 industry call that this guidance means plan sponsors should submit 2020 bids (i.e., cost and premium estimates) under existing rules assuming the AKS safe harbor proposed rule does not apply. Therefore, plan sponsors are not required to reflect drug manufacturer rebates at the POS for plan year 2020 bid submissions. In the event the AKS safe harbor proposed rule applies for plan year 2020 (and thus plan sponsors are required to reflect drug manufacturer rebates at the POS), CMS will conduct an optional risk corridor demonstration program to mitigate plan sponsors' financial exposure.

Our estimates assume manufacturer rebates are applied at the POS starting in plan year 2020, and that plan sponsors reflect the expected impact of the change in their bid submissions to CMS. Estimates would differ if this proposal is implemented later than 2020, or if plan sponsors do not reflect the change in their bid submissions. Based on CMS's April 5, 2019 guidance, Part D plan sponsors are not expected to reflect this potential change in 2020 bid submissions. However, plan sponsors may be required to reflect this change starting in 2021 if the proposed rule is finalized, and thus the estimated 2020 to 2029 impact is representative of the expected ten-year impact of this change. Our estimates do not reflect the potential impact of risk corridor payments between plan sponsors and CMS.

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

[6] CMS (April 5, 2019). Guidance Regarding Part D Bids. Retrieved May 13, 2019, from: https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/Downloads/HPMS-Memos/Weekly/SysHPMS-Memo-2019-Apr-5th.pdf

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 improved formulary coverage of lower list price drugs as support for potentially requiring drug manufacturer rebates to be reflected at the POS.[7]

To estimate the impact of reflecting drug manufacturer rebates at the POS, we modeled replacing rebates with equivalent POS price concessions on brand drugs. We assumed drug manufacturer rebates apply primarily to brand 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 NLI 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 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. CMS projects approximately 66% of 2020 individual Part D beneficiaries will be NLI.[8]

FIGURE 2: PROJECTED 2020 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%	4%	9%
Deductible	27%	9%	36%
Initial Coverage Limit (ICL)	25%	11%	36%
Coverage Gap	7%	4%	11%
Catastrophic	2%	6%	8%
Total	**66%**	**34%**	**100%**

[7] 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.

[8] CMS (June 5, 2018). The 2018 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, p. 141. Retrieved March 18, 2019, from: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2018.pdf

- A beneficiary taking no drugs may see an increase in premium without benefitting from lower out-of-pocket cost sharing. We estimate that approximately 9% of beneficiaries will have no claims in 2020 (see Figure 2).
- We estimate that the beneficiaries most likely to realize reduced overall costs with this change could be the 9% (=7%+2%) 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 and coverage gap phases, while lower-cost generics are typically subject to fixed copays.[9] 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 (e.g., often lower cost generics) 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.

[9] CMS. Medicare Advantage/Part D Contract and Enrollment Data. Benefits Data. Retrieved March 18, 2019, from: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Benefits-Data.html

KEY CONSIDERATIONS

- **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.** As described above, 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. 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

[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 February 28, 2019, from: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2019Part2.pdf

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.

- **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 proposed rule states it does not intend to impact value-based arrangements.
- **Risk corridor demonstration.** For plan year 2020, CMS directed plan sponsors to bid as if the proposed rule were not in effect. That is, plan sponsors are not required to reflect POS rebates in 2020 bid submissions. In the event the proposed rule applies for plan year 2020, CMS will offer an optional risk corridor demonstration program to mitigate plan sponsors' financial risk. Under the demonstration, CMS would share in 95% of a plan sponsor's losses or gains beyond the first 0.5% of claims. This offers plan sponsors more protection than the current risk corridor program, in which the risk sharing percentages are lower and threshold is higher than the proposed demonstration. This additional protection could affect plan sponsor's bidding strategies. For example, this could place downward pressure on the national average bid amount, national average member premium, and direct subsidy, relative to if it were not in place for plan year 2020.

Methodology

Modeling detail: Our analysis begins with a cost model calibrated to the 2019 market-wide national average bid results under a defined standard benefit design. The 2019 national average bid amount, national average member premium, and federal reinsurance are $51.28, $33.19, and $78.88, 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 (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.

2020 to 2029 projection: We based our impact analysis on the estimated nationwide average individual Medicare Part D market for a ten-year projection period (2020 to 2029). To develop our 2020 to 2029 baseline projections, we trended the 2019 results using enrollment and trend projections developed from the 2018 Medicare Trustees Report and Milliman Part D cost and utilization trends. 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 2018 Medicare Trustees Report to estimate nationwide individual Medicare Part D enrollment by income status.

Trend: The pricing projections for years 2020 to 2029 reflect allowed cost trends based on the Part D per capita cost trend from page 143 of the 2018 Medicare Trustees Report. Trends for 2028 and 2029 were assumed to equal those for 2027. 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 2019 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: 2020 benefit parameters reflect those in CMS' CY2020 Medicare Advantage and Part D Rate Announcement. Benefit parameters for years 2021 to 2029 are based on the projections on page 198 of the 2018 Medicare Trustees Report. In line with the 2019 CMS Medicare Part D Rate Announcement, 2028 and 2029 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. Our analysis reflects the larger than average TrOOP increase projected for 2020.

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 assume total 2019 rebates of 28.5% of allowed cost based on Milliman's annual survey of Part D sponsors. We assume drug manufacturer rebates account for 80% of total rebates in 2019 based on Milliman's annual survey of Part D sponsors, with the remaining 20% comprised of pharmacy rebates. We assume pharmacy rebates will remain post-POS through 2029, though that may change in the future based on pending proposals from CMS. For 2020 to 2029, we assumed the same drug manufacturer rebates as a percent of brand allowed cost as estimated for 2019. This results in projected drug manufacturer rebates equal to 24.6% of allowed cost by 2029. Future rebates could vary depending on behavior changes resulting from proposed program changes.

Disclosures

Tracy A. Margiott is an 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 February 28, 2019 apply to this report and its use.

Appendix I: Scenario Detail

Figure 3 provides the estimated financial impact from 2020 through 2029 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 (2020-2029) COST (SAVINGS) OF DRUG MANUFACTURER REBATES AT POS FOR THE INDIVIDUAL PART D MARKET[1,2]

STAKEHOLDER COMPONENT	BASELINE (BILLIONS)	DOLLAR CHANGE FROM BASELINE (BILLIONS)	PERCENT CHANGE FROM BASELINE
Federal Government			
Risk-Adjusted Direct Subsidy	$98.4	$192.7	196%
Federal Reinsurance	$628.1	($81.1)	(13%)
LIPS	$75.5	$11.6	15%
LICS	$391.4	($75.2)	(19%)
Beneficiaries			
Premium	$166.0	$25.5	15%
Cost Sharing	$329.0	($42.1)	(13%)
Drug Manufacturers			
CGDP	$98.4	($31.5)	(32%)

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

[2] Ten-year values assume plan sponsors reflect drug manufacturer rebates at POS in bid submissions for all ten years, including for plan year 2020. This differs from CMS's plan year 2020 guidance that plan sponsors should bid as if POS drug manufacturer rebates are not required, regardless of whether or not POS rebates will be required for 2020.

Appendix II: 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 43 million people are enrolled in a Part D plan,[11] and a majority (58%) are in a standalone PDP.

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.

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 2020 parameters:

Deductible phase: In the deductible phase, the beneficiary is responsible for 100% of drug costs up to the deductible ($435). Drug cost is defined as negotiated drug price after POS discounts and prior to application of post-POS DIR.

Initial coverage phase: After the deductible is met, the beneficiary pays 25% of drug costs until $4,020 in total drug costs, the 2020 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 has been narrowing each year through 2020 under the Affordable Care Act (ACA). In 2020, 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 $6,350, the 2020 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 DIR (i.e., that is collected for all claims during the four coverage phases for a beneficiary). The amount of DIR attributed to federal reinsurance is proportional to federal reinsurance as a share of annual drug costs.

[11] Henry J Kaiser Family Foundation (May 17, 2018). Medicare Part D in 2018: The Latest on Enrollment, Premiums, and Cost Sharing. Retrieved March 1, 2019, from: https://www.kff.org/medicare/issue-brief/medicare-part-d-in-2018-the-latest-on-enrollment-premiums-and-cost-sharing

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. More than 12 million people receive these subsidies.[12]

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.

If the AKS safe harbor proposed rule goes into effect for plan year 2020 such that POS drug manufacturer rebates are required, CMS will conduct an optional alternate risk corridor demonstration. Under the demonstration, No payments would be made if actual experience is within 0.5% of the target amount. Payments would cover 95% of claims in excess of the 0.5% threshold.

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.

[12] Henry J Kaiser Family Foundation (May 17, 2018). Medicare Part D in 2018: The Latest on Enrollment, Premiums, and Cost Sharing, ibid.

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